IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas, *Plaintiff*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*.	Civil Action No. 5:24-cv-00204-H

MEMORANDUM IN SUPPORT OF
PROPOSED INTERVENOR-DEFENDANTS' MOTION FOR LEAVE TO INTERVENE

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INTRODUCTION

Proposed Intervenor-Defendants, the City of Columbus, Ohio ("Columbus"), the City of Madison, Wisconsin ("Madison"), and Doctors for America ("DFA") (collectively, "Proposed Intervenors") move to intervene as of right as defendants under Rule 24(a) of the Federal Rules of Civil Procedure to protect their legal interests in upholding the two regulations at issue in this case. In the alternative, Proposed Intervenors seek permissive intervention under Rule 24(b).

Texas challenges two regulations promulgated by the Department of Health and Human Services (the "Department") under the Health Insurance Portability and Accountability Act ("HIPAA"), Appx. 0037 (Pub. L. 104-191, 110 Stat. 1936). Texas alleges they exceed the Department's statutory authority and are arbitrary and capricious, an abuse of discretion, and not in accordance with law, all in violation of the Administrative Procedure Act. Appx. 0162 (5 U.S.C. § 706(2)). Texas asks this Court to declare both violative of the APA and vacate and set them aside.

The first challenged rule, the *Standards for Privacy of Individually Identifiable Health Information*, is a 24-year-old regulation that serves as the foundation for medical privacy nationwide. Appx. 0164 (65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164)) (the "2000 Privacy Rule"). If it were vacated, it would drastically increase levels of medical mistrust, inhibit the ability of health care providers to protect the confidentiality of patient information, impair the ability of public health authorities to protect the public health, and throw the nation's health care system into chaos.

The Department promulgated the second challenged rule, the *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, to provide heightened protections for sensitive medical information sought to investigate the provision and reception of lawful reproductive health care. Appx. 0776–934 (89 Fed. Reg. 32976-01 (Apr. 26, 2024) (codified at 45 C.F.R. pts. 160,

164) (the "2024 Rule") (both rules together, the "Privacy Rules"). The 2024 Rule offers providers and their patients additional critical assurances and protections at a time when patients are increasingly concerned about the confidentiality of their discussions with and treatment by health care providers.

Proposed Intervenors are entitled to intervene as of right to defend both Privacy Rules. The Rules regulate health care providers such as the public health departments of the City of Columbus and the City of Madison and, in the case of DFA, its members. They are vital for protecting patient confidentiality and, in turn, ensuring that patients trust their clinicians and that their clinicians can provide them with needed medical care. And fostering trust and honesty between clinicians and their patients is essential to overall public health: accurate data allows providers and public health departments to identify and address troubling public health trends. Proposed Intervenors' motion is timely; absent successful intervention, Proposed Intervenors' interests will be impaired by the relief Texas seeks; and these unique interests cannot be adequately defended by the federal government, both because Proposed Intervenors and the government have divergent interests in this litigation and because the government is unlikely to defend the Privacy Rules after President-Elect Donald J. Trump takes office. In the alternative, Proposed Intervenors should be permitted to intervene.

"Federal courts should allow intervention where no one would be hurt and the greater justice could be attained." *Texas v. United States*, 805 F.3d 653, 657 (5th Cir. 2015) (quoting *Sierra Club v. Espy*, 18 F.3d 1202, 1205 (5th Cir. 1994)). These two principles dictate one result here: the Court should grant Proposed Intervenors' motion.

PROPOSED INTERVENORS

City of Columbus, Ohio. Proposed Intervenor City of Columbus is a municipal corporation organized under Ohio law. *See* Appx. 0936 (Ohio Const. art. XVIII § 1). Columbus has all the

powers of local self-government and home rule under the constitution and laws of the State of Ohio, which are exercised in the manner prescribed by the Charter of the City of Columbus. Columbus's public health department, Columbus Public Health, operates HIPAA-covered clinics, expends significant resources ensuring HIPAA compliance by its relevant staff, and provides a wide range of health care services on behalf of its residents, including sexual and reproductive health care. Because Columbus Public Health relies on HIPAA protections to preserve trust between its clinicians and patients as well as to protect the public health, the City of Columbus opposes Plaintiff's efforts to erode the privacy protections in the HIPAA Rules.

City of Madison, Wisconsin. Proposed Intervenor City of Madison is a municipal corporation organized under Wisconsin law. *See* Appx. 1023–29 (Wis. Stat. Ch. 66.0201–03). Madison has all the powers of local self-government and home rule under the constitution and laws of Wisconsin, which are exercised in the manner prescribed in the ordinances of the City of Madison. Madison's public health department, Public Health Madison and Dane County,[1] operates as a HIPAA-covered entity, expends significant resources ensuring HIPAA compliance by its relevant staff, and provides a wide variety of health care services to its residents, including sexual and reproductive health care. Because Public Health Madison and Dane County relies on HIPAA protections to preserve trust between its clinicians and patients as well as to protect the public health, the City of Madison also opposes Plaintiff's efforts to erode the privacy protections in the HIPAA Rules.

Doctors for America. Proposed Intervenor DFA is a nonpartisan, nonprofit organization comprised of more than 27,000 physicians, medical students, and other health professionals across the country, representing all medical specialties. DFA members are subject to HIPAA, and they

[1] The City of Madison jointly operates Public Health Madison and Dane County with Dane County.

rely on the law's protections to help preserve the physician-patient relationship and maintain trust with their patients. Because trust between providers and their patients is a critical component to delivering effective care, DFA vehemently opposes Plaintiff's efforts to erode the privacy protections in the Privacy Rules.

LEGAL STANDARD

Rule 24(a) of the Federal Rules of Civil Procedure governs intervention of right and requires intervention be granted where (1) the motion to intervene is timely; (2) the movant claims an interest relating to the property or transaction that is the subject of the action; (3) the disposition of the action may impair or impede the movant's ability to protect that interest; and (4) the movant's interest is inadequately represented by the existing parties to the suit. Fed. R. Civ. P. 24(a)(2); *La Union del Pueblo Entero v. Abbott*, 29 F.4th 299, 305 (5th Cir. 2022); *Edwards v. City of Houston*, 78 F.3d 983, 999 (5th Cir. 1996) (en banc). These factors are "measured by a practical rather than technical yardstick." *Edwards*, 78 F.3d at 999 (internal quotation marks and citation omitted); *see Brumfield v. Dodd*, 749 F.3d 339, 341 (5th Cir. 2014) ("Rule 24 is to be liberally construed."); *NBIS Constr. & Transp. Ins. Servs. v. Kirby Smith Mach., Inc.*, No. 5:20-CV-182-H, 2021 WL 4227787, at *1 (N.D. Tex. Apr. 8, 2021) (citation omitted) ("The inquiry is a flexible one, and a practical analysis of the facts and circumstances of each case is appropriate."). While would-be intervenors bear the burden of establishing all four elements, that burden is "minimal." *Texas*, 805 F.3d at 661.

Federal Rule of Civil Procedure 24(b) allows a court to permit intervention where the movant makes a timely motion and "has a claim or defense that shares with the main action a common question of law or fact," Fed. R. Civ. P. 24(b)(1)(B), taking into consideration "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights," Fed. R. Civ. P. 24(b)(3).

ARGUMENT

Proposed Intervenors satisfy all requirements for intervention as of right and, accordingly, are entitled to intervene. Alternatively, Proposed Intervenors should be permitted to intervene, as their motion is timely, their defense of the Privacy Rules shares common questions of law and fact with this case, and their intervention will not delay or prejudice the existing parties' rights.

I. Proposed Intervenors are entitled to intervention as of right.

a. Proposed Intervenors' motion is timely.

Whether a motion to intervene is timely is assessed on (1) the length of time the movant waited to file after knowing its interests were unlikely to be protected; (2) the prejudice to existing parties resulting from any delay in the movant's filing; (3) the prejudice to the movant that would result if intervention were denied; (4) and the existence of any other unusual circumstances weighing for or against timeliness. *Stallworth v. Monsanto Co.*, 558 F.2d 257, 263–66 (5th Cir. 1977). Courts do not assess these factors in a rote manner. They are "a framework and not a formula," and a motion may be timely even where all factors do not weigh in favor of timeliness. *John Doe No. 1 v. Glickman*, 256 F.3d 371, 376 (5th Cir. 2001).

On all counts relevant here, Proposed Intervenors' motion is timely.[2]

First, start with an easy metric: Motions, such as this one, made before a trial or final judgment are generally considered timely. *See John Doe No. 1 v. Glickman*, 256 F.3d 371, 378 (5th Cir. 2001); *Edwards v. City of Houston*, 78 F.3d 983, 1001 (5th Cir. 1996) ("[M]ost of our case law rejecting petitions for intervention as untimely concerns motions filed after judgment was entered in the litigation."); *Alliance for Hippocratic Med. v. U.S. Food & Drug Admin.*, No. 2:22-CV-223-Z, 2024 WL 1260639, at *2 (N.D. Tex. Jan. 12, 2024).

[2] No unusual factors militate against timeliness here. *Stallworth*, 558 F.2d at 266.

Proposed Intervenors seek to join this case in its still early stages, and before anything of substance has occurred, because the government—obligated to consider a diverse array of interests in defense of this rule—cannot adequately represent the more specific interests of Proposed Intervenors in this litigation. *See infra* Section I(d).

Proposed Intervenors have another reason to intervene at this time: The statements and actions of leaders in the incoming administration have made it apparent that, following the change in presidential administration on January 20, 2025, the federal government will likely cease defending the challenged regulations and will not adequately represent Proposed Intervenors' interests moving forward. *See infra* Section I(d). This anticipated change in defensive posture is something that Proposed Intervenors have been able to glean as the incoming administration has moved from election to office—announcing cabinet nominees and firming up its policy agenda. *See* Appx. 1415 (Texas's Memo. In Support of Mot. to Intervene at 4, *Commonwealth of Pennsylvania et al. v. Devos et al.*, 1:20-cv-01468 (D.D.C. Jan. 19, 2021), ECF No. 130-1) ("The motion is timely because it was filed close in time to the change in circumstances requiring intervention: President-elect Biden's inauguration on January 20."); *Cook County v. Mayorkas*, 340 F.R.D. 35, 45 (N.D. Ill. 2021), aff'd sub nom. *Cook County v. Texas*, 37 F.4th 1335 (7th Cir. 2022) (noting that until the end of the "administration that soon would leave office, Texas could count on [the federal agency] to defend the challenged regulation").

Second, intervention will not cause any prejudice to the existing parties as a result of "delay." *Edwards*, 78 F.3d at 1002. Proposed Intervenors move before any responsive pleading has been filed. The only activity in this litigation so far has been on a proposed schedule for the resolution of the case, with which Proposed Intervenors intend to comply. Proposed Intervenors concurrently file a proposed dispositive motion—on the date the Court had originally ordered the

existing parties to file theirs—to avoid disruption to the briefing schedule. *See* ECF No. 15, Order Granting Motion to Enter Briefing Schedule and Hold Defendants' Deadline to Respond to Complaint In Abeyance. If this motion is granted, no deadlines will need to be moved, no portions of the litigation that have already occurred will need to be rehashed or delayed, and no discovery will be disrupted. *See Wal-Mart Stores, Inc. v. Texas Alcoholic Beverage Comm'n*, 834 F.3d 562, 565–66 (5th Cir. 2016); *NBIS Constr. & Transp. Ins. Servs.*, 2021 WL 4227787, at *1 ("Here, the second factor weighs in favor of timeliness because no deadlines will need to be moved, no additional discovery will be necessary, and no delay will occur, and, therefore, the parties will not be prejudiced by [the applicant's] intervention."); *Alliance for Hippocratic Med.*, 2024 WL 1260639, at *3 ("Any delay in filing a motion to intervene 'cause[s] no prejudice whatsoever' where, during the period in question, 'the parties to [the] litigation did nothing except anticipate and prepare to address' arguments to be presented later on." (quoting *Edwards*, 78 F.3d at 1002)).

Third, by contrast, Proposed Intervenors' interests will be severely prejudiced if intervention is denied at this juncture. Without intervention, Proposed Intervenors will lose out on the "legal rights associated with formal intervention," such as the ability to brief the issues, appeal, and raise objections to a settlement (and appeal a decision granting a settlement agreement). *See Espy*, 18 F.3d at 1207. And without the participation of Proposed Intervenors actively defending the rules at stake, a decision in this case could result in significant harm to Columbus, Madison, and DFA and its members, parties with interests that are not adequately defended by the federal government. *See infra* Section I(d).

b. The Proposed Intervenors have a legally protectable interest in this matter.

To intervene under Rule 24(a)(2), an intervenor must have a "direct, substantial, legally protectable interest in the proceedings." *Edwards*, 78 F.3d at 1004 (internal quotation marks and citation omitted). This requirement is less stringent than that of Article III standing. *Texas*, 805

F.3d at 659; *see Alliance for Hippocratic Med.*, 2024 WL 1260639, at *3 (citation omitted). Instead, the inquiry "turns on whether the intervenor has a stake in the matter that goes beyond a generalized preference that the case come out a certain way." *Id.* at 657. And where, as here, the case involves a public interest question, "the interest requirement may be judged by a more lenient standard." *Brumfield*, 749 F.3d at 344 (citation omitted) (noting that the en banc Fifth Circuit has compared the interest requirement to the "zone of interest" test in public law cases); *Alliance for Hippocratic Med.*, 2024 WL 1260639, at *4 (quoting *id.*).

Organizational intervenors may seek to intervene to protect the interests of their organization, and they may also seek to intervene to assert the "interests of their individual members." *Franciscan Alliance, Inc. v. Azar*, 414 F. Supp. 3d 928, 937 (N.D. Tex. 2019). DFA seeks to do both.

i. The Cities of Columbus and Madison and DFA's members are regulated by the Privacy Rules.

Parties, like the Cities of Columbus and Madison and DFA's members, plainly have an interest in a suit "challenging the regulatory scheme that governs" them. *Wal-Mart*, 834 F.3d 562; *see Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, No. 5:21-CV-071-H, 2022 WL 974335, at *5 (N.D. Tex. Mar. 31, 2022); *accord Michigan State AFL-CIO v. Miller*, 103 F.3d 1240, 1244–48 (6th Cir. 1997).

DFA's members include providers who themselves are "covered entities" subject to the Privacy Rules. Appx. 1429–30 (45 C.F.R. § 160.103); Appx. 0008 (Petrin Decl. ¶ 10). DFA's members are subject to both civil and criminal liability for violating HIPAA. *See* Appx. 1438–43 (42 U.S.C. § 1320d-5); Appx. 1444–45 (42 U.S.C. § 1320d-6(b)). They may also be subject to professional discipline for violating the patient privacy rules of the hospitals and practices in which they work. *See* Appx. 0008 (Petrin Decl. ¶ 11). And they expend significant time and money on

HIPAA compliance and training. *See* Appx. 0009 (Petrin Decl. ¶ 14); Appx. 0015 (Oller Decl. ¶ 14); *Texas*, 805 F.3d at 658 (citation omitted); *Wal-Mart*, 834 F.3d at 567–68.

Similarly, Columbus and Madison operate public health departments that are "covered entities" subject to the HIPAA rules. Appx. 1429–30 (45 C.F.R. § 160.103); Appx. 0018 (Mitchell Decl. ¶ 5); Appx. 0025 (Johnson Decl. ¶ 15); Appx. 0032 (Heinrich Decl. ¶ 15). Columbus Public Health and Public Health Madison and Dane County operate a number of outpatient clinics and treat thousands of patients each year. Appx. 0024 (Johnson Decl. ¶ 10); Appx. 0032 (Heinrich Decl. ¶ 10). They too spend a significant amount of time and money on HIPAA compliance and training. *See* Appx. 0018 (Mitchell Decl. ¶ 6); Appx. 0025 (Johnson Decl. ¶ 16); *Nat'l Horsemen's Benevolent & Protective Ass'n v. Black*, 2022 WL 974335, at *5 (N.D. Tex. Mar. 31, 2022) (citing *Texas*, 805 F.3d at 658). Columbus Public Health has already devoted staff time toward implementing the 2024 Rule. Appx. 0020 (Mitchell Decl. ¶ 14). "If the [Rules are] overturned, their time and money will have been spent in vain." *City of Houston v. Am Traffic Sols., Inc.*, 668 F.3d 291, 294 (5th Cir. 2012) (finding that proposed intervenors were sufficiently interested to justify mandatory intervention where architects of a successful campaign to change a city's charter sought to intervene in litigation that threatened to overturn the change).

That the public health departments of Columbus and Madison and DFA's members are regulated by the Privacy Rules gives them "real, concrete stake[s] in the outcome of this litigation." *Texas*, 805 F.3d at 661. No further inquiry is needed.

ii. The Cities of Columbus and Madison and DFA's members have an interest in the provider-patient relationship.

Proposed Intervenors' interests go beyond their status as regulated parties. They also have an interest in the challenged Privacy Rules because of their interest in maintaining and strengthening the provider-patient relationship by promoting trust between patients and providers.

As the Fifth Circuit has recognized, "[t]he doctor-patient relationship requires trust and confidentiality to facilitate the candid disclosure of sensitive health information." *Huntington Ingalls, Inc. v. Director, Office of Workers' Compensation Programs, U.S. Dep't of Labor*, 70 F.4th 245, 251 (5th Cir. 2023) (citation omitted).[3]

DFA members know first-hand how difficult it can be to build a relationship with a patient and how quickly a relationship can be fractured. *See* Appx. 0009 (Petrin Decl. ¶ 13); Appx. 0014–15 (Oller Decl. ¶¶ 9–12, 15). Patients have a "reasonable expectation" that the medical information they share with their providers will be used only to treat them. Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)). If patients believe their sensitive health information will be used by law enforcement for non-health care purposes, it endangers the very relationships that DFA members and all health care providers work so hard to build. *See* Appx. 0010 (Petrin Decl. ¶ 16); Appx. 0014 (Oller Decl. ¶ 12); Appx. 0789 (89 Fed. Reg. 32984 (Apr. 26, 2024)). This risk has only increased since the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), as patients find some health care banned, and providers and patients may face investigations into the legal treatment they provide and receive. *See* Appx. 0010 (Petrin Decl. ¶ 16); Appx. 0014 (Oller Decl. ¶ 12); Appx. 0789 (89 Fed. Reg. 32984 (Apr. 26, 2024)).

Patient trust is especially vital to the Columbus and Madison public health departments which serve as providers of last resort in their communities. Appx. 0025 (Johnson Decl. ¶ 19); Appx. 0031 (Heinrich Decl. ¶ 12). Many of the patients that Columbus Public Health and Public Health Madison and Dane County treat come from historically marginalized populations. Appx.

[3] For centuries, the patient-clinician relationship has been at the heart of medical practice. This relationship has an ethical foundation and is built on confidentiality, trust, and honesty. *See* Appx. 1446–52 (Am. Med. Ass'n, *Opinion 1.1.1: Patient-Physician Relationships*, Code of Medical Ethics (Aug. 2022), https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/1.1.1%20Patient-physician%20relationships--background%20reports_0.pdf).

0025 (Johnson Decl. ¶ 19); Appx. 0033 (Heinrich Decl. ¶ 22). "[M]edical mistrust—especially in communities of color or other communities that have been marginalized or negatively affected by historical and current health care disparities—can create damaging and chilling effects on individuals' willingness to seek appropriate and lawful health care for medical conditions that can worsen without treatment." Appx. 0789–90 (89 Fed. Reg. 32985 (Apr. 26, 2024)). Patients seek out care from Columbus Public Health and Public Health Madison and Dane County instead of a family physician to preserve their anonymity and avoid stigma that can be associated with particular statuses (e.g., sex work) or health conditions (e.g., sexually transmitted infections). *See* Appx. 0026 (Johnson Decl. ¶ 20); Appx. 0033 (Heinrich Decl. ¶ 23). Trust that their personal health information will remain confidential is paramount.

Preserving this relationship of trust between providers and their patients is an aim of the Privacy Rules. *See, e.g.*, Appx. 0169 (65 Fed. Reg. 82463 (Dec. 28, 2000)) (noting that "improv[ing] the quality of health care in the U.S. by restoring trust in the health care system among consumers, health care professionals, and the multitude of organizations and individuals committed to the delivery of care" is a "major purpose[]" of the 2000 Privacy Rule); Appx. 0781 (89 Fed. Reg. 32978 (Apr. 26, 2024)) (specifying that the 2024 Rule was necessary to "continue to protect privacy in a manner that promotes trust between individuals and health care providers" in light of the "changing legal landscape").

Strong privacy protections on patient medical information and the trust they engender between patients and their providers, in turn, allow Columbus Public Health, Public Health Madison and Dane County, and DFA's members to provide competent care and comport with their ethical obligations to do so. *See* Appx. 0009 (Petrin Decl. ¶ 13); Appx. 0014–15 (Oller Decl. ¶¶ 9, 11–13); Appx. 0019 (Mitchell Decl. ¶ 8); Appx. 0032 (Heinrich Decl. ¶ 17); Appx. 1453 (Am.

Med. Ass'n, *Opinion 3.1.1: Privacy in Health Care, Code of Medical Ethics*, https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2024-12/3.1.1.pdf (last visited Jan.16, 2025)). The provision of effective care depends on the sharing of sensitive health information, which will only happen where patients trust that their information will be kept confidential. Appx. 0009 (Petrin Decl. ¶ 13); Appx. 0014–15 (Oller Decl. ¶¶ 9–13); Appx. 0025 (Johnson Decl. ¶ 18); Appx. 0032–33 (Heinrich Decl. ¶ 20); *see* Appx. 0019 (Mitchell Decl. ¶ 9); Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)). When patients fear sharing their medical history or other relevant sensitive information with their providers, it risks misdiagnosis or mistreatment and puts patients' lives at risk. Put simply, "high-quality health care cannot be attained without patient candor." Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)).

As discussed, the Privacy Rules protect against that. More fundamentally, the provision of competent care is only possible where patients actually seek such care. Without robust privacy protections, patients may be afraid to seek certain health care because they are concerned about how their sensitive medical information will be used or shared. Appx. 0010 (Petrin Decl. ¶ 17); Appx. 0014 (Oller Decl.¶ 11); Appx. 0027 (Johnson Decl. ¶ 25); Appx. 0035 (Heinrich Decl. ¶ 29).

iii. The Cities of Columbus and Madison have an interest in the promotion of public health.

Columbus and Madison additionally have an interest in promoting the public health of their communities. Courts have long recognized the interest of local governmental bodies to protect public health. *See, e.g.*, *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 27 (1905)

("Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members.").

Protecting individual privacy while promoting public health is an express purpose of the Privacy Rules. Robust privacy protections engender accurate reporting and "[a]ccurate medical records assist communities in identifying troubling public health trends and in evaluating the effectiveness of various public health efforts." Appx. 0177 (65 Fed. Reg. 82467 (Dec. 28, 2000)). Put differently, "[b]arriers that undermine the willingness of individuals to seek health care in a timely manner or to provide complete and accurate health information to their health care providers undermine the overall objective of public health." Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)).

Columbus Public Health and Public Health Madison and Dane County are the public health authorities for their jurisdictions, responsible not just for treating individual patients but also for preventing disease and improving the overall health of their residents as a whole. *See* Appx. 0023 (Johnson Decl. ¶ 8); Appx. 0030 (Heinrich Decl. ¶ 7); Appx. 0789 (89 Fed. Reg. 32985 (Apr. 26, 2024)). The cities' ability to identify and address concerning health trends depends, in part, on the willingness of patients to seek care and be honest with public health department providers. Appx. 0026 (Johnson Decl. ¶ 22); Appx. 0034 (Heinrich Decl. ¶ 26). The cities' interest in vindicating

their public health mandates gives them sufficient interest in this litigation. *See Edwards*, 78 F.3d at 995.

iv. DFA will have to expend significant resources if either Privacy Rule is undone.

An organization satisfies Rule 24(a)(2)'s interest requirement where it "expend[s] significant resources" on efforts that may be impacted by the outcome of the proceedings. *La Union del Pueblo Entero*, 29 F.4th at 306. There is no question that DFA surpasses this threshold.

DFA spends significant resources advocating on behalf of providers for accessible, equitable health care at the local, state, and federal levels. It also works to increase the physician voice in health policy decisions. *See* Appx. 0007–08 (Petrin Decl. ¶¶ 7–8). In addition to advocating for legislative and regulatory change, DFA provides resources and trainings, including HIPAA-specific resources, for its members on legal and policy issues. *See* Appx. 0007–08 (Petrin Decl. ¶¶ 7–8). And in 2022, DFA co-founded the Reproductive Health Coalition—a group of more than a hundred health professional organizations—specifically focused on protecting access to reproductive care. Appx. 0009 (Petrin Decl. ¶ 9).

If either of the Privacy Rules were to fall, DFA would be required to expend significant resources advocating for increased privacy protections elsewhere (for example, at the state level) and educating and training its members on the reworked legal landscape. *See* Appx. 0010 (Petrin Decl. ¶ 17). "This interest goes beyond a purely 'ideological' reason for intervention and amounts to a 'direct' and 'substantial' interest in the proceedings." *La Union del Pueblo Entero*, 29 F.4th at 306.

c. Resolution of this action would practically impair and impede Proposed Intervenors' interests.

An intervenor must demonstrate that the disposition of the case "may, as a practical matter" impair or impede its ability to protect its interests. *Brumfield*, 749 F.3d. at 344. This threshold is low—a party "need only show that if [it] cannot intervene, there is *a possibility* that [its] interest could be impaired or impeded." *La Union del Pueblo Entero*, 29 F.4th at 307 (citing *Brumfield*, 749 F.3d at 344–45) (emphasis added).

It takes little imagination to see how a partial or complete resolution of the case in favor of Texas would impair Proposed Intervenors' interests. If either Privacy Rule is vacated, Proposed Intervenors will face severe costs, in both time and money, to understand and comply with the new legal landscape in which they operate. And patients' trust will be compromised, harming the provider-patient relationship, endangering Proposed Intervenors' ability to provide effective care to their patients, and undermining the public health missions of Columbus and Madison.

If Texas is afforded even part of its broad-sweeping requests for relief, Proposed Intervenors will be bound by the judgment. There will be no way to appeal or—depending on the grounds upon which this Court would hypothetically rule—advocate for the agency to revive the rules. *See Sierra Club v. Glickman*, 82 F.3d 106, 109 (5th Cir. 1196) ("[T]he *stare decisis* effect of an adverse judgment constitutes a sufficient impairment to compel intervention." (citing *Espy*, 18 F.3d at 1207)). And if the Proposed Intervenors are prevented from joining this litigation, they will have no other recourse—such as affirmative litigation—through which to vindicate their interests. *See Deus v. Allstate Ins. Co.*, 15 F.3d 506, 526 (5th Cir. 1994) ("Intervention generally is not appropriate where the applicant can protect its interests and/or recover on its claim through some other means." (citation omitted)). Precluding Proposed Intervenors from involvement in this

litigation would significantly impede and impair their abilities to protect the interests they have outlined.

d. The government's representation of Proposed Intervenors' interests is inadequate.

To make the "minimal" showing required for this factor, Proposed Intervenors need only demonstrate that the government's representation of their interests "*may* be inadequate," *Heaton v. Monogram Credit Card Bank of Georgia*, 297 F.3d 416, 425 (5th Cir. 2002) (emphasis added), which Proposed Intervenors can more than do here. Indeed, intervention has been permitted even in cases where the movant's interest "may diverge in the future, even though, at [the time of intervention] they appear to share common ground." *Id.*

Although adequacy of representation will be presumed (1) where the existing party is a government charged by law with representing a putative intervenor's interests; or (2) where the putative intervenor has the same "ultimate objective" as a party to the lawsuit, *Edwards*, 78 F.3d at 1005, the federal government is not entitled to either presumption of adequacy here. To begin, this case is not one in which the government defendants are "charged by law" with representing Proposed Intervenors' interests. *Id.* Although the Department has considered the interests of covered entities in crafting the Privacy Rules, *see, e.g.*, Appx. 0182 (65 Fed. Reg. 82471 (Dec. 28, 2000)), "there is no suggestion" that it is their "legal representative," *Brumfield*, 749 F.3d at 345*; see also Espy*, 18 F.3d at 1207–08. Moreover, if the government, as expected, imminently abandons its defense of either Privacy Rule, Proposed Intervenors and the existing defendants will not share the same ultimate goal of maintaining them.

If either presumption of adequacy did apply, Proposed Intervenors could easily rebut them. An intervenor overcomes the government-representative presumption by showing that the intervenors' interests are distinct from the existing governmental party and thus may not be

adequately represented by it. *La Union del Pueblo Entero*, 29 F.4th at 308 (citations and internal quotation marks omitted). An intervenor overcomes the same-objective presumption by showing "adversity of interest." *Id.* In this case, the same facts rebut both. *See Texas*, 805 F.3d at 662 (analyzing both under "adversity of interest").

Proposed Intervenors have outlined their specific interests in this case. *See* Section I(b) *supra*. The government's potential interests—in balancing patient privacy with the public interest in using health information and law enforcement needs, defending the integrity of its rulemaking process, managing its relationship with the states, and implementing the agenda of a new administration—are both broader and distinct. These competing interests are something the Department itself recognized in both Privacy Rules. *See, e.g.*, Appx. 0781 (89 Fed. Reg. 32978 (Apr. 26, 2024)) ("This final rule balances the interests of society in obtaining PHI for non-health care purposes with the interests of the individual, the Federal Government, and society . . . ."); Appx. 0527 (65 Fed. Reg. 82685 (Dec. 28, 2000)) ("The final rule seeks to strike a balance in protecting privacy and facilitating legitimate law enforcement inquiries."). These more extensive interests that the Department was obliged to consider at the rulemaking stage may lead to divergent legal strategies, such as a willingness to settle, agree to an injunction limited in scope, or not appeal relief ordered against it. *See Glickman*, 256 F.3d at 381 ("The USDA is a governmental agency that must represent the broad public interest, not just the [intervenors'] concerns.").

If that were not enough to overcome the presumption, the imminent change in administration "raises 'the possibility of divergence of interest' or a 'shift' during litigation." *W. Energy Alliance v. Zinke*, 877 F.3d 1157, 1169 (10th Cir. 2017) (citation omitted); *see Heaton*, 297 F.3d at 425 ("That the [intervenor's] interests and [existing party's] may diverge in the future, even though, at this moment, they appear to share common ground, is enough to meet the

[intervenor's] burden on this issue."). *Alliance for Hippocratic Med.*, 2024 WL 1260639, at *6 ("[I]n any event, 'it is enough' for the purposes of this factor that the Intervenors' broader interests 'may diverge' from Plaintiffs' interests 'in the future.'" (citing *Heaton* , 297 F.3d at 425)). This possibility alone satisfies the minimal requirement that the government's representation "may be" inadequate. *Espy*, 18 F.3d at 1207 (citing *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972)). Proposed Intervenors note abundant recent evidence that the incoming administration will abandon its defense of the challenged Privacy Rules. For example, the Nominee for Department Secretary, Robert F. Kennedy, Jr., has indicated his willingness to rescind Department regulations related to reproductive health care, including the 2024 Rule. *See* Appx. 1454–59 (Megan Messerly et al., *Anti-abortion groups have 2 asks. RFK Jr. is listening*, Politico (Nov. 20, 2024), https://www.politico.com/news/2024/11/20/anti-abortion-rfk-jr-00190552); Appx. 1460–64 (Tyler Arnold, *Trump's HHS nominee Robert F. Kennedy Jr. reassures pro-life senators with policy plans*, Catholic News Agency (Dec. 19, 2024), https://www.catholicnewsagency.com/news/261111/trump-hhs-nominee-robert-kennedy-jr-reassures-pro-life-senators) (noting that Kennedy has told Senators that he "will back certain pro-life policies if the Senate confirms him," and that abortion should go "back to the states").[4] Further,

[4] President-Elect Trump and his administration have demonstrated that they believe the federal government should not take any actions to protect access to abortion. *See* Appx. 1462 (Arnold, *supra*) (quoting Senator Tommy Tuberville as saying, "Basically, [Kennedy] and President Trump have sat down and talked about it and both of them came to an agreement," and "Roe v. Wade is gone, [abortion has] gone back to the states"). Within the past year, President-Elect Trump has indicated that he "would let red states monitor women's pregnancies," a sentiment completely diametric to the 2024 Rule's intent and Proposed Intervenors' interests. Appx. 1467 (Eric Cortellessa, *How Far Would Trump Go*, TIME (Apr. 30, 2024), https://time.com/magazine/us/6979410/may-27th-2024-vol-203-no-17-u-s/). Vice President-Elect Vance opposed the new rule from its inception, submitting a comment that makes many of the same arguments that Texas does here. *See* Appx. 1477–87 (Members of Congress, Comment on Proposed HIPAA Privacy Rule To Support Reproductive Health Care Privacy 9 (June 16, 2023), https://www.regulations.gov/comment/HHS-OCR-2023-0006-0171).

opposed similar HHS efforts to protect reproductive health information. Appx. 1490 (The Heritage Foundation, *Mandate for Leadership: The Conservative Promise* 497 (2023), https://tinyurl.com/55dbtvkx).[5]

Although the incoming administration has been less outspoken on the 2000 Privacy Rule, Texas's opposition to the 2000 Privacy Rule appears to be focused on provisions that it argues inhibit its ability to receive unlimited patient information pursuant to an administrative subpoena or investigative demands: requests that have increased following *Dobbs*. *See* Appx. 0792 (89 Fed. Reg. 32988 (Apr. 26, 2024)). Given the incoming administration's opposition to robust protections for reproductive care, its leaders may very well agree with Texas that the limits in the 2000 Privacy Rule overreach and also cease to defend that Rule.

Although Proposed Intervenors "cannot say for sure that the state's more extensive interests will *in fact* result in inadequate representation, . . . surely they might, which is all that the rule requires." *Brumfield*, 749 F.3d at 346 (emphasis in original).

II. Alternatively, this Court should permit Proposed Intervenors to intervene under Rule 24(b).

Federal Rule of Civil Procedure 24(b) provides that a court may permit intervention where an intervenor makes a timely motion and "has a claim or defense that shares with the main action a common question of law or fact," taking into consideration "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(1), (3). "The 'claim or defense' portion of Rule 24(b) . . . [is to be] construed liberally.'" *U.S. ex rel Hernandez v. Team Finance, LLC*, 80 F.4th 571, 577 (5th Cir. 2023) (quoting *Newby v. Enron*

[5] Although President-Elect Trump has endeavored to distance himself from Project 2025, he has since picked "major architects" of the blueprint for key posts in his next administration. Appx. 1491 (Amanda Becker, *How Trump's nominees could make Project 2025 a reality*, News from the States (Jan. 2, 2025), https://www.newsfromthestates.com/article/how-trump-nominees-could-make-project-2025-reality).

Corp., 443 F.3d 416, 422 (5th Cir. 2023)). On all counts, Proposed Intervenors should be permitted to intervene permissively if they are not entitled to under Rule 24(a)(2).

First, as explained above, Proposed Intervenors motion is timely. *See* Section I(a) *supra*. Although timeliness is analyzed with more scrutiny in the context of permissive intervention, *Rotstain v. Mendez*, 986 F.3d 931, 942 (5th Cir. 2021), Proposed Intervenors move to intervene promptly, before the matter proceeds substantively, to protect their interests. Second, Proposed Intervenors seek to take up the position (defending the Privacy Rules) and arguments that they believe the federal government will shortly abandon; their claims and defenses do not just share a common question of law or fact with the main action, they are practically identical. If the incoming administration does not abandon its defense of the rules, Proposed Intervenors' specific interests still easily satisfy this requirement. *See* Section I(b) *supra*. Lastly, intervention here would not cause any delay or prejudice, as this litigation is in its nascent stages. *See* Section I(a) *supra*.

CONCLUSION

For the foregoing reasons, Proposed Intervenors respectfully request that this Court grants their motion for leave to intervene under Rule 24(a), or, in the alternative, Rule 24(b).

Date: January 17, 2025

Respectfully submitted,

/s/ Jennifer R. Ecklund
Jennifer R. Ecklund
THOMPSON COBURN LLP
2100 Ross Avenue Suite 3200
Dallas, Texas 75201
(972) 629-7100 (phone)
(972) 629-7171 (fax)
jecklund@thompsoncoburn.com

Counsel to Intervenor-Defendants

Shannon Rose Selden – *Pro Hac Vice Pending*
Adam Aukland Peck – *Pro Hac Vice Pending*
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
(212) 909-6000 (phone)
(212) 909-6836 (fax)
srselden@debevoise.com
aauklandpeck@debevoise.com

Counsel to Intervenor-Defendants

-and-

Anna A. Moody – *Pro Hac Vice Pending*
Gabriel A. Kohan – *Pro Hac Vice Pending*
DEBEVOISE & PLIMPTON LLP
801 Pennsylvania Avenue NW
Washington, DC 20004
(202) 383-8000 (phone)
(202) 383-8118 (fax)
amoody@debevoise.com
gakohan@debevoise.com

Counsel to Intervenor-Defendants

-and-

Carrie Y. Flaxman – *Pro Hac Vice Pending*
Madeline H. Gitomer – *Pro Hac Vice Pending*
Emma R. Leibowitz – *Pro Hac Vice Pending*
DEMOCRACY FORWARD
P.O. Box 34553
Washington, DC 20043
(202) 448-9090 (phone)
cflaxman@democracyforward.org
mgitomer@democracyforward.org
eleibowitz@democracyforward.org

Counsel to Intervenor-Defendants

-and-

Aisha Rich – *Pro Hac Vice Pending*
PUBLIC RIGHTS PROJECT
490 43rd Street, Unit #115
Oakland, California 94609
(510) 214-6960 (phone)
aisha@publicrightsproject.org

Counsel to City of Columbus and City of Madison

CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Jennifer R. Ecklund
Jennifer R. Ecklund

IN THE UNITED STATES OF AMERICA
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas,

Plaintiff,

v.

United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services,

Defendants,

Civil Action No. 5:24-cv-00204-H

APPENDIX IN SUPPORT OF PROPOSED INTERVENOR-DEFENDANTS' MOTION TO INTERVENE

Ex.	Exhibit Description	Bates Number
D	Declaration of Edward Johnson	Appx. 0022
E	Declaration of Janel Heinrich	Appx. 0029
F	Health Insurance Portability and Accountability Act, Pub. L. 104-191, 110 Stat. 1936	Appx. 0037
G	Administrative Procedure Act, 5 U.S.C. § 706(2)	Appx. 0162
H	Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164)	Appx. 0164
I	HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32976-01 (Apr. 26, 2024)	Appx. 0776
J	Ohio Const. art. XVIII	Appx. 0935
K	Wis. Stat. Ch. 66	Appx. 0950
L	Texas's Memo. In Support of Mot.to Intervene, *Commonwealth of Pennsylvania et al. v. Devos et al.*, 1:20-cv-01468 (D.D.C. Jan. 19, 2021), ECF No. 130-1	Appx. 1407
M	45 C.F.R. § 160.103	Appx. 1428
N	42 U.S.C. § 1320d-5	Appx. 1438
O	42 U.S.C. § 1320d-6(b)	Appx. 1444
P	Am. Med. Ass'n, *Opinion 1.1.1: Patient-Physician Relationships*, Code of Medical Ethics (Aug. 2022), https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/1.1.1%20Patient-physician%20relationships--background%20reports_0.pdf	Appx. 1446
Q	Am. Med. Ass'n, *Opinion 3.1.1: Privacy in Health Care, Code of Medical Ethics*, https://code-medical-ethics.ama-assn.org/sites/amacoedb/files/2024-12/3.1.1.pdf (last visited Jan. 17, 2025)	Appx. 1453
R	Megan Messerly et al., *Anti-abortion groups have 2 asks. RFK Jr. is listening*, Politico (Nov. 20, 2024), https://www.politico.com/news/2024/11/20/anti-abortion-rfk-jr-00190552	Appx. 1454
S	Tyler Arnold, *Trump's HHS nominee Robert F. Kennedy Jr. reassures pro-life senators with policy plans*, Catholic News Agency (Dec. 19, 2024), https://www.catholicnewsagency.com/news/261111/trump-hhs-nominee-robert-kennedy-jr-reassures-pro-life-senators	Appx. 1460
T	Eric Cortellessa, *How Far Would Trump Go*, TIME (Apr. 30, 2024), https://time.com/magazine/us/6979410/may-27th-2024-vol-203-no-17-u-s/	Appx. 1465

Ex.	Exhibit Description	Bates Number
U	Members of Congress, Comment on Proposed HIPAA Privacy Rule To Support Reproductive Health Care Privacy 9 (June 16, 2023), https://www.regulations.gov/comment/HHS-OCR-2023-0006-0171	Appx. 1477
V	The Heritage Foundation, *Mandate for Leadership: The Conservative Promise* 497 (2023), https://tinyurl.com/55dbtvkx	Appx. 1488
W	Amanda Becker, *How Trump's nominees could make Project 2025 a reality*, News from the States (Jan. 2, 2025), https://www.newsfromthestates.com/article/how-trump-nominees-could-make-project-2025-reality	Appx. 1491

Date: January 17, 2025

Respectfully submitted,

/s/ Jennifer R. Ecklund

Jennifer R. Ecklund
THOMPSON COBURN LLP
2100 Ross Avenue Suite 3200
Dallas, Texas 75201
(972) 629-7100 (phone)
(972) 629-7171 (fax)
jecklund@thompsoncoburn.com

Counsel to Intervenor-Defendants

-and-

Carrie Y. Flaxman – *Pro Hac Vice Pending*
Madeline H. Gitomer – *Pro Hac Vice Pending*
Emma R. Leibowitz – *Pro Hac Vice Pending*
DEMOCRACY FORWARD
P.O. Box 34553
Washington, DC 20043
(202) 448-9090 (phone)
cflaxman@democracyforward.org
mgitomer@democracyforward.org
eleibowitz@democracyforward.org

Counsel to Intervenor-Defendants

-and-

Aisha Rich – *Pro Hac Vice Pending*
PUBLIC RIGHTS PROJECT
490 43rd Street, Unit #115

Shannon Rose Selden – *Pro Hac Vice Pending*
Adam Aukland Peck – *Pro Hac Vice Pending*
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
(212) 909-6000 (phone)
(212) 909-6836 (fax)
srselden@debevoise.com
aauklandpeck@debevoise.com

Counsel to Intervenor-Defendants

-and-

Anna A. Moody – *Pro Hac Vice Pending*
Gabriel A. Kohan – *Pro Hac Vice Pending*
DEBEVOISE & PLIMPTON LLP
801 Pennsylvania Avenue NW

Washington, DC 20004
(202) 383-8000 (phone)
(202) 383-8118 (fax)
amoody@debevoise.com
gakohan@debevoise.com

Counsel to Intervenor-Defendants

Oakland, California 94609
(510) 214-6960 (phone)
aisha@publicrightsproject.org

Counsel to City of Columbus and City of Madison

CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Jennifer R. Ecklund
Jennifer R. Ecklund

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas, *Plaintiff*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*.	Civil Action No. 5:24-cv-00204-H

DECLARATION OF DR. CHRISTINE PETRIN

I, Christine Petrin, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Christine Petrin. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I provide this declaration in support of the motion to intervene.

2. I am a primary care physician at Settlement Health and a Clinical Instructor of Internal Medicine & Pediatrics at Mount Sinai Hospital, both in New York, New York. My driving mission as a physician is to improve the lives of children, adults, and their communities.

3. I received my medical degree from Tulane University School of Medicine in New Orleans, Louisiana. I did a dual medical residency in internal medicine and pediatrics at MedStar Georgetown University Hospital in Washington, D.C., where I was the Chief Resident.

4. Since February 2024, I have served as the President and Chair of the Board of Doctors for America (DFA). I previously served as both Vice Chair and Secretary of the Board and have been a member of DFA since 2018.

DFA and its Members

5. DFA is a nonprofit organization organized under Section 501(c)(3) of the Internal Revenue Code. Founded in 2009, DFA works on behalf of its members to improve the health of patients, communities, and the nation. One of our guiding principles is that clinicians must take a leading role in improving health care and ending health disparities, and we provide our members with the tools to do so. We advocate on our members' behalf for policies that allow them to provide equitable and accessible care to patients.

6. DFA is comprised of more than 27,000 medical professionals, medical students, and health care advocates who live in all fifty states and the District of Columbia, work in various practice settings, including in hospitals, academia, and in private practice, and represent all areas of specialization.

7. DFA members have access to various DFA resources, including continuing medical education and other training, events, and advocacy tools. DFA also drafts resources to keep our members up to date on the latest developments in health policy.

8. DFA members, including myself, serve in various capacities in the organization, including on the Board of Directors, and drive our organizational focus areas: health justice and equity; access to affordable care; and community health and prevention. In each of these

buckets, DFA provides education and training to its members and engages in advocacy at the state and federal levels. Through these efforts, we work to improve outcomes for the patients we serve.

9. DFA's health justice and equity work involves efforts to reduce health disparities among marginalized communities and populations. As part of that work, DFA works to protect access to reproductive health care services for all patients. DFA is also one of two founding organizational members of the Reproductive Health Coalition, a group of 120 medical-professional associations and allied organizations that collectively represent over 150 million voices in medicine, health care, and other groups.

DFA Members and HIPAA

10. Many DFA members are "health care providers" and "covered entities" subject to the Health Insurance Portability and Accountability Act ("HIPAA") and its regulations, including the HIPAA 2000 Privacy Rule ("2000 Privacy Rule") and the 2024 HIPAA Reproductive Health Rule ("2024 Rule," and together, the "HIPAA Rules").

11. As professionals who are required to comply with HIPAA, these DFA members are impacted by any changes to the law and its regulations, which covered entities have relied on for decades. These DFA members are required to have in place and adhere to HIPAA policies and procedures (and are subject to the internal HIPAA policies of the entities they work for), receive at least annual training on what HIPAA requires, and offer patients information about their rights under HIPAA.

12. Day-to-day, our clinician members rely on HIPAA to guide when and how patient information may and may not be used or disclosed. The presence of national baseline requirements regarding the use and disclosure of patient information helps DFA members stay

confident that they are appropriately safeguarding patient information and adhering to their ethical obligations to do so. In response to administrative subpoenas and investigative demands, for example, medical practices can rely on the three preconditions under HIPAA that must be met prior to disclosing medical information in order to appropriately protect patient information.

13. DFA and its members believe that the privacy protections that HIPAA affords are integral to maintaining trust between clinicians and their patients—a key but fragile component of providing quality care. We believe that privacy is necessary for the efficient and effective delivery of health care because trust and confidentiality are at the very core of the provider-patient relationship, and those relationships and the health care system as a whole, are built upon the willingness of individuals to share the most intimate details of their lives with their health care providers. HIPAA is a key tool for assuring patients that their medical information will be protected, which increases patient trust, encourages patients to be open with their clinicians, and, in turn, allows us to give them the best possible care.

14. If the 2000 Privacy Rule was vacated, it would inject significant confusion into our jobs and impair the provider-patient relationship necessary to deliver adequate health care. Without a federal standard to govern the use and disclosure of medical information, I do not know how clinicians could reliably share information without becoming expert in numerous state laws. That would be time-consuming, costly, and unworkable, including because medical professionals would need to completely rebuild their privacy compliance programs, of which HIPAA has been the foundation for decades, thereby incurring unexpected and potentially significant compliance costs.

15. The 2024 Rule put in place important restrictions on using and sharing patient information about their reproductive health care, providing DFA's members with clarity on how

they can use and disclose this particularly sensitive patient information. Many DFA members provide reproductive health services on a regular basis, while others provide such care as necessary. Members who do not provide reproductive health care may obtain sensitive information about their patients' medical care in the course of providing treatment and record that information in the medical record.

16. DFA members have been increasingly concerned that patient medical information may be sought and used improperly for non-health care purposes following the *Dobbs* decision, including from investigations into doctors providing legal and necessary health care and patients obtaining it. The 2024 Rule has helped mitigate these risks to providers like many of DFA members and strengthened the doctor-patient relationship because it allows them to explain to patients how their reproductive health information is protected from misuse. If the 2024 Rule is vacated, it is likely that some patients seeking reproductive health care would forgo such care, and that patients will withhold critical reproductive health information relevant for proper medical treatment from their clinicians.

17. Without the protections of the 2000 and 2024 Rules, providers would have less ability to protect the sensitive medical information they receive from misuse, and our members would face increased challenges in their ethical and professional duties to provide effective care to their patients. Patients would not be willing to share relevant medical information with their providers for fear it may not be protected. Other patients may forgo care altogether. The provider-patient relationship, based on trust, would be fractured. And, fundamentally, that would negatively affect patient care. In turn, DFA would need to expend significant resources to account for this sea change in patient protection privacy—updating its materials and reorienting its advocacy work.

Executed on January 12, 2025

Dr. Christine Petrin

THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas, *Plaintiff*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*.	Civil Action No. 5:24-cv-00204-H

DECLARATION OF DR. BETH OLLER

I, Beth Oller, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Beth Oller. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I submit this declaration in support of Doctors for America's ("DFA") motion to intervene.

2. I have a Bachelor of Science in Nursing from the University of Kansas and received my medical degree from the University of Kansas School of Medicine. I did my residency at the Wesley Family Medicine Residency Program in Wichita, Kansas. Since I

completed my residency more than fifteen years ago, I have practiced medicine in Rooks County, Kansas—a rural part of the state with approximately 5,000 residents.

3. I am currently a primary care provider at the Rooks County Health Center. I treat hundreds of patients. For more than a decade before that, I ran a small private practice in Rooks County.

4. I have been a member of DFA since 2022. I became a member of DFA when I became increasingly concerned that the Supreme Court would overturn the constitutional protections related to abortion.

5. Since then, I have relied on DFA's resources to educate myself and advocate for laws and policies that increase access to reproductive and other health care. For example, Kansas is one of only a few states that has not expanded Medicaid. I have used DFA's resources to understand how I can directly support efforts to change that. I have also attended several DFA webinars and use DFA's communications to stay up to date on the laws and policies relevant to my practice.

6. As a family medicine physician, I care for patients of all ages. My daily practice involves everything from conducting yearly check-ups to treating common illnesses such as colds and the flu and screening and treating for conditions such as high blood pressure or diabetes.

7. I also provide a range of reproductive healthcare. For example, I provide birth control and talk with my patients about family planning, refer pregnant patients to nearby obstetricians and may provide them with interim care, help my patients manage miscarriages, and treat moms (and their babies) post-birth. For more than a decade of my career, I also delivered babies. My patients often provide me with their medical histories, which can include

sensitive information that my patients intend to keep otherwise confidential, such as whether they have had an abortion.

8. As a physician, I am subject to and must comply with the Health Insurance Portability and Accountability Act ("HIPAA") and its privacy rules.

9. I use HIPAA and its privacy rules as tools to improve my work. My ethical and professional duties are to provide the care my patients need. An important part of satisfying those duties is making sure my patients know that they can trust me and that my clinic is safe for them.

10. HIPAA and its privacy rules provide a backstop when I need to explain to my patients how their information may or may not be shared, including with family members who—especially in the small community in which I practice—may ask for it. It's a foundational protection that my patients know and understand, and it's crucial to maintaining the confidentiality of my patients' records and, in turn, their trust.

11. This trust is essential to my practice. If patients don't believe that I'll keep their information private, they won't come to my office or they won't tell me everything I need to know to provide them with optimal care. For example, if a patient who has miscarried before doesn't feel safe sharing that fact with me, I can't give her correct advice on how much time she should wait before trying to get pregnant again.

12. In the context of providing reproductive health, this trust has been increasingly threatened since the *Dobbs* decision. The newest HIPAA privacy rule gives my patients an extra assurance that their particularly sensitive information will be kept private. Without it, I would be concerned that my patients considering abortion care, for example, would no longer come to me to learn about their options.

13. HIPAA and its privacy rules also help me work effectively with the other providers my patients see. To provide comprehensive, quality care to my patients—and for my patients' other providers to do the same—we must share patient information. Where I work in rural Kansas, that might even require me to share and receive patient information across state lines. HIPAA and its privacy rules allow all providers to operate under a common baseline of patient privacy protections.

14. If HIPAA and its privacy rules were struck down, it would sow chaos in the medical profession and negatively impact my patients. HIPAA and its privacy rules are the building blocks on which other patient privacy laws and policies are crafted. If they were thrown out, health care providers would need to update their policies based on the patchwork of state laws that would emerge (many of which had previously relied on HIPAA and its privacy rules) and their own assessments of the proper balance between patient privacy and other concerns. And different practices might reach different conclusions, making it hard to share information among providers. That would cause complications in my own practice when, for example, I had to send critical health information from a patient's neurologist in Nebraska or get information from a patient's OB-GYN three hours away in Wichita.

15. Undermining HIPAA and its privacy rules would be detrimental to patient health and public health generally. They are the foundation of patient privacy, and my patients understand that their information is protected by federal law. If HIPAA and its privacy rules were to be overturned, it would deeply harm the level of trust my patients have in me, threatening my relationships with them, and inhibiting my ability to provide care for them.

Executed on January 14, 2025

Dr. Beth Oller

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas, *Plaintiff*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*.	Civil Action No. 5:24-cv-00204-H

DECLARATION OF SHELLY MITCHELL

I, Shelly Mitchell, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Shelly Mitchell. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I provide this declaration in support of the motion for intervention.

2. I am the Health Information Manager and HIPAA Privacy and Security Officer for the Columbus Department of Public Health ("Columbus Public Health"). Columbus Public Health is a city department charged with protecting the health and improving the lives of all the residents of Columbus, Ohio.

3. I have worked for Columbus Public Health for nearly 24 years. As Columbus Public Health's HIPAA Privacy and Security Officer, I have developed and keep up to date our HIPAA compliance program. This includes ensuring that our HIPAA policies are enforced and

that our patients' private health information remains secure. My responsibilities include providing HIPAA training to the roughly 600 employees of Columbus Public Health.

4. Columbus Public Health operates a number of outpatient clinics where medical providers treat thousands of patients each year. All clinics accept and bill both private and public insurers for patients who have health insurance.

5. Columbus Public Health's clinics and many of its employees are "health care providers," and the clinics are a "covered entity" subject to the Health Insurance Portability and Accountability Act ("HIPAA") and its regulations, including the HIPAA 2000 Privacy Rule ("2000 Privacy Rule") and the 2024 HIPAA Reproductive Health Rule ("2024 Rule," and together, the "HIPAA Rules"). As a covered entity, Columbus Public Health is impacted by any changes to HIPAA and its regulations, which it has relied upon for more than 20 years. Because it is a HIPAA covered entity, Columbus Public Health clinics are required to have in place and adhere to HIPAA policies and procedures, provide at least annual training on what HIPAA requires, and offer patients information about their rights under HIPAA.

6. I develop and update the annual HIPAA training materials and ensure that they reflect any changes to HIPAA rules and regulations. In addition to training, I provide updates on HIPAA compliance to all employees through a periodic department-wide newsletter.

7. Columbus Public Health and our clinic providers have an interest in protecting the HIPAA Rules. The HIPAA Rules are a critical tool to support patient trust in their medical providers and to protect the confidentiality of sensitive patient information. Columbus Public Health clinicians rely on HIPAA to guide when and how patient information can and cannot be used or disclosed.

8. The presence of national baseline requirements regarding the use and disclosure of patient information helps Columbus Public Health employees be confident that they are appropriately safeguarding patient information and adhering to their ethical obligations.

9. Patients are often worried about their medical information being improperly disclosed or used to harm them. The HIPAA Privacy Rules help strengthen the provider-patient relationship and assure patients that they can trust their providers to safeguard their medical information.

10. The 2000 Privacy Rule is foundational to our work at Columbus Public Health. The rule was promulgated shortly after I began my service at Columbus Public Health, and it serves as the basis for how patient information can be used and disclosed. Our providers have relied on it for more than 20 years. Columbus Public Health shaped its compliance programs around the 2000 Privacy Rule's requirements, and our employees have spent decades explaining to patients the rights and protections it affords them.

11. If the 2000 Privacy Rule is vacated, it would create significant confusion across Columbus Public Health and impair the provider-patient relationship necessary for our clinics to deliver adequate health care. The legal basis underpinning our privacy policies would be gone, and we would need to think through our privacy compliance program from scratch. It would be difficult to understand how patient information would be protected. I would need to re-develop our privacy policies and training and re-train 600 employees on the impact of the HIPAA rules being struck down.

12. This work would be time-consuming and costly. We would incur significant unexpected costs in both time and money to re-develop all of our patient privacy and compliance

systems and to analyze how we are able to use and share patient information in the absence of HIPAA.

13. The 2024 Rule is also important to our work at Columbus Public Health. Columbus Public Health clinics and providers offer reproductive health care. The 2024 Rule put in place important restrictions on using and sharing patient information about their reproductive health care, giving Columbus Public Health's providers clarity on how they can use and disclose this sensitive patient information.

14. Since the finalization of the 2024 Rule in April 2024, and in anticipation of the December 23, 2024 compliance deadline, I tracked developments regarding new requirements and spent numerous hours ensuring that our processes reflect the 2024 Rule's requirements. In preparation for the compliance deadline, I created our HIPAA attestation form and met with the managers affected by the 2024 Rule to discuss changes to our practices.

15. If the 2024 Rule is vacated, our providers would have less ability to protect the sensitive medical information they receive from misuse and would face increased challenges in their ethical and professional duties to provide effective care to our residents. Additionally, Columbus Public Health would need to re-educate leadership and once again revise our processes to reflect those changes.

(signature on following page)

Executed on January 16, 2025

Shelly Mitchell
SHELLY MITCHELL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas, *Plaintiff*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*.	Civil Action No. 5:24-cv-00204-H

DECLARATION OF EDWARD JOHNSON

I, Edward Johnson, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Edward Johnson. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I provide this declaration in support of the motion for intervention.

2. I am currently the Assistant Public Health Commissioner for External Affairs and Acting Chief Health Equity Officer for the Columbus Department of Public Health ("Columbus Public Health"). I have served as an Assistant Public Health Commissioner for close to three years.

3. Prior to my role as Assistant Public Health Commissioner, I served Columbus Public Health as the Director of Public Health Policy for over four years.

4. As Columbus Public Health's Assistant Public Health Commissioner for External Affairs and Acting Chief Health Equity Officer, I assist the Health Commissioner with representing the needs and concerns of Columbus' residents to protect their health and improve their lives.

Columbus Public Health

5. The City of Columbus, Ohio, is a municipal corporation organized under Ohio law. Columbus has all the powers of local self-government and home rule under the constitution and laws of the state of Ohio, which are exercised in the manner prescribed by the Charter of the City of Columbus.

6. Columbus, located in Franklin County, is the capital of Ohio. It is the largest city in the state and the fourteenth largest city in the United States, with a population of over 905,000, according to 2020 Census estimates.

7. Columbus provides a wide range of services on behalf of its residents, including health services for families and children, public health, public assistance, and emergency medical care.

8. Columbus's public health department, Columbus Public Health, is a city agency charged with protecting the health and improving the lives of all the residents of Columbus, Ohio. Columbus Public Health works to ensure that the Columbus community is protected from disease and other public health threats and that Columbus residents are empowered to live healthier lives.

9. Columbus Public Health employs close to 600 employees who operate more than 90 different public health programs and provide critical services to residents. These programs and services include testing and treatment for sexually transmitted infections, including human

immunodeficiency virus ("HIV"), women's health and wellness services, postpartum and newborn home visiting, immunizations, dental services, and medication assisted treatment for substance use, among others.

10. Columbus Public Health operates 9 outpatient clinics where doctors and nurse practitioners treat approximately 10,000 patients each year. Many of Columbus Public Health's employees work in these clinics, which include the Women's Health and Wellness Center and the Sexual Health and Wellness Center.

11. All Columbus Public Health clinics accept and bill both private and public insurers for patients who have health insurance. Clinic staff members assist uninsured patients with enrolling in Medicaid. Clinics also provide free services for uninsured and underinsured patients.

12. Columbus Public Health's Women's Health and Wellness Center provides confidential reproductive health care for women, their partners and teens; testing, treatment and prevention education for sexually transmitted infections; well woman annual exams and cancer screenings; contraceptive services, including long-acting methods (implant and IUD); reproductive life planning; pregnancy testing; and other medical services.

13. A critical part of the Women's Health and Wellness Center's work relates to the provision of reproductive health care services. These services enable every Columbus resident to make and carry out their own reproductive decisions, consistent with Article I, Section 22 of the Ohio Constitution.

14. Columbus's Sexual Health and Wellness Clinic offers testing and treatment for sexually transmitted infections, medication to prevent HIV infections, preconception health and

pregnancy testing, emergency contraception, and wellness services such as diabetes and cholesterol screenings, among others.

Columbus Public Health and HIPAA Privacy Protections

15. Columbus Public Health's clinics are subject to HIPAA. Columbus Public Health is impacted by any changes to HIPAA and its regulations, which it has relied upon for decades.

16. Columbus Public Health takes its HIPAA obligations seriously and employs a dedicated Health Information Manager and HIPAA Privacy and Security Officer.

17. HIPAA and its relevant regulations, including the 2000 Privacy Rule and the 2024 HIPAA Reproductive Health Rule ("2024 Rule"), support the work of Columbus Public Health. National baseline requirements regarding the use and disclosure of patient information allow Columbus Public Health clinicians to be confident that they are appropriately protecting their patients' medical information.

18. The privacy protections that HIPAA affords are critical to establishing and maintaining trust between our doctors and nurses and their patients. The delivery of quality health care depends on individuals being willing to share the most intimate details of their lives with their health care providers. HIPAA is a key tool providers can use to assure patients that their medical information will be kept safe. This increases patient trust, encourages patients to be open, and, in turn, allows clinicians to give them the best possible care.

19. This is especially so for health care services provided by Columbus Public Health. Our clinics are often providers of last resort, serving patients who have no other options to receive care. Many of the clinics' patients come from historically marginalized communities. Medical mistrust can be even more common in communities of color and other communities that have been negatively affected by historical and current health care disparities.

20. Many Columbus Public Health patients use our services because of the confidentiality they expect to receive from a community-based health center. Many of our patients seek treatment for sexually transmitted infections, substance abuse, and other forms of health care they fear may subject them to stigma. Even if they have family doctors, some patients—survivors of intimate partner violence, sex trafficking, and other vulnerable patients—seek our care because of the guarantee of confidentiality we can provide.

21. Without the protection of HIPAA rules, some of our patients would be less likely to seek care.

22. Fostering trust between clinicians and patients is also important to our public health mission. Accurate medical records assist Columbus Public Health in identifying problematic trends in public health and in evaluating the effectiveness of various public health programs. Policies that undermine the willingness of patients to share complete and accurate health information with providers undermine the overall objective of public health departments and can have negative impacts on a department's efforts to address community health concerns, like communicable diseases and vaccinations.

23. If the 2000 Privacy Rule is vacated, it would create significant confusion for Columbus Public Health and harm the relationship between our clinicians and their patients. A trusting patient-provider relationship is necessary to deliver quality health care and to adequately address public health concerns across the City of Columbus. Without a federal standard to govern the use and disclosure of medical information, it is not clear to me know how Columbus Public Health clinicians could reliably share information without acquiring expertise in numerous state laws.

24. The 2024 Rule placed important restrictions on using and disclosing information about a patient's reproductive health care. Columbus Public Health's Women's Health and Wellness Center and Sexual Health and Wellness Center provide reproductive health services on a regular basis. The 2024 Rule provided Columbus Public Health's clinics with clarity on how to manage this particularly sensitive patient information. If the 2024 Rule is vacated, it is likely that some patients seeking reproductive health care would forgo such care, and that other patients would withhold critical reproductive health information relevant for proper medical treatment from their clinicians.

25. Without the protections of the 2000 and 2024 Privacy Rules, it would be more difficult for Columbus Public Health providers to protect the sensitive medical information they receive from misuse. In turn, they may lose the trust of their patients, who would fear the release of their private information and be unwilling to be honest with providers or may choose not to seek treatment all together. Without the 2000 and 2024 Privacy Rules, Columbus Public Health will face increased challenges to providing effective care to patients and to identifying and addressing troubling health trends in the community. In addition, Columbus Public Health would need to expend significant resources to account for and address this development in patient privacy.

(signature on following page)

Executed on January 16, 2025

EDWARD JOHNSON

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

State of Texas, *Plaintiff*, v. United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; and Melanie Fontes Rainer, in her official capacity as Director of the Office for Civil Rights of the United States Department of Health and Human Services, *Defendants*.	Civil Action No. 5:24-cv-00204-H

DECLARATION OF JANEL HEINRICH

I, JANEL HEINRICH, hereby declare under penalty of perjury as prescribed in 28 U.S.C. § 1746 that the following is true and correct:

1. My name is Janel Heinrich. I am over eighteen years old, of sound mind, and fully competent to make this declaration. I also have personal knowledge of the factual statements contained herein. I provide this declaration in support of the motion for intervention.

2. I am currently the Director of Public Health Madison and Dane County. I have held that position since I was appointed to it pursuant to Wis. Stat. § 62.51 and Wis. Stat. § 251.06(4)(a) by the Mayor of the City of Madison and the Dane County Executive and confirmed by a vote of the Common Council of Madison and County Board. I have served in this position for more than 14 years.

3. In my position as the Director of Public Health, I serve as the "local health officer" for the City of Madison and the County of Dane under Wis. Stat. § 251.06. This position

carries many responsibilities, including but not limited to administering the department, enforcing state public health statutes, and providing information to the public "as to the causes, nature and prevention of prevalent diseases, and the preservation and improvement of health."

Madison and Public Health Madison and Dane County

4. The City of Madison, Wisconsin, is a municipal corporation organized under Wisconsin law. Wis. Stat. Ch. 66. Madison has all the powers of local self-government and home rule under the constitution and laws of the state of Wisconsin.

5. Madison, located in Dane County, is the capital of Wisconsin. It is the second largest city in the state, with a population of over 269,000, according to 2020 Census estimates.

6. Madison provides a wide range of services on behalf of its residents, including health services for families and children, public health, and emergency medical care. It carries out these essential duties in part through Public Health Madison and Dane County.

7. Public Health Madison and Dane County is an agency with the mission of "working with the community to enhance, protect, and promote the health of the environment and the well-being of all people." We work to ensure that the Madison and Dane County community is protected from disease and other public health threats and that our residents are empowered to live healthier lives.

8. Public Health Madison and Dane County employs over 200 people operating several public health programs and providing critical services to residents. These programs and services include sexual and reproductive health testing, testing and treatment for tuberculosis, cancer screening, immunizations, treatment for sexually transmitted infections, Nurse Family Partnership providing home visits for maternal and infant health, communicable disease testing, among others.

9. Because our mission encompasses the health of the entire community, our programs not only provide treatment to our community, but also prevention and improvement of health outcomes.

10. Public Health Madison and Dane County operates a number of outpatient clinics where staff treat thousands of patients per year. At least 2000 patients sought sexual or reproductive health services in the past year.

11. Public Health Madison and Dane County clinics accept and bill public insurers for patients who have health insurance. Clinics provide services to both uninsured and underinsured patients.

12. Public Health Madison and Dane County serves the community regardless of ability to pay. Our clinics are often providers of last resort, serving the city's most vulnerable populations.

13. A critical part of our work relates to the provision of reproductive and sexual health care services. These services enable every Madison resident to make and carry out their own reproductive decisions consistent with Wisconsin law.

14. Public Health Madison and Dane County operates a sexual health clinic, where we provide reproductive health care; testing, treatment and prevention education for sexually transmitted infections; immunizations; contraceptive services; pregnancy testing; and other medical services.

Public Health and HIPAA Privacy Protections

15. Public Health Madison and Dane County is a covered entity under Health Insurance Portability and Accountability Act ("HIPAA") and its regulations. Public Health Madison and Dane County is impacted by any changes to HIPAA and its regulations, which it has relied upon for decades.

16. Patient privacy is foundational to Public Health Madison and Dane County's work. We regularly train all our employees on HIPAA compliance, regardless of whether they work in a clinical setting.

17. HIPAA and its regulations, including the 2000 Privacy Rule and the 2024 Rule, have made the work of Public Health Madison and Dane County stronger and better. The presence of national baseline requirements regarding the use and disclosure of patient information helps Public Health Madison and Dane County providers stay confident that they are appropriately safeguarding patient information and adhering to their ethical obligations to do so.

18. In the event of requests for information from third parties, for example, Public Health Madison and Dane County can rely on HIPAA to disclose medical information in a way that appropriately protects patient information.

19. Our patients expect confidentiality as part of our services, and we have a reputation of trust in our community. This reputation is built, in part, by the infrastructure created to comply with the 2000 Privacy Rule in our clinics. Our clinicians, patients and community have relied on the protections established by these practices for more than two decades.

20. HIPAA's privacy protections help us maintain trust between our clinicians and our patients. Privacy is necessary for the efficient and effective delivery of health care because trust and confidentiality are at the very core of the provider-patient relationship, and those relationships and the health care system as a whole, are built upon the willingness of individuals

to share the most intimate details of their lives with their health care providers. If patients are not confident in the privacy of their medical information, they will not disclose as much to their providers.

21. HIPAA is a key tool for assuring patients that their medical information will be protected, which increases patient trust, encourages patients to be open and honest with their clinicians, and, in turn, allows us to give them the best possible care.

22. This is especially so for health care services provided by Public Health Madison and Dane County. As providers of last resort, we serve patients who often have no other options to receive care. Many of the clinics' patients come from historically marginalized communities, including immigrant community members. Medical mistrust can be even more common in communities of color and other communities that have been negatively affected by historical and current health care disparities.

23. Public Health Madison and Dane County provides services to all, no matter what their background or circumstances. Many of our patients are only willing to seek care with us because of the confidentiality they expect to receive from a community-based health center, especially patients who seek treatment for sexually transmitted infections and other forms of health care they fear may subject them to stigma.

24. Even if they have family doctors, some patients – survivors of intimate partner violence, minors facing difficult or even dangerous circumstances, and other vulnerable patients, for example – seek our care because of the guarantee of confidentiality we can provide.

25. Public Health Madison and Dane County is trusted in our community and we have support for the work we do. The HIPAA privacy rules are part and parcel to this reputation. They help us maintain trusting relationships between patients from historically disadvantaged

communities and their clinical providers. The importance of this trust relationship is heightened for us as a governmental entity, where many may hold fears associated with seeking help from or sharing information with the government.

26. Fostering trust between clinicians and patients is important to Public Health Madison and Dane County both as a provider of direct services and as the public health authority for the City of Madison. Accurate medical records assist communities in identifying troubling public health trends and in evaluating the effectiveness of various public health efforts. Policies that undermine the willingness of individuals to provide complete and accurate health information to providers undermine the overall objective of public health departments and can have negative impacts on a department's efforts to address community health concerns, like communicable diseases and vaccinations.

27. If the 2000 Privacy Rule is vacated, it would create significant confusion for Public Health Madison and Dane County and impair the provider-patient relationship necessary to deliver adequate health care as well as to adequately address public health concerns in the City of Madison. Without a federal standard to govern the use and disclosure of medical information, I do not know how Public Health Madison and Dane County clinicians could reliably share information without becoming expert in numerous state laws. We would have to re-develop protocols and re-train all of our staff. That would be time-consuming, costly, and unworkable, including because Public Health Madison and Dane County may need to completely rebuild its privacy compliance programs, of which HIPAA has been the foundation for decades, thereby incurring unexpected and potentially significant compliance costs.

28. The 2024 Rule put in place important restrictions on sharing patient information about their reproductive health care, providing Public Health Madison and Dane County's clinics

with clarity on how they can use and disclose this particularly sensitive patient information. Public Health Madison and Dane County's Sexual Health Clinic provides reproductive health services on a regular basis. Clinics and clinicians may obtain sensitive information about their patients' medical care in the course of providing treatment wholly unrelated to reproductive or sexual health and record that information in the medical record. If the 2024 Rule is vacated, it is likely that some patients seeking reproductive health care would forgo such care, and that patients will withhold critical reproductive health information relevant for proper medical treatment from their clinicians.

29. Without the protections of the 2000 and 2024 Rules, Public Health Madison and Dane County providers would have less ability to protect sensitive medical information they receive from misuse. Public Health Madison and Dane County will face increased challenges to provide effective care to patients and to identify and address troubling health trends in the community. Patients would not be willing to share relevant medical information with their providers for fear it may not be protected. Other patients may forgo care altogether. Without these protections, health care professionals, such as those employed by Public Health Madison and Dane County, lose the trust of their patients and cannot deliver high-quality care. In turn, Public Health Madison and Dane County would need to expend significant resources to account for and address this development in patient privacy.

(signature on following page)

Executed on January 16, 2025

JANEL HEINRICH

PL 104–191, August 21, 1996, 110 Stat 1936

UNITED STATES PUBLIC LAWS

104th Congress - Second Session

Convening January 3, 1996

Additions and Deletions are not identified in this document.
8848

PL 104–191 (HR 3103)

August 21, 1996
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

An Act to amend the Internal Revenue Code of 1986 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

<< 42 USCA § 210 NOTE >>

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Health Insurance Portability and Accountability Act of 1996".
(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE II—PREVENTING HEALTH CARE FRAUD AND ABUSE;
ADMINISTRATIVE SIMPLIFICATION; MEDICAL LIABILITY REFORM

(a) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new part:

<< 29 USCA Ch. 18 >>

"PART 7—GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

<< 29 USCA § 1181 >>

"SEC. 701. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

"(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan, and a health insurance issuer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

"(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6–month period ending on the enrollment date;

"(2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and

"(3) the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage (if any, as defined in subsection (c)(1)) applicable to the participant or beneficiary as of the enrollment date.

"(b) DEFINITIONS.—For purposes of this part—

"(1) PREEXISTING CONDITION EXCLUSION.—

"(A) IN GENERAL.—The term 'preexisting condition exclusion' means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

"(B) TREATMENT OF GENETIC INFORMATION.—Genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

"(2) ENROLLMENT DATE.—The term 'enrollment date' means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

"(3) LATE ENROLLEE.—The term 'late enrollee' means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

"(A) the first period in which the individual is eligible to enroll under the plan, or

"(B) a special enrollment period under subsection (f).

"(4) WAITING PERIOD.—The term 'waiting period' means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

"(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

"(1) CREDITABLE COVERAGE DEFINED.—For purposes of this part, the term 'creditable coverage' means, with respect to an individual, coverage of the individual under any of the following:

"(A) A group health plan.

"(B) Health insurance coverage.

"(C) Part A or part B of title XVIII of the Social Security Act.

"(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

"(E) Chapter 55 of title 10, United States Code.

"(F) A medical care program of the Indian Health Service or of a tribal organization.

"(G) A State health benefits risk pool.

"(H) A health plan offered under chapter 89 of title 5, United States Code.

"(I) A public health plan (as defined in regulations).

"(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 706(c)).

"(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

"(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group health plan, if, after such period and before the enrollment date, there was a 63–day period during all of which the individual was not covered under any creditable coverage.

"(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group health plan (or for group health insurance coverage) or is in an affiliation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

"(3) METHOD OF CREDITING COVERAGE.—

"(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan, and a health insurance issuer offering group health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

"(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan, or a health insurance issuer offering group health insurance coverage, may elect to apply subsection (a)(3) based on coverage of benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

"(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

"(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

"(ii) include in such statements a description of the effect of this election.

"(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

"(d) EXCEPTIONS.—

"(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30–day period beginning with the date of birth, is covered under creditable coverage.

"(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30–day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

"(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—A group health plan, and health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

"(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63–day period during all of which the individual was not covered under any creditable coverage.

"(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

"(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

"(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide the certification described in subparagraph (B)—

"(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

"(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

"(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

"(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

"(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and

"(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

"(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

"(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

"(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information on coverage of classes and categories of health benefits available under such entity's plan or coverage, and

"(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

"(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

"(f) SPECIAL ENROLLMENT PERIODS.—

"(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

"(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

"(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

"(C) The employee's or dependent's coverage described in subparagraph (A)—

"(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

"(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

"(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

"(2) FOR DEPENDENT BENEFICIARIES.—

"(A) IN GENERAL.—If—

"(i) a group health plan makes coverage available with respect to a dependent of an individual,

"(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

"(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

"(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

"(i) the date dependent coverage is made available, or

"(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

"(C) NO WAITING PERIOD.—If an individual seeks to enroll a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

"(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

"(ii) in the case of a dependent's birth, as of the date of such birth; or

"(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

"(g) USE OF AFFILIATION PERIOD BY HMOS AS ALTERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

"(1) IN GENERAL.—In the case of a group health plan that offers medical care through health insurance coverage offered by a health maintenance organization, the plan may provide for an affiliation period with respect to coverage through the organization only if—

"(A) no preexisting condition exclusion is imposed with respect to coverage through the organization,

"(B) the period is applied uniformly without regard to any health status-related factors, and

"(C) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

"(2) AFFILIATION PERIOD.—

"(A) DEFINED.—For purposes of this part, the term 'affiliation period' means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such period and no premium shall be charged to the participant or beneficiary for any coverage during the period.

"(B) BEGINNING.—Such period shall begin on the enrollment date.

"(C) RUNS CONCURRENTLY WITH WAITING PERIODS.—An affiliation period under a plan shall run concurrently with any waiting period under the plan.

"(3) ALTERNATIVE METHODS.—A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of part A of title XXVII of the Public Health Service Act for the State involved with respect to such issuer.

<< 29 USCA § 1182 >>

"SEC. 702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

"(a) IN ELIGIBILITY TO ENROLL.—

"(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

"(A) Health status.

"(B) Medical condition (including both physical and mental illnesses).

"(C) Claims experience.

"(D) Receipt of health care.

"(E) Medical history.

"(F) Genetic information.

"(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

"(H) Disability.

"(2) NO APPLICATION TO BENEFITS OR EXCLUSIONS.—To the extent consistent with section 701, paragraph (1) shall not be construed—

"(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or

"(B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

"(3) CONSTRUCTION.—For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

"(b) IN PREMIUM CONTRIBUTIONS.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

"(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

"(A) to restrict the amount that an employer may be charged for coverage under a group health plan; or

"(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 29 USCA § 1183 >>

"SEC. 703. GUARANTEED RENEWABILITY IN MULTIEMPLOYER PLANS AND MULTIPLE EMPLOYER WELFARE ARRANGEMENTS.

"A group health plan which is a multiemployer plan or which is a multiple employer welfare arrangement may not deny an employer whose employees are covered under such a plan continued access to the same or different coverage under the terms of such a plan, other than—

"(1) for nonpayment of contributions;

"(2) for fraud or other intentional misrepresentation of material fact by the employer;

"(3) for noncompliance with material plan provisions;

"(4) because the plan is ceasing to offer any coverage in a geographic area;

"(5) in the case of a plan that offers benefits through a network plan, there is no longer any individual enrolled through the employer who lives, resides, or works in the service area of the network plan and the plan applies this paragraph uniformly without regard to the claims experience of employers or any health status-related factor in relation to such individuals or their dependents; and

"(6) for failure to meet the terms of an applicable collective bargaining agreement, to renew a collective bargaining or other agreement requiring or authorizing contributions to the plan, or to employ employees covered by such an agreement.

<< 29 USCA § 1184 >>

"SEC. 704. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

"(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

"(1) IN GENERAL.—Subject to paragraph (2) and except as provided in subsection (b), this part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

"(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this part shall be construed to affect or modify the provisions of section 514 with respect to group health plans.

"(b) SPECIAL RULES IN CASE OF PORTABILITY REQUIREMENTS.—

"(1) IN GENERAL.—Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 which differs from the standards or requirements specified in such section.

"(2) EXCEPTIONS.—Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

"(A) substitutes for the reference to '6–month period' in section 701(a)(1) a reference to any shorter period of time;

"(B) substitutes for the reference to '12 months' and '18 months' in section 701(a)(2) a reference to any shorter period of time;

"(C) substitutes for the references to '63 days' in sections 701(c)(2)(A) and (d)(4)(A) a reference to any greater number of days;

"(D) substitutes for the reference to '30–day period' in sections 701(b)(2) and (d)(1) a reference to any greater period;

"(E) prohibits the imposition of any preexisting condition exclusion in cases not described in section 701(d) or expands the exceptions described in such section;

"(F) requires special enrollment periods in addition to those required under section 701(f); or

"(G) reduces the maximum period permitted in an affiliation period under section 701(g)(1)(B).

"(c) RULES OF CONSTRUCTION.—Nothing in this part shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

"(d) DEFINITIONS.—For purposes of this section—

"(1) STATE LAW.—The term 'State law' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

"(2) STATE.—The term 'State' includes a State, the Northern Mariana Islands, any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

<< 29 USCA § 1185 >>

"SEC. 705. SPECIAL RULES RELATING TO GROUP HEALTH PLANS.

"(a) GENERAL EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

"(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 706(c)(1).

"(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

"(1) LIMITED, EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 706(c)(2) if the benefits—

"(A) are provided under a separate policy, certificate, or contract of insurance; or

"(B) are otherwise not an integral part of the plan.

"(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 706(c)(3) if all of the following conditions are met:

"(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

"(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

"(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

"(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 706(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

"(d) TREATMENT OF PARTNERSHIPS.—For purposes of this part—

"(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

"(2) EMPLOYER.—In the case of a group health plan, the term 'employer' also includes the partnership in relation to any partner.

"(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term 'participant' also includes —

"(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

"(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

<< 29 USCA § 1186 >>

"SEC. 706. DEFINITIONS.

"(a) GROUP HEALTH PLAN.—For purposes of this part—

"(1) IN GENERAL.—The term 'group health plan' means an employee welfare benefit plan to the extent that the plan provides medical care (as defined in paragraph (2) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

"(2) MEDICAL CARE.—The term 'medical care' means amounts paid for—

"(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,

"(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

"(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

"(b) DEFINITIONS RELATING TO HEALTH INSURANCE.—For purposes of this part—

"(1) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

"(2) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2)). Such term does not include a group health plan.

"(3) HEALTH MAINTENANCE ORGANIZATION.—The term 'health maintenance organization' means—

"(A) a federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a))),

"(B) an organization recognized under State law as a health maintenance organization, or

"(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

"(4) GROUP HEALTH INSURANCE COVERAGE.—The term 'group health insurance coverage' means, in connection with a group health plan, health insurance coverage offered in connection with such plan.

"(c) EXCEPTED BENEFITS.—For purposes of this part, the term 'excepted benefits' means benefits under one or more (or any combination thereof) of the following:

"(1) BENEFITS NOT SUBJECT TO REQUIREMENTS.—

"(A) Coverage only for accident, or disability income insurance, or any combination thereof.

"(B) Coverage issued as a supplement to liability insurance.

"(C) Liability insurance, including general liability insurance and automobile liability insurance.

"(D) Workers' compensation or similar insurance.

"(E) Automobile medical payment insurance.

"(F) Credit-only insurance.

"(G) Coverage for on-site medical clinics.

"(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

"(2) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED SEPARATELY.—

"(A) Limited scope dental or vision benefits.

"(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

"(C) Such other similar, limited benefits as are specified in regulations.

"(3) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS INDEPENDENT, NONCOORDINATED BENEFITS.—

"(A) Coverage only for a specified disease or illness.

"(B) Hospital indemnity or other fixed indemnity insurance.

"(4) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS SEPARATE INSURANCE POLICY.—Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act), coverage supplemental to the coverage provided under chapter 55 of title 10, United States Code, and similar supplemental coverage provided to coverage under a group health plan.

"(d) OTHER DEFINITIONS.—For purposes of this part—

"(1) COBRA CONTINUATION PROVISION.—The term 'COBRA continuation provision' means any of the following:

"(A) Part 6 of this subtitle.

"(B) Section 4980B of the Internal Revenue Code of 1986, other than subsection (f)(1) of such section insofar as it relates to pediatric vaccines.

"(C) Title XXII of the Public Health Service Act.

"(2) HEALTH STATUS–RELATED FACTOR.—The term 'health status-related factor' means any of the factors described in section 702(a)(1).

"(3) NETWORK PLAN.—The term 'network plan' means health insurance coverage offered by a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

"(4) PLACED FOR ADOPTION.—The term 'placement', or being 'placed', for adoption, has the meaning given such term in section 609(c)(3)(B).

<< 29 USCA § 1187 >>

"SEC. 707. REGULATIONS.

"The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this part. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this part.".

<< 29 USCA § 1132 >>

(b) ENFORCEMENT WITH RESPECT TO HEALTH INSURANCE ISSUERS.—Section 502(b) of such Act (29 U.S.C. 1132(b)) is amended by adding at the end the following new paragraph:

"(3) The Secretary is not authorized to enforce under this part any requirement of part 7 against a health insurance issuer offering health insurance coverage in connection with a group health plan (as defined in section 706(a)(1)). Nothing in this paragraph shall affect the authority of the Secretary to issue regulations to carry out such part.".

(c) DISCLOSURE OF INFORMATION TO PARTICIPANTS AND BENEFICIARIES.—

<< 29 USCA § 1024 >>

(1) IN GENERAL.—Section 104(b)(1) of such Act (29 U.S.C. 1024(b)(1)) is amended in the matter following subparagraph (B)—

(A) by striking "102(a)(1)," and inserting "102(a)(1) (other than a material reduction in covered services or benefits provided in the case of a group health plan (as defined in section 706(a)(1))),"; and

(B) by adding at the end the following new sentences: "If there is a modification or change described in section 102(a)(1) that is a material reduction in covered services or benefits provided under a group health plan (as defined in section 706(a)(1)), a summary description of such modification or change shall be furnished to participants and beneficiaries not later than 60 days after the date of the adoption of the modification or change. In the alternative, the plan sponsors may provide such description at regular intervals of not more than 90 days. The Secretary shall issue regulations within 180 days after the date of enactment of the Health Insurance Portability and Accountability Act of 1996, providing alternative mechanisms to delivery by mail through which group health plans (as so defined) may notify participants and beneficiaries of material reductions in covered services or benefits.".

<< 29 USCA § 1022 >>

(2) PLAN DESCRIPTION AND SUMMARY.—Section 102(b) of such Act (29 U.S.C. 1022(b)) is amended—

(A) by inserting "in the case of a group health plan (as defined in section 706(a)(1)), whether a health insurance issuer (as defined in section 706(b)(2)) is responsible for the financing or administration (including payment of claims) of the plan and (if so) the name and address of such issuer;" after "type of administration of the plan;"; and

(B) by inserting "including the office at the Department of Labor through which participants and beneficiaries may seek assistance or information regarding their rights under this Act and the Health Insurance Portability and Accountability Act of 1996 with respect to health benefits that are offered through a group health plan (as defined in section 706(a)(1))" after "benefits under the plan".

<< 29 USCA § 1003 >>

(d) TREATMENT OF HEALTH INSURANCE ISSUERS OFFERING HEALTH INSURANCE COVERAGE TO NONCOVERED PLANS.—Section 4(b) of such Act (29 U.S.C. 1003(b)) is amended by adding at the end (after and below paragraph (5)) the following:

"The provisions of part 7 of subtitle B shall not apply to a health insurance issuer (as defined in section 706(b)(2)) solely by reason of health insurance coverage (as defined in section 706(b)(1)) provided by such issuer in connection with a group health plan (as defined in section 706(a)(1)) if the provisions of this title do not apply to such group health plan.".

(e) REPORTING AND ENFORCEMENT WITH RESPECT TO CERTAIN ARRANGEMENTS.—

<< 29 USCA § 1021 >>

(1) IN GENERAL.—Section 101 of such Act (29 U.S.C. 1021) is amended—

(A) by redesignating subsection (g) as subsection (h), and

(B) by inserting after subsection (f) the following new subsection:

"(g) REPORTING BY CERTAIN ARRANGEMENTS.—The Secretary may, by regulation, require multiple employer welfare arrangements providing benefits consisting of medical care (within the meaning of section 706(a)(2)) which are not group health plans to report, not more frequently than annually, in such form and such manner as the Secretary may require for the purpose of determining the extent to which the requirements of part 7 are being carried out in connection with such benefits.".

<< 29 USCA § 1132 >>

(2) ENFORCEMENT.—

(A) IN GENERAL.—Section 502 of such Act (29 U.S.C. 1132) is amended—

(i) in subsection (a)(6), by striking "under subsection (c)(2) or (i) or (l)" and inserting "under paragraph (2), (4), or (5) of subsection (c) or under subsection (i) or (l)"; and

(ii) in the last 2 sentences of subsection (c), by striking "For purposes of this paragraph" and all that follows through "The Secretary and" and inserting the following:

"(5) The Secretary may assess a civil penalty against any person of up to $1,000 a day from the date of the person's failure or refusal to file the information required to be filed by such person with the Secretary under regulations prescribed pursuant to section 101(g).

"(6) The Secretary and".

(B) TECHNICAL AND CONFORMING AMENDMENT.—Section 502(c)(1) of such Act (29 U.S.C. 1132(c)(1)) is amended by adding at the end the following sentence: "For purposes of this paragraph, each violation described in subparagraph (A) with respect to any single participant, and each violation described in subparagraph (B) with respect to any single participant or beneficiary, shall be treated as a separate violation.".

<< 29 USCA § 1136 >>

(3) COORDINATION.—Section 506 of such Act (29 U.S.C. 1136) is amended by adding at the end the following new subsection:

"(c) COORDINATION OF ENFORCEMENT WITH STATES WITH RESPECT TO CERTAIN ARRANGEMENTS.—A State may enter into an agreement with the Secretary for delegation to the State of some or all of the Secretary's authority under sections 502 and 504 to enforce the requirements under part 7 in connection with multiple employer welfare arrangements, providing medical care (within the meaning of section 706(a)(2)), which are not group health plans.".

(f) CONFORMING AMENDMENTS.—

<< 29 USCA § 1144 >>

(1) Section 514(b) of such Act (29 U.S.C. 1144(b)) is amended by adding at the end the following new paragraph:

"(9) For additional provisions relating to group health plans, see section 704.".

(2)(A) Part 6 of subtitle B of title I of such Act (29 U.S.C. 1161 et seq.) is amended by striking the heading and inserting the following:

<< 29 USCA Ch. 18 >>

"PART 6—CONTINUATION COVERAGE AND ADDITIONAL STANDARDS FOR GROUP HEALTH PLANS".

(B) The table of contents in section 1 of such Act is amended by striking the item relating to the heading for part 6 of subtitle B of title I and inserting the following:

"PART 6—CONTINUATION COVERAGE AND ADDITIONAL STANDARDS FOR GROUP HEALTH PLANS".

(3) The table of contents in section 1 of such Act (as amended by the preceding provisions of this section) is amended by inserting after the items relating to part 6 the following new items:

"PART 7—GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

"Sec. 701. Increased portability through limitation on preexisting condition exclusions.

"Sec. 702. Prohibiting discrimination against individual participants and beneficiaries based on health status.

"Sec. 703. Guaranteed renewability in multiemployer plans and multiple employer welfare arrangements.

"Sec. 704. Preemption; State flexibility; construction.

"Sec. 705. Special rules relating to group health plans.

"Sec. 706. Definitions.

"Sec. 707. Regulations.".

<< 29 USCA §§ 1003 nt, 1021 nt, 1022 nt, 1024 nt, 1132 nt, 1136 nt, 1144 nt >>

<< 29 USCA §§ 1181 NOTE, 1182 nt, 1183 nt, 1184 nt, 1185 nt, 1186 nt, 1187 nt >>

(g) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in this section, this section (and the amendments made by this section) shall apply with respect to group health plans for plan years beginning after June 30, 1997.

(2) DETERMINATION OF CREDITABLE COVERAGE.—

(A) PERIOD OF COVERAGE.—

(i) IN GENERAL.—Subject to clause (ii), no period before July 1, 1996, shall be taken into account under part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (as added by this section) in determining creditable coverage.

(ii) SPECIAL RULE FOR CERTAIN PERIODS.—The Secretary of Labor, consistent with section 104, shall provide for a process whereby individuals who need to establish creditable coverage for periods before July 1, 1996, and who would have such coverage credited but for clause (i) may be given credit for creditable coverage for such periods through the presentation of documents or other means.

(B) CERTIFICATIONS, ETC.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), subsection (e) of section 701 of the Employee Retirement Income Security Act of 1974 (as added by this section) shall apply to events occurring after June 30, 1996.

(ii) NO CERTIFICATION REQUIRED TO BE PROVIDED BEFORE JUNE 1, 1997.—In no case is a certification required to be provided under such subsection before June 1, 1997.

(iii) CERTIFICATION ONLY ON WRITTEN REQUEST FOR EVENTS OCCURRING BEFORE OCTOBER 1, 1996.—In the case of an event occurring after June 30, 1996, and before October 1, 1996, a certification is not required to be provided under such subsection unless an individual (with respect to whom the certification is otherwise required to be made) requests such certification in writing.

(C) TRANSITIONAL RULE.—In the case of an individual who seeks to establish creditable coverage for any period for which certification is not required because it relates to an event occurring before June 30, 1996—

(i) the individual may present other credible evidence of such coverage in order to establish the period of creditable coverage; and

(ii) a group health plan and a health insurance issuer shall not be subject to any penalty or enforcement action with respect to the plan's or issuer's crediting (or not crediting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under the amendments made by this section.

(3) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—Except as provided in paragraph (2), in the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, part 7 of subtitle B of title I of Employee Retirement Income Security Act of 1974 (other than section 701(e) thereof) shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 1997.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of such part shall not be treated as a termination of such collective bargaining agreement.

(4) TIMELY REGULATIONS.—The Secretary of Labor, consistent with section 104, shall first issue by not later than April 1, 1997, such regulations as may be necessary to carry out the amendments made by this section.

(5) LIMITATION ON ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this section, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before January 1, 1998, or, if later, the date of issuance of regulations referred to in paragraph (4), if the plan or issuer has sought to comply in good faith with such requirements.

SEC. 102. THROUGH THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—The Public Health Service Act is amended by adding at the end the following new title:

<< 42 USCA Ch. 6A >>

"TITLE XXVII—ASSURING PORTABILITY, AVAILABILITY, AND RENEWABILITY OF HEALTH INSURANCE COVERAGE

"PART A—GROUP MARKET REFORMS

"Subpart 1—Portability, Access, and Renewability Requirements

<< 42 USCA § 300gg >>

"SEC. 2701. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

"(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan, and a health insurance issuer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

"(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6–month period ending on the enrollment date;

"(2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and

"(3) the period of any such preexisting condition exclusion is reduced by the aggregate of the periods of creditable coverage (if any, as defined in subsection (c)(1)) applicable to the participant or beneficiary as of the enrollment date.

"(b) DEFINITIONS.—For purposes of this part—

"(1) PREEXISTING CONDITION EXCLUSION.—

"(A) IN GENERAL.—The term 'preexisting condition exclusion' means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

"(B) TREATMENT OF GENETIC INFORMATION.—Genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

"(2) ENROLLMENT DATE.—The term 'enrollment date' means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

"(3) LATE ENROLLEE.—The term 'late enrollee' means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

"(A) the first period in which the individual is eligible to enroll under the plan, or

"(B) a special enrollment period under subsection (f).

"(4) WAITING PERIOD.—The term 'waiting period' means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

"(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

"(1) CREDITABLE COVERAGE DEFINED.—For purposes of this title, the term 'creditable coverage' means, with respect to an individual, coverage of the individual under any of the following:

"(A) A group health plan.

"(B) Health insurance coverage.

"(C) Part A or part B of title XVIII of the Social Security Act.

"(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

"(E) Chapter 55 of title 10, United States Code.

"(F) A medical care program of the Indian Health Service or of a tribal organization.

"(G) A State health benefits risk pool.

"(H) A health plan offered under chapter 89 of title 5, United States Code.

"(I) A public health plan (as defined in regulations).

"(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 2791(c)).

"(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

"(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group health plan, if, after such period and before the enrollment date, there was a 63–day period during all of which the individual was not covered under any creditable coverage.

"(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group health plan (or for group health insurance coverage) or is in an affiliation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

"(3) METHOD OF CREDITING COVERAGE.—

"(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan, and a health insurance issuer offering group health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

"(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan, or a health insurance issuer offering group health insurance, may elect to apply subsection (a)(3) based on coverage of benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform

basis for all participants and beneficiaries. Under such election a group health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

"(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

"(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

"(ii) include in such statements a description of the effect of this election.

"(D) ISSUER NOTICE.—In the case of an election under subparagraph (B) with respect to health insurance coverage offered by an issuer in the small or large group market, the issuer—

"(i) shall prominently state in any disclosure statements concerning the coverage, and to each employer at the time of the offer or sale of the coverage, that the issuer has made such election, and

"(ii) shall include in such statements a description of the effect of such election.

"(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

"(d) EXCEPTIONS.—

"(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30–day period beginning with the date of birth, is covered under creditable coverage.

"(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

"(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—A group health plan, and health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

"(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63–day period during all of which the individual was not covered under any creditable coverage.

"(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

"(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

"(A) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, shall provide the certification described in subparagraph (B)—

"(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

"(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

"(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

"(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

"(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and

"(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

"(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

"(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

"(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information on coverage of classes and categories of health benefits available under such entity's plan or coverage, and

"(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

"(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

"(f) SPECIAL ENROLLMENT PERIODS.—

"(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

"(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

"(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

"(C) The employee's or dependent's coverage described in subparagraph (A)—

"(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

"(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

"(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

"(2) FOR DEPENDENT BENEFICIARIES.—

"(A) IN GENERAL.—If—

"(i) a group health plan makes coverage available with respect to a dependent of an individual,

"(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

"(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

"(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

"(i) the date dependent coverage is made available, or

"(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

"(C) NO WAITING PERIOD.—If an individual seeks to enroll a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

"(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

"(ii) in the case of a dependent's birth, as of the date of such birth; or

"(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

"(g) USE OF AFFILIATION PERIOD BY HMOS AS ALTERNATIVE TO PREEXISTING CONDITION EXCLUSION.—

"(1) IN GENERAL.—A health maintenance organization which offers health insurance coverage in connection with a group health plan and which does not impose any preexisting condition exclusion allowed under subsection (a) with respect to any particular coverage option may impose an affiliation period for such coverage option, but only if—

"(A) such period is applied uniformly without regard to any health status-related factors; and

"(B) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

"(2) AFFILIATION PERIOD.—

"(A) DEFINED.—For purposes of this title, the term 'affiliation period' means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such period and no premium shall be charged to the participant or beneficiary for any coverage during the period.

"(B) BEGINNING.—Such period shall begin on the enrollment date.

"(C) RUNS CONCURRENTLY WITH WAITING PERIODS.—An affiliation period under a plan shall run concurrently with any waiting period under the plan.

"(3) ALTERNATIVE METHODS.—A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of this part for the State involved with respect to such issuer.

<< 42 USCA § 300gg–1 >>

"SEC. 2702. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

"(a) IN ELIGIBILITY TO ENROLL.—

"(1) IN GENERAL.—Subject to paragraph (2), a group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

"(A) Health status.

"(B) Medical condition (including both physical and mental illnesses).

"(C) Claims experience.

"(D) Receipt of health care.

"(E) Medical history.

"(F) Genetic information.

"(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

"(H) Disability.

"(2) NO APPLICATION TO BENEFITS OR EXCLUSIONS.—To the extent consistent with section 701, paragraph (1) shall not be construed—

"(A) to require a group health plan, or group health insurance coverage, to provide particular benefits other than those provided under the terms of such plan or coverage, or

"(B) to prevent such a plan or coverage from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

"(3) CONSTRUCTION.—For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

"(b) IN PREMIUM CONTRIBUTIONS.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled

in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

"(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

"(A) to restrict the amount that an employer may be charged for coverage under a group health plan; or

"(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 42 USCA Ch. 6A >>

"Subpart 2—Provisions Applicable Only to Health Insurance Issuers

<< 42 USCA § 300gg–11 >>

"SEC. 2711. GUARANTEED AVAILABILITY OF COVERAGE FOR EMPLOYERS IN THE GROUP MARKET.

"(a) ISSUANCE OF COVERAGE IN THE SMALL GROUP MARKET.—

"(1) IN GENERAL.—Subject to subsections (c) through (f), each health insurance issuer that offers health insurance coverage in the small group market in a State—

"(A) must accept every small employer (as defined in section 2791(e)(4)) in the State that applies for such coverage; and

"(B) must accept for enrollment under such coverage every eligible individual (as defined in paragraph (2)) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan and may not place any restriction which is inconsistent with section 2702 on an eligible individual being a participant or beneficiary.

"(2) ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, the term 'eligible individual' means, with respect to a health insurance issuer that offers health insurance coverage to a small employer in connection with a group health plan in the small group market, such an individual in relation to the employer as shall be determined—

"(A) in accordance with the terms of such plan,

"(B) as provided by the issuer under rules of the issuer which are uniformly applicable in a State to small employers in the small group market, and

"(C) in accordance with all applicable State laws governing such issuer and such market.

"(b) ASSURING ACCESS IN THE LARGE GROUP MARKET.—

"(1) REPORTS TO HHS.—The Secretary shall request that the chief executive officer of each State submit to the Secretary, by not later December 31, 2000, and every 3 years thereafter a report on—

"(A) the access of large employers to health insurance coverage in the State, and

"(B) the circumstances for lack of access (if any) of large employers (or one or more classes of such employers) in the State to such coverage.

"(2) TRIENNIAL REPORTS TO CONGRESS.—The Secretary, based on the reports submitted under paragraph (1) and such other information as the Secretary may use, shall prepare and submit to Congress, every 3 years, a report describing the extent to which large employers (and classes of such employers) that seek health insurance coverage in the different States are able to obtain access to such coverage. Such report shall include such recommendations as the Secretary determines to be appropriate.

"(3) GAO REPORT ON LARGE EMPLOYER ACCESS TO HEALTH INSURANCE COVERAGE.—The Comptroller General shall provide for a study of the extent to which classes of large employers in the different States are able to obtain access to health insurance coverage and the circumstances for lack of access (if any) to such coverage. The Comptroller General shall submit to Congress a report on such study not later than 18 months after the date of the enactment of this title.

"(c) SPECIAL RULES FOR NETWORK PLANS.—

"(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

"(A) limit the employers that may apply for such coverage to those with eligible individuals who live, work, or reside in the service area for such network plan; and

"(B) within the service area of such plan, deny such coverage to such employers if the issuer has demonstrated, if required, to the applicable State authority that—

"(i) it will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees, and

"(ii) it is applying this paragraph uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such employees and dependents.

"(2) 180–DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the small group market within such service area for a period of 180 days after the date such coverage is denied.

"(d) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

"(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated, if required, to the applicable State authority that—

"(A) it does not have the financial reserves necessary to underwrite additional coverage; and

"(B) it is applying this paragraph uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such employees and dependents.

"(2) 180–DAY SUSPENSION UPON DENIAL OF COVERAGE.—A health insurance issuer upon denying health insurance coverage in connection with group health plans in accordance with paragraph (1) in a State may not offer coverage in connection with group health plans in the small group market in the State for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. An applicable State authority may provide for the application of this subsection on a service-area-specific basis.

"(e) EXCEPTION TO REQUIREMENT FOR FAILURE TO MEET CERTAIN MINIMUM PARTICIPATION OR CONTRIBUTION RULES.—

"(1) IN GENERAL.—Subsection (a) shall not be construed to preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

"(2) RULES DEFINED.—For purposes of paragraph (1)—

"(A) the term 'employer contribution rule' means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

"(B) the term 'group participation rule' means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

"(f) EXCEPTION FOR COVERAGE OFFERED ONLY TO BONA FIDE ASSOCIATION MEMBERS.—Subsection (a) shall not apply to health insurance coverage offered by a health insurance issuer if such coverage is made available in the small group market only through one or more bona fide associations (as defined in section 2791(d)(3)).

<< 42 USCA § 300gg–12 >>

"SEC. 2712. GUARANTEED RENEWABILITY OF COVERAGE FOR EMPLOYERS IN THE GROUP MARKET.

"(a) IN GENERAL.—Except as provided in this section, if a health insurance issuer offers health insurance coverage in the small or large group market in connection with a group health plan, the issuer must renew or continue in force such coverage at the option of the plan sponsor of the plan.

"(b) GENERAL EXCEPTIONS.—A health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a group health plan in the small or large group market based only on one or more of the following:

"(1) NONPAYMENT OF PREMIUMS.—The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

"(2) FRAUD.—The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

"(3) VIOLATION OF PARTICIPATION OR CONTRIBUTION RULES.—The plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, as permitted under section 2711(e) in the case of the small group market or pursuant to applicable State law in the case of the large group market.

"(4) TERMINATION OF COVERAGE.—The issuer is ceasing to offer coverage in such market in accordance with subsection (c) and applicable State law.

"(5) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, there is no longer any enrollee in connection with such plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business) and, in the case of the small group market, the issuer would deny enrollment with respect to such plan under section 2711(c)(1)(A).

"(6) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the small or large group market (as the case may be) only through one or more bona fide associations, the membership of an employer in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor relating to any covered individual.

"(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

"(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of group health insurance coverage offered in the small or large group market, coverage of such type may be discontinued by the issuer in accordance with applicable State law in such market only if—

"(A) the issuer provides notice to each plan sponsor provided coverage of this type in such market (and participants and beneficiaries covered under such coverage) of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

"(B) the issuer offers to each plan sponsor provided coverage of this type in such market, the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in such market; and

"(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

"(2) DISCONTINUANCE OF ALL COVERAGE.—

"(A) IN GENERAL.—In any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the small group market or the large group market, or both markets, in a State, health insurance coverage may be discontinued by the issuer only in accordance with applicable State law and if—

"(i) the issuer provides notice to the applicable State authority and to each plan sponsor (and participants and beneficiaries covered under such coverage) of such discontinuation at least 180 days prior to the date of the discontinuation of such coverage; and

"(ii) all health insurance issued or delivered for issuance in the State in such market (or markets) are discontinued and coverage under such health insurance coverage in such market (or markets) is not renewed.

"(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in a market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5–year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

"(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a product offered to a group health plan—

"(1) in the large group market; or

"(2) in the small group market if, for coverage that is available in such market other than only through one or more bona fide associations, such modification is consistent with State law and effective on a uniform basis among group health plans with that product.

"(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, a reference to 'plan sponsor' is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

<< 42 USCA § 300gg–13 >>

"SEC. 2713. DISCLOSURE OF INFORMATION.

"(a) DISCLOSURE OF INFORMATION BY HEALTH PLAN ISSUERS.—In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer—

"(1) shall make a reasonable disclosure to such employer, as part of its solicitation and sales materials, of the availability of information described in subsection (b), and

"(2) upon request of such a small employer, provide such information.

"(b) INFORMATION DESCRIBED.—

"(1) IN GENERAL.—Subject to paragraph (3), with respect to a health insurance issuer offering health insurance coverage to a small employer, information described in this subsection is information concerning—

"(A) the provisions of such coverage concerning issuer's right to change premium rates and the factors that may affect changes in premium rates;

"(B) the provisions of such coverage relating to renewability of coverage;

"(C) the provisions of such coverage relating to any preexisting condition exclusion; and

"(D) the benefits and premiums available under all health insurance coverage for which the employer is qualified.

"(2) FORM OF INFORMATION.—Information under this subsection shall be provided to small employers in a manner determined to be understandable by the average small employer, and shall be sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage.

"(3) EXCEPTION.—An issuer is not required under this section to disclose any information that is proprietary and trade secret information under applicable law.

<< 42 USCA Ch. 6A >>

"Subpart 3—Exclusion of Plans; Enforcement; Preemption

<< 42 USCA § 300gg–21 >>

"SEC. 2721. EXCLUSION OF CERTAIN PLANS.

"(a) EXCEPTION FOR CERTAIN SMALL GROUP HEALTH PLANS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (and health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

"(b) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

"(1) IN GENERAL.—The requirements of subparts 1 and 2 shall apply with respect to group health plans only—

"(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

"(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

"(2) TREATMENT OF NONFEDERAL GOVERNMENTAL PLANS.—

"(A) ELECTION TO BE EXCLUDED.—If the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 and 2 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

"(B) PERIOD OF ELECTION.—An election under subparagraph (A) shall apply—

"(i) for a single specified plan year, or

"(ii) in the case of a plan provided pursuant to a collective bargaining agreement, for the term of such agreement.

An election under clause (i) may be extended through subsequent elections under this paragraph.

"(C) NOTICE TO ENROLLEES.—Under such an election, the plan shall provide for—

"(i) notice to enrollees (on an annual basis and at the time of enrollment under the plan) of the fact and consequences of such election, and

"(ii) certification and disclosure of creditable coverage under the plan with respect to enrollees in accordance with section 2701(e).

"(c) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(1).

"(d) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

"(1) LIMITED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(2) if the benefits—

"(A) are provided under a separate policy, certificate, or contract of insurance; or

"(B) are otherwise not an integral part of the plan.

"(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(3) if all of the following conditions are met:

"(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

"(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

"(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

"(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part shall not apply to any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 27971(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

"(e) TREATMENT OF PARTNERSHIPS.—For purposes of this part—

"(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

"(2) EMPLOYER.—In the case of a group health plan, the term 'employer' also includes the partnership in relation to any partner.

"(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term 'participant' also includes —

"(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

"(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

<< 42 USCA § 300gg–22 >>

"SEC. 2722. ENFORCEMENT.

"(a) STATE ENFORCEMENT.—

"(1) STATE AUTHORITY.—Subject to section 2723, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the small or large group markets meet the requirements of this part with respect to such issuers.

"(2) FAILURE TO IMPLEMENT PROVISIONS.—In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans in such State.

"(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

"(1) LIMITATION.—The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part only—

"(A) as provided under subsection (a)(2); and

"(B) with respect to group health plans that are non-Federal governmental plans.

"(2) IMPOSITION OF PENALTIES.—In the cases described in paragraph (1)—

"(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part applicable to such plan or issuer is subject to a civil money penalty under this subsection.

"(B) LIABILITY FOR PENALTY.—In the case of a failure by—

"(i) a health insurance issuer, the issuer is liable for such penalty, or

"(ii) a group health plan that is a non-Federal governmental plan which is—

"(I) sponsored by 2 or more employers, the plan is liable for such penalty, or

"(II) not so sponsored, the employer is liable for such penalty.

"(C) AMOUNT OF PENALTY.—

"(i) IN GENERAL.—The maximum amount of penalty imposed under this paragraph is $100 for each day for each individual with respect to which such a failure occurs.

"(ii) CONSIDERATIONS IN IMPOSITION.—In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and the gravity of the violation.

"(iii) LIMITATIONS.—

"(I) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

"(II) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30–day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

"(D) ADMINISTRATIVE REVIEW.—

"(i) OPPORTUNITY FOR HEARING.—The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5, United States Code. If no hearing is requested, the assessment shall constitute a final and unappealable order.

"(ii) HEARING PROCEDURE.—If a hearing is requested, the initial agency decision shall be made by an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

"(E) JUDICIAL REVIEW.—

"(i) FILING OF ACTION FOR REVIEW.—Any entity against whom an order imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

"(ii) CERTIFICATION OF ADMINISTRATIVE RECORD.—The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

"(iii) STANDARD FOR REVIEW.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5, United States Code.

"(iv) APPEAL.—Any final decision, order, or judgment of the district court concerning such review shall be subject to appeal as provided in chapter 83 of title 28 of such Code.

"(F) FAILURE TO PAY ASSESSMENT; MAINTENANCE OF ACTION.—

"(i) FAILURE TO PAY ASSESSMENT.—If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who shall recover the amount assessed by action in the appropriate United States district court.

"(ii) NONREVIEWABILITY.—In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

"(G) PAYMENT OF PENALTIES.—Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

<< 42 USCA § 300gg–23 >>

"SEC. 2723. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

"(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

"(1) IN GENERAL.—Subject to paragraph (2) and except as provided in subsection (b), this part and part C insofar as it relates to this part shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

"(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this part shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

"(b) SPECIAL RULES IN CASE OF PORTABILITY REQUIREMENTS.—

"(1) IN GENERAL.—Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 which differs from the standards or requirements specified in such section.

"(2) EXCEPTIONS.—Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

"(i) substitutes for the reference to '6–month period' in section 2701(a)(1) a reference to any shorter period of time;

"(ii) substitutes for the reference to '12 months' and '18 months' in section 2701(a)(2) a reference to any shorter period of time;

"(iii) substitutes for the references to '63' days in sections 2701(c)(2)(A) and 2701(d)(4)(A) a reference to any greater number of days;

"(iv) substitutes for the reference to '30-day period' in sections 2701(b)(2) and 2701(d)(1) a reference to any greater period;

"(v) prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) or expands the exceptions described in such section;

"(vi) requires special enrollment periods in addition to those required under section 2701(f); or

"(vii) reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B).

"(c) RULES OF CONSTRUCTION.—Nothing in this part shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

"(d) DEFINITIONS.—For purposes of this section—

"(1) STATE LAW.—The term 'State law' includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

"(2) STATE.—The term 'State' includes a State (including the Northern Mariana Islands), any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

<< 42 USCA Ch. 6A >>

"PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

<< 42 USCA § 300gg–91 >>

"SEC. 2791. DEFINITIONS.

"(a) GROUP HEALTH PLAN.—

"(1) DEFINITION.—The term 'group health plan' means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974) to the extent that the plan provides medical care (as defined in paragraph (2)) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

"(2) MEDICAL CARE.—The term 'medical care' means amounts paid for—

"(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,

"(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

"(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

"(3) TREATMENT OF CERTAIN PLANS AS GROUP HEALTH PLAN FOR NOTICE PROVISION.—A program under which creditable coverage described in subparagraph (C), (D), (E), or (F) of section 2701(c)(1) is provided shall be treated as a group health plan for purposes of applying section 2701(e).

"(b) DEFINITIONS RELATING TO HEALTH INSURANCE.—

"(1) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

"(2) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974). Such term does not include a group health plan.

"(3) HEALTH MAINTENANCE ORGANIZATION.—The term 'health maintenance organization' means—

"(A) a Federally qualified health maintenance organization (as defined in section 1301(a)),

"(B) an organization recognized under State law as a health maintenance organization, or

"(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

"(4) GROUP HEALTH INSURANCE COVERAGE.—The term 'group health insurance coverage' means, in connection with a group health plan, health insurance coverage offered in connection with such plan.

"(5) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The term 'individual health insurance coverage' means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance.

"(c) EXCEPTED BENEFITS.—For purposes of this title, the term 'excepted benefits' means benefits under one or more (or any combination thereof) of the following:

"(1) BENEFITS NOT SUBJECT TO REQUIREMENTS.—

"(A) Coverage only for accident, or disability income insurance, or any combination thereof.

"(B) Coverage issued as a supplement to liability insurance.

"(C) Liability insurance, including general liability insurance and automobile liability insurance.

"(D) Workers' compensation or similar insurance.

"(E) Automobile medical payment insurance.

"(F) Credit-only insurance.

"(G) Coverage for on-site medical clinics.

"(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

"(2) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED SEPARATELY.—

"(A) Limited scope dental or vision benefits.

"(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

"(C) Such other similar, limited benefits as are specified in regulations.

"(3) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS INDEPENDENT, NONCOORDINATED BENEFITS.—

"(A) Coverage only for a specified disease or illness.

"(B) Hospital indemnity or other fixed indemnity insurance.

"(4) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS SEPARATE INSURANCE POLICY.—Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act), coverage supplemental to the coverage provided under chapter 55 of title 10, United States Code, and similar supplemental coverage provided to coverage under a group health plan.

"(d) OTHER DEFINITIONS.—

"(1) APPLICABLE STATE AUTHORITY.—The term 'applicable State authority' means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of this title for the State involved with respect to such issuer.

"(2) BENEFICIARY.—The term 'beneficiary' has the meaning given such term under section 3(8) of the Employee Retirement Income Security Act of 1974.

"(3) BONA FIDE ASSOCIATION.—The term 'bona fide association' means, with respect to health insurance coverage offered in a State, an association which—

"(A) has been actively in existence for at least 5 years;

"(B) has been formed and maintained in good faith for purposes other than obtaining insurance;

"(C) does not condition membership in the association on any health status-related factor relating to an individual (including an employee of an employer or a dependent of an employee);

"(D) makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to such members (or individuals eligible for coverage through a member);

"(E) does not make health insurance coverage offered through the association available other than in connection with a member of the association; and

"(F) meets such additional requirements as may be imposed under State law.

"(4) COBRA CONTINUATION PROVISION.—The term 'COBRA continuation provision' means any of the following:

"(A) Section 4980B of the Internal Revenue Code of 1986, other than subsection (f)(1) of such section insofar as it relates to pediatric vaccines.

"(B) Part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, other than section 609 of such Act.

"(C) Title XXII of this Act.

"(5) EMPLOYEE.—The term 'employee' has the meaning given such term under section 3(6) of the Employee Retirement Income Security Act of 1974.

"(6) EMPLOYER.—The term 'employer' has the meaning given such term under section 3(5) of the Employee Retirement Income Security Act of 1974, except that such term shall include only employers of two or more employees.

"(7) CHURCH PLAN.—The term 'church plan' has the meaning given such term under section 3(33) of the Employee Retirement Income Security Act of 1974.

"(8) GOVERNMENTAL PLAN.—(A) The term 'governmental plan' has the meaning given such term under section 3(32) of the Employee Retirement Income Security Act of 1974 and any Federal governmental plan.

"(B) FEDERAL GOVERNMENTAL PLAN.—The term 'Federal governmental plan' means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

"(C) NON–FEDERAL GOVERNMENTAL PLAN.—The term 'non-Federal governmental plan' means a governmental plan that is not a Federal governmental plan.

"(9) HEALTH STATUS–RELATED FACTOR.—The term 'health status-related factor' means any of the factors described in section 2702(a)(1).

"(10) NETWORK PLAN.—The term 'network plan' means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

"(11) PARTICIPANT.—The term 'participant' has the meaning given such term under section 3(7) of the Employee Retirement Income Security Act of 1974.

"(12) PLACED FOR ADOPTION DEFINED.—The term 'placement', or being 'placed', for adoption, in connection with any placement for adoption of a child with any person, means the assumption and retention by such person of a legal obligation for total or partial support of such child in anticipation of adoption of such child. The child's placement with such person terminates upon the termination of such legal obligation.

"(13) PLAN SPONSOR.—The term 'plan sponsor' has the meaning given such term under section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

"(14) STATE.—The term 'State' means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

"(e) DEFINITIONS RELATING TO MARKETS AND SMALL EMPLOYERS.—For purposes of this title:

"(1) INDIVIDUAL MARKET.—

"(A) IN GENERAL.—The term 'individual market' means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

"(B) TREATMENT OF VERY SMALL GROUPS.—

"(i) IN GENERAL.—Subject to clause (ii), such terms includes coverage offered in connection with a group health plan that has fewer than two participants as current employees on the first day of the plan year.

"(ii) STATE EXCEPTION.—Clause (i) shall not apply in the case of a State that elects to regulate the coverage described in such clause as coverage in the small group market.

"(2) LARGE EMPLOYER.—The term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

"(3) LARGE GROUP MARKET.—The term 'large group market' means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer.

"(4) SMALL EMPLOYER.—The term 'small employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

"(5) SMALL GROUP MARKET.—The term 'small group market' means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

"(6) APPLICATION OF CERTAIN RULES IN DETERMINATION OF EMPLOYER SIZE.—For purposes of this subsection—

"(A) APPLICATION OF AGGREGATION RULE FOR EMPLOYERS.—all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.

"(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small or large employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

"(C) PREDECESSORS.—Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.

<< 42 USCA § 300gg–92 >>

"SEC. 2792. REGULATIONS.

"The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this title. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this title.".

<< 42 USCA § 300e >>

(b) APPLICATION OF RULES BY CERTAIN HEALTH MAINTENANCE ORGANIZATIONS.—Section 1301 of such Act (42 U.S.C. 300e) is amended by adding at the end the following new subsection:

"(d) An organization that offers health benefits coverage shall not be considered as failing to meet the requirements of this section notwithstanding that it provides, with respect to coverage offered in connection with a group health plan in the small or large group market (as defined in section 2791(e)), an affiliation period consistent with the provisions of section 2701(g).".

<< 42 USCA §§ 300gg NOTE, 300gg–1 nt, 300gg–11 nt, 300gg–12 nt, 300gg–13 nt, 300gg–21 nt, 300gg–22 nt, 300gg–23 nt, 300gg–91 nt, 300gg–92 nt >>

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, part A of title XXVII of the Public Health Service Act (as added by subsection (a)) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997.

(2) DETERMINATION OF CREDITABLE COVERAGE.—

(A) PERIOD OF COVERAGE.—

(i) IN GENERAL.—Subject to clause (ii), no period before July 1, 1996, shall be taken into account under part A of title XXVII of the Public Health Service Act (as added by this section) in determining creditable coverage.

(ii) SPECIAL RULE FOR CERTAIN PERIODS.—The Secretary of Health and Human Services, consistent with section 104, shall provide for a process whereby individuals who need to establish creditable coverage for periods before July 1, 1996, and who would have such coverage credited but for clause (i) may be given credit for creditable coverage for such periods through the presentation of documents or other means.

(B) CERTIFICATIONS, ETC.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), subsection (e) of section 2701 of the Public Health Service Act (as added by this section) shall apply to events occurring after June 30, 1996.

(ii) NO CERTIFICATION REQUIRED TO BE PROVIDED BEFORE JUNE 1, 1997.—In no case is a certification required to be provided under such subsection before June 1, 1997.

(iii) CERTIFICATION ONLY ON WRITTEN REQUEST FOR EVENTS OCCURRING BEFORE OCTOBER 1, 1996.—In the case of an event occurring after June 30, 1996, and before October 1, 1996, a certification is not required to be provided under such subsection unless an individual (with respect to whom the certification is otherwise required to be made) requests such certification in writing.

(C) TRANSITIONAL RULE.—In the case of an individual who seeks to establish creditable coverage for any period for which certification is not required because it relates to an event occurring before June 30, 1996—

(i) the individual may present other credible evidence of such coverage in order to establish the period of creditable coverage; and

(ii) a group health plan and a health insurance issuer shall not be subject to any penalty or enforcement action with respect to the plan's or issuer's crediting (or not crediting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under the amendments made by this section.

(3) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—Except as provided in paragraph (2)(B), in the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, part A of title XXVII of the Public Health Service Act (other than section 2701(e) thereof) shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 1997.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of such part shall not be treated as a termination of such collective bargaining agreement.

(4) TIMELY REGULATIONS.—The Secretary of Health and Human Services, consistent with section 104, shall first issue by not later than April 1, 1997, such regulations as may be necessary to carry out the amendments made by this section and section 111.

(5) LIMITATION ON ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this section, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before January 1, 1998, or, if later, the date of issuance of regulations referred to in paragraph (4), if the plan or issuer has sought to comply in good faith with such requirements.

<< 42 USCA § 300bb–8 >>

(d) MISCELLANEOUS CORRECTION.—Section 2208(1) of the Public Health Service Act (42 U.S.C. 300bb–8(1)) is amended by striking "section 162(i)(2)" and inserting "5000(b)".

SEC. 103. REFERENCE TO IMPLEMENTATION THROUGH THE INTERNAL REVENUE CODE OF 1986.

For provisions amending the Internal Revenue Code of 1986 to provide for application and enforcement of rules for group health plans similar to those provided under the amendments made by section 101(a), see section 401.

<< 42 USCA § 300gg–92 NOTE >>

SEC. 104. ASSURING COORDINATION.

The Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under this subtitle (and the amendments made by this subtitle and section 401) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

Subtitle B—Individual Market Rules

SEC. 111. AMENDMENT TO PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Title XXVII of the Public Health Service Act, as added by section 102(a) of this Act, is amended by inserting after part A the following new part:

<< 42 USCA Ch. 6A >>

"PART B—INDIVIDUAL MARKET RULES

<< 42 USCA § 300gg–41 >>

"SEC. 2741. GUARANTEED AVAILABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE TO CERTAIN INDIVIDUALS WITH PRIOR GROUP COVERAGE.

"(a) GUARANTEED AVAILABILITY.—

"(1) IN GENERAL.—Subject to the succeeding subsections of this section and section 2744, each health insurance issuer that offers health insurance coverage (as defined in section 2791(b)(1)) in the individual market in a State may not, with respect to an eligible individual (as defined in subsection (b)) desiring to enroll in individual health insurance coverage—

"(A) decline to offer such coverage to, or deny enrollment of, such individual; or

"(B) impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) with respect to such coverage.

"(2) SUBSTITUTION BY STATE OF ACCEPTABLE ALTERNATIVE MECHANISM.—The requirement of paragraph (1) shall not apply to health insurance coverage offered in the individual market in a State in which the State is implementing an acceptable alternative mechanism under section 2744.

"(b) ELIGIBLE INDIVIDUAL DEFINED.—In this part, the term 'eligible individual' means an individual—

"(1)(A) for whom, as of the date on which the individual seeks coverage under this section, the aggregate of the periods of creditable coverage (as defined in section 2701(c)) is 18 or more months and (B) whose most recent prior creditable coverage was under a group health plan, governmental plan, or church plan (or health insurance coverage offered in connection with any such plan);

"(2) who is not eligible for coverage under (A) a group health plan, (B) part A or part B of title XVIII of the Social Security Act, or (C) a State plan under title XIX of such Act (or any successor program), and does not have other health insurance coverage;

"(3) with respect to whom the most recent coverage within the coverage period described in paragraph (1)(A) was not terminated based on a factor described in paragraph (1) or (2) of section 2712(b) (relating to nonpayment of premiums or fraud);

"(4) if the individual had been offered the option of continuation coverage under a COBRA continuation provision or under a similar State program, who elected such coverage; and

"(5) who, if the individual elected such continuation coverage, has exhausted such continuation coverage under such provision or program.

"(c) ALTERNATIVE COVERAGE PERMITTED WHERE NO STATE MECHANISM.—

"(1) IN GENERAL.—In the case of health insurance coverage offered in the individual market in a State in which the State is not implementing an acceptable alternative mechanism under section 2744, the health insurance issuer may elect to limit the coverage offered under subsection (a) so long as it offers at least two different policy forms of health insurance coverage both of which—

"(A) are designed for, made generally available to, and actively marketed to, and enroll both eligible and other individuals by the issuer; and

"(B) meet the requirement of paragraph (2) or (3), as elected by the issuer.

For purposes of this subsection, policy forms which have different cost-sharing arrangements or different riders shall be considered to be different policy forms.

"(2) CHOICE OF MOST POPULAR POLICY FORMS.—The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers the policy forms for individual health insurance coverage with the largest, and next to largest, premium volume of all such policy forms offered by the issuer in the State or applicable marketing or service area (as may be prescribed in regulation) by the issuer in the individual market in the period involved.

"(3) CHOICE OF 2 POLICY FORMS WITH REPRESENTATIVE COVERAGE.—

"(A) IN GENERAL.—The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers a lower-level coverage policy form (as defined in subparagraph (B)) and a higher-level coverage policy form (as defined in subparagraph (C)) each of which includes benefits substantially similar to other individual health insurance coverage offered by the issuer in that State and each of which is covered under a method described in section 2744(c)(3)(A) (relating to risk adjustment, risk spreading, or financial subsidization).

"(B) LOWER–LEVEL OF COVERAGE DESCRIBED.—A policy form is described in this subparagraph if the actuarial value of the benefits under the coverage is at least 85 percent but not greater than 100 percent of a weighted average (described in subparagraph (D)).

"(C) HIGHER–LEVEL OF COVERAGE DESCRIBED.—A policy form is described in this subparagraph if—

"(i) the actuarial value of the benefits under the coverage is at least 15 percent greater than the actuarial value of the coverage described in subparagraph (B) offered by the issuer in the area involved; and

"(ii) the actuarial value of the benefits under the coverage is at least 100 percent but not greater than 120 percent of a weighted average (described in subparagraph (D)).

"(D) WEIGHTED AVERAGE.—For purposes of this paragraph, the weighted average described in this subparagraph is the average actuarial value of the benefits provided by all the health insurance coverage issued (as elected by the issuer) either by that issuer or by all issuers in the State in the individual market during the previous year (not including coverage issued under this section), weighted by enrollment for the different coverage.

"(4) ELECTION.—The issuer elections under this subsection shall apply uniformly to all eligible individuals in the State for that issuer. Such an election shall be effective for policies offered during a period of not shorter than 2 years.

"(5) ASSUMPTIONS.—For purposes of paragraph (3), the actuarial value of benefits provided under individual health insurance coverage shall be calculated based on a standardized population and a set of standardized utilization and cost factors.

"(d) SPECIAL RULES FOR NETWORK PLANS.—

"(1) IN GENERAL.—In the case of a health insurance issuer that offers health insurance coverage in the individual market through a network plan, the issuer may—

"(A) limit the individuals who may be enrolled under such coverage to those who live, reside, or work within the service area for such network plan; and

"(B) within the service area of such plan, deny such coverage to such individuals if the issuer has demonstrated, if required, to the applicable State authority that—

"(i) it will not have the capacity to deliver services adequately to additional individual enrollees because of its obligations to existing group contract holders and enrollees and individual enrollees, and

"(ii) it is applying this paragraph uniformly to individuals without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

"(2) 180–DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the individual market within such service area for a period of 180 days after such coverage is denied.

"(e) APPLICATION OF FINANCIAL CAPACITY LIMITS.—

"(1) IN GENERAL.—A health insurance issuer may deny health insurance coverage in the individual market to an eligible individual if the issuer has demonstrated, if required, to the applicable State authority that—

"(A) it does not have the financial reserves necessary to underwrite additional coverage; and

"(B) it is applying this paragraph uniformly to all individuals in the individual market in the State consistent with applicable State law and without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

"(2) 180–DAY SUSPENSION UPON DENIAL OF COVERAGE.—An issuer upon denying individual health insurance coverage in any service area in accordance with paragraph (1) may not offer such coverage in the individual market within such service area for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated, if required under applicable State law, to the applicable State authority that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. A State may provide for the application of this paragraph on a service-area-specific basis.

"(e) MARKET REQUIREMENTS.—

"(1) IN GENERAL.—The provisions of subsection (a) shall not be construed to require that a health insurance issuer offering health insurance coverage only in connection with group health plans or through one or more bona fide associations, or both, offer such health insurance coverage in the individual market.

"(2) CONVERSION POLICIES.—A health insurance issuer offering health insurance coverage in connection with group health plans under this title shall not be deemed to be a health insurance issuer offering individual health insurance coverage solely because such issuer offers a conversion policy.

"(f) CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to restrict the amount of the premium rates that an issuer may charge an individual for health insurance coverage provided in the individual market under applicable State law; or

"(2) to prevent a health insurance issuer offering health insurance coverage in the individual market from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 42 USCA § 300gg–42 >>

"SEC. 2742. GUARANTEED RENEWABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE.

"(a) IN GENERAL.—Except as provided in this section, a health insurance issuer that provides individual health insurance coverage to an individual shall renew or continue in force such coverage at the option of the individual.

"(b) GENERAL EXCEPTIONS.—A health insurance issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

"(1) NONPAYMENT OF PREMIUMS.—The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

"(2) FRAUD.—The individual has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

"(3) TERMINATION OF PLAN.—The issuer is ceasing to offer coverage in the individual market in accordance with subsection (c) and applicable State law.

"(4) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, the individual no longer resides, lives, or works in the service area (or in an area for which the issuer is authorized to do business) but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

"(5) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the individual market only through one or more bona fide associations, the membership of the individual in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

"(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

"(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of health insurance coverage offered in the individual market, coverage of such type may be discontinued by the issuer only if—

"(A) the issuer provides notice to each covered individual provided coverage of this type in such market of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

"(B) the issuer offers to each individual in the individual market provided coverage of this type, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in such market; and

"(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to any health status-related factor of enrolled individuals or individuals who may become eligible for such coverage.

"(2) DISCONTINUANCE OF ALL COVERAGE.—

"(A) IN GENERAL.—Subject to subparagraph (C), in any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the individual market in a State, health insurance coverage may be discontinued by the issuer only if—

"(i) the issuer provides notice to the applicable State authority and to each individual of such discontinuation at least 180 days prior to the date of the expiration of such coverage, and

"(ii) all health insurance issued or delivered for issuance in the State in such market are discontinued and coverage under such health insurance coverage in such market is not renewed.

"(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in the individual market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5–year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

"(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a policy form offered to individuals in the individual market so long as such modification is consistent with State law and effective on a uniform basis among all individuals with that policy form.

"(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the individual market to individuals only through one or more associations, a reference to an 'individual' is deemed to include a reference to such an association (of which the individual is a member).

<< 42 USCA § 300gg–43 >>

"SEC. 2743. CERTIFICATION OF COVERAGE.

"The provisions of section 2701(e) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

<< 42 USCA § 300gg–44 >>

"SEC. 2744. STATE FLEXIBILITY IN INDIVIDUAL MARKET REFORMS.

"(a) WAIVER OF REQUIREMENTS WHERE IMPLEMENTATION OF ACCEPTABLE ALTERNATIVE MECHANISM.—

"(1) IN GENERAL.—The requirements of section 2741 shall not apply with respect to health insurance coverage offered in the individual market in the State so long as a State is found to be implementing, in accordance with this section and consistent with section 2746(b), an alternative mechanism (in this section referred to as an 'acceptable alternative mechanism')—

"(A) under which all eligible individuals are provided a choice of health insurance coverage;

"(B) under which such coverage does not impose any preexisting condition exclusion with respect to such coverage;

"(C) under which such choice of coverage includes at least one policy form of coverage that is comparable to comprehensive health insurance coverage offered in the individual market in such State or that is comparable to a standard option of coverage available under the group or individual health insurance laws of such State; and

"(D) in a State which is implementing—

"(i) a model act described in subsection (c)(1),

"(ii) a qualified high risk pool described in subsection (c)(2), or

"(iii) a mechanism described in subsection (c)(3).

"(2) PERMISSIBLE FORMS OF MECHANISMS.—A private or public individual health insurance mechanism (such as a health insurance coverage pool or programs, mandatory group conversion policies, guaranteed issue of one or more plans of individual health insurance coverage, or open enrollment by one or more health insurance issuers), or combination of such mechanisms, that is designed to provide access to health benefits for individuals in the individual market in the State in accordance with this section may constitute an acceptable alternative mechanism.

"(b) APPLICATION OF ACCEPTABLE ALTERNATIVE MECHANISMS.—

"(1) PRESUMPTION.—

"(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, a State is presumed to be implementing an acceptable alternative mechanism in accordance with this section as of July 1, 1997, if, by not later than April 1, 1997, the chief executive officer of a State—

"(i) notifies the Secretary that the State has enacted or intends to enact (by not later than January 1, 1998, or July 1, 1998, in the case of a State described in subparagraph (B)(ii)) any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998, (or, in the case of a State described in subparagraph (B)(ii), July 1, 1998); and

"(ii) provides the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this subsection.

"(B) DELAY PERMITTED FOR CERTAIN STATES.—

"(i) EFFECT OF DELAY.—In the case of a State described in clause (ii) that provides notice under subparagraph (A)(i), for the presumption to continue on and after July 1, 1998, the chief executive officer of the State by April 1, 1998—

"(I) must notify the Secretary that the State has enacted any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of July 1, 1998; and

"(II) must provide the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this subsection.

"(ii) STATES DESCRIBED.—A State described in this clause is a State that has a legislature that does not meet within the 12–month period beginning on the date of enactment of this Act.

"(C) CONTINUED APPLICATION.—In order for a mechanism to continue to be presumed to be an acceptable alternative mechanism, the State shall provide the Secretary every 3 years with information described in subparagraph (A)(ii) or (B)(i)(II) (as the case may be).

"(2) NOTICE.—If the Secretary finds, after review of information provided under paragraph (1) and in consultation with the chief executive officer of the State and the insurance commissioner or chief insurance regulatory official of the State, that such a mechanism is not an acceptable alternative mechanism or is not (or no longer) being implemented, the Secretary—

"(A) shall notify the State of—

"(i) such preliminary determination, and

"(ii) the consequences under paragraph (3) of a failure to implement such a mechanism; and

"(B) shall permit the State a reasonable opportunity in which to modify the mechanism (or to adopt another mechanism) in a manner so that may be an acceptable alternative mechanism or to provide for implementation of such a mechanism.

"(3) FINAL DETERMINATION.—If, after providing notice and opportunity under paragraph (2), the Secretary finds that the mechanism is not an acceptable alternative mechanism or the State is not implementing such a mechanism, the Secretary shall notify the State that the State is no longer considered to be implementing an acceptable alternative mechanism and that the requirements of section 2741 shall apply to health insurance coverage offered in the individual market in the State, effective as of a date specified in the notice.

"(4) LIMITATION ON SECRETARIAL AUTHORITY.—The Secretary shall not make a determination under paragraph (2) or (3) on any basis other than the basis that a mechanism is not an acceptable alternative mechanism or is not being implemented.

"(5) FUTURE ADOPTION OF MECHANISMS.—If a State, after January 1, 1997, submits the notice and information described in paragraph (1), unless the Secretary makes a finding described in paragraph (3) within the 90–day period beginning on the date of submission of the notice and information, the mechanism shall be considered to be an acceptable alternative mechanism for purposes of this section, effective 90 days after the end of such period, subject to the second sentence of paragraph (1).

"(c) PROVISION RELATED TO RISK.—

"(1) ADOPTION OF NAIC MODELS.—The model act referred to in subsection (a)(1)(D)(i) is the Small Employer and Individual Health Insurance Availability Model Act (adopted by the National Association of Insurance Commissioners on June 3, 1996) insofar as it applies to individual health insurance coverage or the Individual Health Insurance Portability Model Act (also adopted by such Association on such date).

"(2) QUALIFIED HIGH RISK POOL.—For purposes of subsection (a)(1)(D)(ii), a 'qualified high risk pool' described in this paragraph is a high risk pool that—

"(A) provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, and

"(B) provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of the date of the enactment of this title).

"(3) OTHER MECHANISMS.—For purposes of subsection (a)(1)(D)(iii), a mechanism described in this paragraph—

"(A) provides for risk adjustment, risk spreading, or a risk spreading mechanism (among issuers or policies of an issuer) or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers; or

"(B) is a mechanism under which each eligible individual is provided a choice of all individual health insurance coverage otherwise available.

<< 42 USCA § 300gg–45 >>

"SEC. 2745. ENFORCEMENT.

"(a) STATE ENFORCEMENT.—

"(1) STATE AUTHORITY.—Subject to section 2746, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual market meet the requirements established under this part with respect to such issuers.

"(2) FAILURE TO IMPLEMENT REQUIREMENTS.—In the case of a State that fails to substantially enforce the requirements set forth in this part with respect to health insurance issuers in the State, the Secretary shall enforce the requirements of this part under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in the individual market in such State.

"(b) SECRETARIAL ENFORCEMENT AUTHORITY.—The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 2722(b)(2) in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.

<< 42 USCA § 300gg–46 >>

"SEC. 2746. PREEMPTION.

"(a) IN GENERAL.—Subject to subsection (b), nothing in this part (or part C insofar as it applies to this part) shall be construed to prevent a State from establishing, implementing, or continuing in effect standards and requirements unless such standards and requirements prevent the application of a requirement of this part.

"(b) RULES OF CONSTRUCTION.—Nothing in this part (or part C insofar as it applies to this part) shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144).

<< 42 USCA § 300gg–47 >>

"SEC. 2747. GENERAL EXCEPTIONS.

"(a) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in section 2791(c)(1).

"(b) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in paragraph (2), (3), or (4) of section 2791(c) if the benefits are provided under a separate policy, certificate, or contract of insurance.".

<< 42 USCA §§ 300gg–41 NOTE, 300gg–42 nt, 300gg–43 nt, 300gg–44 nt, 300gg–45 nt, 300gg–46 nt, 300gg–47 nt >>

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in this subsection, part B of title XXVII of the Public Health Service Act (as inserted by subsection (a)) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

(2) APPLICATION OF CERTIFICATION RULES.—The provisions of section 102(d)(2) of this Act shall apply to section 2743 of the Public Health Service Act in the same manner as it applies to section 2701(e) of such Act.

Subtitle C—General and Miscellaneous Provisions

<< 42 USCA § 300gg NOTE >>

SEC. 191. HEALTH COVERAGE AVAILABILITY STUDIES.

(a) STUDIES.—

(1) STUDY ON EFFECTIVENESS OF REFORMS.—The Secretary of Health and Human Services shall provide for a study on the effectiveness of the provisions of this title and the various State laws, in ensuring the availability of reasonably priced health coverage to employers purchasing group coverage and individuals purchasing coverage on a non-group basis.

(2) STUDY ON ACCESS AND CHOICE.—The Secretary also shall provide for a study on—

(A) the extent to which patients have direct access to, and choice of, health care providers, including specialty providers, within a network plan, as well as the opportunity to utilize providers outside of the network plan, under the various types of coverage offered under the provisions of this title; and

(B) the cost and cost-effectiveness to health insurance issuers of providing access to out-of-network providers, and the potential impact of providing such access on the cost and quality of health insurance coverage offered under provisions of this title.

(3) CONSULTATION.—The studies under this subsection shall be conducted in consultation with the Secretary of Labor, representatives of State officials, consumers, and other representatives of individuals and entities that have expertise in health insurance and employee benefits.

(b) REPORTS.—Not later than January 1, 2000, the Secretary shall submit to the appropriate committees of Congress a report on each of the studies under subsection (a).

SEC. 192. REPORT ON MEDICARE REIMBURSEMENT OF TELEMEDICINE.

The Health Care Financing Administration shall complete its ongoing study of Medicare reimbursement of all telemedicine services and submit a report to Congress on Medicare reimbursement of telemedicine services by not later than March 1, 1997. The report shall—

(1) utilize data compiled from the current demonstration projects already under review and gather data from other ongoing telemedicine networks;

(2) include an analysis of the cost of services provided via telemedicine; and

(3) include a proposal for Medicare reimbursement of such services.

<< 42 USCA § 300e >>

SEC. 193. ALLOWING FEDERALLY–QUALIFIED HMOS TO OFFER HIGH DEDUCTIBLE PLANS.

Section 1301(b) of the Public Health Service Act (42 U.S.C. 300e(b)) is amended by adding at the end the following new paragraph:

"(6) A health maintenance organization that otherwise meets the requirements of this title may offer a high-deductible health plan (as defined in section 220(c)(2) of the Internal Revenue Code of 1986).".

<< 42 USCA § 233 >>

SEC. 194. VOLUNTEER SERVICES PROVIDED BY HEALTH PROFESSIONALS AT FREE CLINICS.

Section 224 of the Public Health Service Act (42 U.S.C. 233) is amended by adding at the end the following subsection:

"(o)(1) For purposes of this section, a free clinic health professional shall in providing a qualifying health service to an individual be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (6)(D). The preceding sentence is subject to the provisions of this subsection.

"(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a free clinic health professional if the following conditions are met:

"(A) The service is provided to the individual at a free clinic, or through offsite programs or events carried out by the free clinic.

"(B) The free clinic is sponsoring the health care practitioner pursuant to paragraph (5)(C).

"(C) The service is a qualifying health service (as defined in paragraph (4)).

"(D) Neither the health care practitioner nor the free clinic receives any compensation for the service from the individual or from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program). With respect to compliance with such condition:

"(i) The health care practitioner may receive repayment from the free clinic for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.

"(ii) The free clinic may accept voluntary donations for the provision of the service by the health care practitioner to the individual.

"(E) Before the service is provided, the health care practitioner or the free clinic provides written notice to the individual of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection (or in the case of an emergency, the written notice is provided to the individual as soon after the emergency as is practicable). If the individual is a minor or is otherwise legally incompetent, the condition under this subparagraph is that the written notice be provided to a legal guardian or other person with legal responsibility for the care of the individual.

"(F) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

"(3)(A) For purposes of this subsection, the term 'free clinic' means a health care facility operated by a nonprofit private entity meeting the following requirements:

"(i) The entity does not, in providing health services through the facility, accept reimbursement from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).

"(ii) The entity, in providing health services through the facility, either does not impose charges on the individuals to whom the services are provided, or imposes a charge according to the ability of the individual involved to pay the charge.

"(iii) The entity is licensed or certified in accordance with applicable law regarding the provision of health services.

"(B) With respect to compliance with the conditions under subparagraph (A), the entity involved may accept voluntary donations for the provision of services.

"(4) For purposes of this subsection, the term 'qualifying health service' means any medical assistance required or authorized to be provided in the program under title XIX of the Social Security Act, without regard to whether the medical assistance is included in the plan submitted under such program by the State in which the health care practitioner involved provides the medical assistance. References in the preceding sentence to such program shall as applicable be considered to be references to any successor to such program.

"(5) Subsection (g) (other than paragraphs (3) through (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (6) and subject to the following:

"(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

"(B) This subsection may not be construed as deeming any free clinic to be an employee of the Public Health Service for purposes of this section.

"(C) With respect to a free clinic, a health care practitioner is not a free clinic health professional unless the free clinic sponsors the health care practitioner. For purposes of this subsection, the free clinic shall be considered to be sponsoring the health care practitioner if—

"(i) with respect to the health care practitioner, the free clinic submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

"(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

"(D) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a free clinic health professional, this subsection applies to the health care practitioner (with respect to the free clinic sponsoring the health care practitioner pursuant to subparagraph (C)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

"(E) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

"(6)(A) For purposes of making payments for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of free clinic health professionals, there is authorized to be appropriated $10,000,000 for each fiscal year.

"(B) The Secretary shall establish a fund for purposes of this subsection. Each fiscal year amounts appropriated under subparagraph (A) shall be deposited in such fund.

"(C) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of free clinic health professionals, will be paid pursuant to this section during the calendar year that begins in the following fiscal year. Subsection (k)(1)(B) applies to the estimate under the preceding sentence regarding free clinic health professionals to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

"(D) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subparagraph (B) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (C) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

"(7)(A) This subsection takes effect on the date of the enactment of the first appropriations Act that makes an appropriation under paragraph (6)(A), except as provided in subparagraph (B)(i).

"(B)(i) Effective on the date of the enactment of the Health Insurance Portability and Accountability Act of 1996—

"(I) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (5)(C); and

"(II) reports under paragraph (6)(C) may be submitted to the Congress.

"(ii) For the first fiscal year for which an appropriation is made under subparagraph (A) of paragraph (6), if an estimate under subparagraph (C) of such paragraph has not been made for the calendar year beginning in such fiscal year, the transfer under subparagraph (D) of such paragraph shall be made notwithstanding the lack of the estimate, and the transfer shall be made in an amount equal to the amount of such appropriation.".

<< 42 USCA § 300gg NOTE >>

SEC. 195. FINDINGS; SEVERABILITY.

(a) FINDINGS RELATING TO EXERCISE OF COMMERCE CLAUSE AUTHORITY.—Congress finds the following in relation to the provisions of this title:

(1) Provisions in group health plans and health insurance coverage that impose certain preexisting condition exclusions impact the ability of employees to seek employment in interstate commerce, thereby impeding such commerce.

(2) Health insurance coverage is commercial in nature and is in and affects interstate commerce.

(3) It is a necessary and proper exercise of Congressional authority to impose requirements under this title on group health plans and health insurance coverage (including coverage offered to individuals previously covered under group health plans) in order to promote commerce among the States.

(4) Congress, however, intends to defer to States, to the maximum extent practicable, in carrying out such requirements with respect to insurers and health maintenance organizations that are subject to State regulation, consistent with the provisions of the Employee Retirement Income Security Act of 1974.

<< 29 USCA §§ 1003 nt, 1021 nt, 1022 nt, 1024 nt, 1132 nt, 1136 nt, 1144 nt, 1181 nt, 1182 nt, 1183 nt, 1184 nt, 1185 nt, 1186 nt, 1187 nt >>

<< 42 USCA §§ 233 nt, 300e nt, 300bb–8 nt, 300gg–1 nt, 300gg–11 nt, 300gg–12 nt, 300gg–13 nt, 300gg–21 nt, 300gg–22 nt, 300gg–23 nt, 300gg–41 nt, 300gg–42 nt, 300gg–43 nt, 300gg–44 nt, 300gg–45 nt, 300gg–46 nt, 300gg–47 nt, 300gg–91 nt, 300gg–92 nt >>

(b) SEVERABILITY.—If any provision of this title or the application of such provision to any person or circumstance is held to be unconstitutional, the remainder of this title and the application of the provisions of such to any person or circumstance shall not be affected thereby.

TITLE II—PREVENTING HEALTH CARE FRAUD AND ABUSE; ADMINISTRATIVE SIMPLIFICATION

SEC. 200. REFERENCES IN TITLE.

Except as otherwise specifically provided, whenever in this title an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

Subtitle A—Fraud and Abuse Control Program

SEC. 201. FRAUD AND ABUSE CONTROL PROGRAM.

<< 42 USCA § 1320a–7c >>

(a) ESTABLISHMENT OF PROGRAM.—Title XI (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128B the following new section:

"FRAUD AND ABUSE CONTROL PROGRAM

"SEC. 1128C. (a) ESTABLISHMENT OF PROGRAM.—

"(1) IN GENERAL.—Not later than January 1, 1997, the Secretary, acting through the Office of the Inspector General of the Department of Health and Human Services, and the Attorney General shall establish a program—

"(A) to coordinate Federal, State, and local law enforcement programs to control fraud and abuse with respect to health plans,

"(B) to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States,

"(C) to facilitate the enforcement of the provisions of sections 1128, 1128A, and 1128B and other statutes applicable to health care fraud and abuse,

"(D) to provide for the modification and establishment of safe harbors and to issue advisory opinions and special fraud alerts pursuant to section 1128D, and

"(E) to provide for the reporting and disclosure of certain final adverse actions against health care providers, suppliers, or practitioners pursuant to the data collection system established under section 1128E.

"(2) COORDINATION WITH HEALTH PLANS.—In carrying out the program established under paragraph (1), the Secretary and the Attorney General shall consult with, and arrange for the sharing of data with representatives of health plans.

"(3) GUIDELINES.—

"(A) IN GENERAL.—The Secretary and the Attorney General shall issue guidelines to carry out the program under paragraph (1). The provisions of sections 553, 556, and 557 of title 5, United States Code, shall not apply in the issuance of such guidelines.

"(B) INFORMATION GUIDELINES.—

"(i) IN GENERAL.—Such guidelines shall include guidelines relating to the furnishing of information by health plans, providers, and others to enable the Secretary and the Attorney General to carry out the program (including coordination with health plans under paragraph (2)).

"(ii) CONFIDENTIALITY.—Such guidelines shall include procedures to assure that such information is provided and utilized in a manner that appropriately protects the confidentiality of the information and the privacy of individuals receiving health care services and items.

"(iii) QUALIFIED IMMUNITY FOR PROVIDING INFORMATION.—The provisions of section 1157(a) (relating to limitation on liability) shall apply to a person providing information to the Secretary or the Attorney General in conjunction with their performance of duties under this section.

"(4) ENSURING ACCESS TO DOCUMENTATION.—The Inspector General of the Department of Health and Human Services is authorized to exercise such authority described in paragraphs (3) through (9) of section 6 of the Inspector General Act of 1978 (5 U.S.C.App.) as necessary with respect to the activities under the fraud and abuse control program established under this subsection.

"(5) AUTHORITY OF INSPECTOR GENERAL.—Nothing in this Act shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978 (5 U.S.C.App.).

"(b) ADDITIONAL USE OF FUNDS BY INSPECTOR GENERAL.—

"(1) REIMBURSEMENTS FOR INVESTIGATIONS.—The Inspector General of the Department of Health and Human Services is authorized to receive and retain for current use reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans when such costs are ordered by a court, voluntarily agreed to by the payor, or otherwise.

"(2) CREDITING.—Funds received by the Inspector General under paragraph (1) as reimbursement for costs of conducting investigations shall be deposited to the credit of the appropriation from which initially paid, or to appropriations for similar purposes currently available at the time of deposit, and shall remain available for obligation for 1 year from the date of the deposit of such funds.

"(c) HEALTH PLAN DEFINED.—For purposes of this section, the term 'health plan' means a plan or program that provides health benefits, whether directly, through insurance, or otherwise, and includes—

"(1) a policy of health insurance;

"(2) a contract of a service benefit organization; and

"(3) a membership agreement with a health maintenance organization or other prepaid health plan.".

<< 42 USCA § 1395i >>

(b) ESTABLISHMENT OF HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT IN FEDERAL HOSPITAL INSURANCE TRUST FUND.—Section 1817 (42 U.S.C. 1395i) is amended by adding at the end the following new subsection:

"(k) HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT.—

"(1) ESTABLISHMENT.—There is hereby established in the Trust Fund an expenditure account to be known as the 'Health Care Fraud and Abuse Control Account' (in this subsection referred to as the 'Account').

"(2) APPROPRIATED AMOUNTS TO TRUST FUND.—

"(A) IN GENERAL.—There are hereby appropriated to the Trust Fund—

"(i) such gifts and bequests as may be made as provided in subparagraph (B);

"(ii) such amounts as may be deposited in the Trust Fund as provided in sections 242(b) and 249(c) of the Health Insurance Portability and Accountability Act of 1996, and title XI; and

"(iii) such amounts as are transferred to the Trust Fund under subparagraph (C).

"(B) AUTHORIZATION TO ACCEPT GIFTS.—The Trust Fund is authorized to accept on behalf of the United States money gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Account or any activity financed through the Account.

"(C) TRANSFER OF AMOUNTS.—The Managing Trustee shall transfer to the Trust Fund, under rules similar to the rules in section 9601 of the Internal Revenue Code of 1986, an amount equal to the sum of the following:

"(i) Criminal fines recovered in cases involving a Federal health care offense (as defined in section 982(a)(6)(B) of title 18, United States Code).

"(ii) Civil monetary penalties and assessments imposed in health care cases, including amounts recovered under titles XI, XVIII, and XIX, and chapter 38 of title 31, United States Code (except as otherwise provided by law).

"(iii) Amounts resulting from the forfeiture of property by reason of a Federal health care offense.

"(iv) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

"(D) APPLICATION.—Nothing in subparagraph (C)(iii) shall be construed to limit the availability of recoveries and forfeitures obtained under title I of the Employee Retirement Income Security Act of 1974 for the purpose of providing equitable or remedial relief for employee welfare benefit plans, and for participants and beneficiaries under such plans, as authorized under such title.

"(3) APPROPRIATED AMOUNTS TO ACCOUNT FOR FRAUD AND ABUSE CONTROL PROGRAM, ETC.—

"(A) DEPARTMENTS OF HEALTH AND HUMAN SERVICES AND JUSTICE.—

"(i) IN GENERAL.—There are hereby appropriated to the Account from the Trust Fund such sums as the Secretary and the Attorney General certify are necessary to carry out the purposes described in subparagraph (C), to be available without further appropriation, in an amount not to exceed—

"(I) for fiscal year 1997, $104,000,000,

"(II) for each of the fiscal years 1998 through 2003, the limit for the preceding fiscal year, increased by 15 percent; and

"(III) for each fiscal year after fiscal year 2003, the limit for fiscal year 2003.

"(ii) MEDICARE AND MEDICAID ACTIVITIES.—For each fiscal year, of the amount appropriated in clause (i), the following amounts shall be available only for the purposes of the activities of the Office of the Inspector General of the Department of Health and Human Services with respect to the Medicare and medicaid programs—

"(I) for fiscal year 1997, not less than $60,000,000 and not more than $70,000,000;

"(II) for fiscal year 1998, not less than $80,000,000 and not more than $90,000,000;

"(III) for fiscal year 1999, not less than $90,000,000 and not more than $100,000,000;

"(IV) for fiscal year 2000, not less than $110,000,000 and not more than $120,000,000;

"(V) for fiscal year 2001, not less than $120,000,000 and not more than $130,000,000;

"(VI) for fiscal year 2002, not less than $140,000,000 and not more than $150,000,000; and

"(VII) for each fiscal year after fiscal year 2002, not less than $150,000,000 and not more than $160,000,000.

"(B) FEDERAL BUREAU OF INVESTIGATION.—There are hereby appropriated from the general fund of the United States Treasury and hereby appropriated to the Account for transfer to the Federal Bureau of Investigation to carry out the purposes described in subparagraph (C), to be available without further appropriation—

"(i) for fiscal year 1997, $47,000,000;

"(ii) for fiscal year 1998, $56,000,000;

"(iii) for fiscal year 1999, $66,000,000;

"(iv) for fiscal year 2000, $76,000,000;

"(v) for fiscal year 2001, $88,000,000;

"(vi) for fiscal year 2002, $101,000,000; and

"(vii) for each fiscal year after fiscal year 2002, $114,000,000.

"(C) USE OF FUNDS.—The purposes described in this subparagraph are to cover the costs (including equipment, salaries and benefits, and travel and training) of the administration and operation of the health care fraud and abuse control program established under section 1128C(a), including the costs of—

"(i) prosecuting health care matters (through criminal, civil, and administrative proceedings);

"(ii) investigations;

"(iii) financial and performance audits of health care programs and operations;

"(iv) inspections and other evaluations; and

"(v) provider and consumer education regarding compliance with the provisions of title XI.

"(4) APPROPRIATED AMOUNTS TO ACCOUNT FOR MEDICARE INTEGRITY PROGRAM.—

"(A) IN GENERAL.—There are hereby appropriated to the Account from the Trust Fund for each fiscal year such amounts as are necessary to carry out the Medicare Integrity Program under section 1893, subject to subparagraph (B) and to be available without further appropriation.

"(B) AMOUNTS SPECIFIED.—The amount appropriated under subparagraph (A) for a fiscal year is as follows:

"(i) For fiscal year 1997, such amount shall be not less than $430,000,000 and not more than $440,000,000.

"(ii) For fiscal year 1998, such amount shall be not less than $490,000,000 and not more than $500,000,000.

"(iii) For fiscal year 1999, such amount shall be not less than $550,000,000 and not more than $560,000,000.

"(iv) For fiscal year 2000, such amount shall be not less than $620,000,000 and not more than $630,000,000.

"(v) For fiscal year 2001, such amount shall be not less than $670,000,000 and not more than $680,000,000.

"(vi) For fiscal year 2002, such amount shall be not less than $690,000,000 and not more than $700,000,000.

"(vii) For each fiscal year after fiscal year 2002, such amount shall be not less than $710,000,000 and not more than $720,000,000.

"(5) ANNUAL REPORT.—Not later than January 1, the Secretary and the Attorney General shall submit jointly a report to Congress which identifies—

"(A) the amounts appropriated to the Trust Fund for the previous fiscal year under paragraph (2)(A) and the source of such amounts; and

"(B) the amounts appropriated from the Trust Fund for such year under paragraph (3) and the justification for the expenditure of such amounts.

"(6) GAO REPORT.—Not later than January 1 of 2000, 2002, and 2004, the Comptroller General of the United States shall submit a report to Congress which—

"(A) identifies—

"(i) the amounts appropriated to the Trust Fund for the previous two fiscal years under paragraph (2)(A) and the source of such amounts; and

"(ii) the amounts appropriated from the Trust Fund for such fiscal years under paragraph (3) and the justification for the expenditure of such amounts;

"(B) identifies any expenditures from the Trust Fund with respect to activities not involving the Medicare program under title XVIII;

"(C) identifies any savings to the Trust Fund, and any other savings, resulting from expenditures from the Trust Fund; and

"(D) analyzes such other aspects of the operation of the Trust Fund as the Comptroller General of the United States considers appropriate.".

SEC. 202. MEDICARE INTEGRITY PROGRAM.

(a) ESTABLISHMENT OF MEDICARE INTEGRITY PROGRAM.—Title XVIII is amended by adding at the end the following new section:

<< 42 USCA § 1395ddd >>

"MEDICARE INTEGRITY PROGRAM

"SEC. 1893. (a) ESTABLISHMENT OF PROGRAM.—There is hereby established the Medicare Integrity Program (in this section referred to as the 'Program') under which the Secretary shall promote the integrity of the Medicare program by entering into contracts in accordance with this section with eligible entities to carry out the activities described in subsection (b).

"(b) ACTIVITIES DESCRIBED.—The activities described in this subsection are as follows:

"(1) Review of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this title (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies used in the review of claims under this title as of the date of the enactment of this section).

"(2) Audit of cost reports.

"(3) Determinations as to whether payment should not be, or should not have been, made under this title by reason of section 1862(b), and recovery of payments that should not have been made.

"(4) Education of providers of services, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues.

"(5) Developing (and periodically updating) a list of items of durable medical equipment in accordance with section 1834(a)(15) which are subject to prior authorization under such section.

"(c) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract under the Program to carry out any of the activities described in subsection (b) if—

"(1) the entity has demonstrated capability to carry out such activities;

"(2) in carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to this title and in other cases arising out of such activities;

"(3) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement; and

"(4) the entity meets such other requirements as the Secretary may impose.

In the case of the activity described in subsection (b)(5), an entity shall be deemed to be eligible to enter into a contract under the Program to carry out the activity if the entity is a carrier with a contract in effect under section 1842.

"(d) PROCESS FOR ENTERING INTO CONTRACTS.—The Secretary shall enter into contracts under the Program in accordance with such procedures as the Secretary shall by regulation establish, except that such procedures shall include the following:

"(1) Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

"(2) Competitive procedures to be used—

"(A) when entering into new contracts under this section;

"(B) when entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and

"(C) at any other time considered appropriate by the Secretary,

except that the Secretary may continue to contract with entities that are carrying out the activities described in this section pursuant to agreements under section 1816 or contracts under section 1842 in effect on the date of the enactment of this section.

"(3) Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

The Secretary may enter into such contracts without regard to final rules having been promulgated.

"(e) LIMITATION ON CONTRACTOR LIABILITY.—The Secretary shall by regulation provide for the limitation of a contractor's liability for actions taken to carry out a contract under the Program, and such regulation shall, to the extent the Secretary finds appropriate, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1157.".

(b) ELIMINATION OF FI AND CARRIER RESPONSIBILITY FOR CARRYING OUT ACTIVITIES SUBJECT TO PROGRAM.—

<< 42 USCA § 1395h >>

(1) RESPONSIBILITIES OF FISCAL INTERMEDIARIES UNDER PART A.—Section 1816 (42 U.S.C. 1395h) is amended by adding at the end the following new subsection:

"(l) No agency or organization may carry out (or receive payment for carrying out) any activity pursuant to an agreement under this section to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893.".

<< 42 USCA § 1395u >>

(2) RESPONSIBILITIES OF CARRIERS UNDER PART B.—Section 1842(c) (42 U.S.C. 1395u(c)) is amended by adding at the end the following new paragraph:

"(6) No carrier may carry out (or receive payment for carrying out) any activity pursuant to a contract under this subsection to the extent that the activity is carried out pursuant to a contract under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).".

<< 42 USCA § 1395b–5 >>

SEC. 203. BENEFICIARY INCENTIVE PROGRAMS.

(a) CLARIFICATION OF REQUIREMENT TO PROVIDE EXPLANATION OF MEDICARE BENEFITS.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall provide an explanation of benefits under the Medicare program under title XVIII of the Social Security Act with respect to each item or service for which payment may be

made under the program which is furnished to an individual, without regard to whether or not a deductible or coinsurance may be imposed against the individual with respect to the item or service.

(b) PROGRAM TO COLLECT INFORMATION ON FRAUD AND ABUSE.—

(1) ESTABLISHMENT OF PROGRAM.—Not later than 3 months after the date of the enactment of this Act, the Secretary shall establish a program under which the Secretary shall encourage individuals to report to the Secretary information on individuals and entities who are engaging in or who have engaged in acts or omissions which constitute grounds for the imposition of a sanction under section 1128, 1128A, or 1128B of the Social Security Act, or who have otherwise engaged in fraud and abuse against the Medicare program under title XVIII of such act for which there is a sanction provided under law. The program shall discourage provision of, and not consider, information which is frivolous or otherwise not relevant or material to the imposition of such a sanction.

(2) PAYMENT OF PORTION OF AMOUNTS COLLECTED.—If an individual reports information to the Secretary under the program established under paragraph (1) which serves as the basis for the collection by the Secretary or the Attorney General of any amount of at least $100 (other than any amount paid as a penalty under section 1128B of the Social Security Act), the Secretary may pay a portion of the amount collected to the individual (under procedures similar to those applicable under section 7623 of the Internal Revenue Code of 1986 to payments to individuals providing information on violations of such Code).

(c) PROGRAM TO COLLECT INFORMATION ON PROGRAM EFFICIENCY.—

(1) ESTABLISHMENT OF PROGRAM.—Not later than 3 months after the date of the enactment of this Act, the Secretary shall establish a program under which the Secretary shall encourage individuals to submit to the Secretary suggestions on methods to improve the efficiency of the Medicare program.

(2) PAYMENT OF PORTION OF PROGRAM SAVINGS.—If an individual submits a suggestion to the Secretary under the program established under paragraph (1) which is adopted by the Secretary and which results in savings to the program, the Secretary may make a payment to the individual of such amount as the Secretary considers appropriate.

SEC. 204. APPLICATION OF CERTAIN HEALTH ANTIFRAUD AND ABUSE SANCTIONS TO FRAUD AND ABUSE AGAINST FEDERAL HEALTH CARE PROGRAMS.

<< 42 USCA § 1320a–7b >>

(a) IN GENERAL.—Section 1128B (42 U.S.C. 1320a–7b) is amended as follows:

(1) In the heading, by striking "MEDICARE OR STATE HEALTH CARE PROGRAMS" and inserting "FEDERAL HEALTH CARE PROGRAMS".

(2) In subsection (a)(1), by striking "a program under title XVIII or a State health care program (as defined in section 1128(h))" and inserting "a Federal health care program (as defined in subsection (f))".

(3) In subsection (a)(5), by striking "a program under title XVIII or a State health care program" and inserting "a Federal health care program".

(4) In the second sentence of subsection (a)—

(A) by striking "a State plan approved under title XIX" and inserting "a Federal health care program", and

(B) by striking "the State may at its option (notwithstanding any other provision of that title or of such plan)" and inserting "the administrator of such program may at its option (notwithstanding any other provision of such program)".

(5) In subsection (b), by striking "title XVIII or a State health care program" each place it appears and inserting "a Federal health care program".

(6) In subsection (c), by inserting "(as defined in section 1128(h))" after "a State health care program".

(7) By adding at the end the following new subsection:

"(f) For purposes of this section, the term 'Federal health care program' means—

"(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code); or

"(2) any State health care program, as defined in section 1128(h).".

<< 42 USCA § 1320a–7b NOTE >>

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 1997.

SEC. 205. GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND ABUSE SANCTIONS.

Title XI (42 U.S.C. 1301 et seq.), as amended by section 201, is amended by inserting after section 1128C the following new section:

<< 42 USCA § 1320a–7d >>

"GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND ABUSE SANCTIONS

"SEC. 1128d. (a) SOLICITATION AND PUBLICATION OF MODIFICATIONS TO EXISTING SAFE HARBORS AND NEW SAFE HARBORS.—

"(1) IN GENERAL.—

"(A) SOLICITATION OF PROPOSALS FOR SAFE HARBORS.—Not later than January 1, 1997, and not less than annually thereafter, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60–day period, for—

"(i) modifications to existing safe harbors issued pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 (42 U.S.C. 1320a–7b note);

"(ii) additional safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) and shall not serve as the basis for an exclusion under section 1128(b)(7);

"(iii) advisory opinions to be issued pursuant to subsection (b); and

"(iv) special fraud alerts to be issued pursuant to subsection (c).

"(B) PUBLICATION OF PROPOSED MODIFICATIONS AND PROPOSED ADDITIONAL SAFE HARBORS.—After considering the proposals described in clauses (i) and (ii) of subparagraph (A), the Secretary, in consultation with the Attorney General, shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors, if appropriate, with a 60–day comment period. After considering any public comments received during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors, as appropriate.

"(C) REPORT.—The Inspector General of the Department of Health and Human Services (in this section referred to as the 'Inspector General') shall, in an annual report to Congress or as part of the year-end semiannual report required by section 5 of the Inspector General Act of 1978 (5 U.S.C.App.), describe the proposals received under clauses (i) and (ii) of subparagraph (A) and explain which proposals were included in the publication described in subparagraph (B), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

"(2) CRITERIA FOR MODIFYING AND ESTABLISHING SAFE HARBORS.—In modifying and establishing safe harbors under paragraph (1)(B), the Secretary may consider the extent to which providing a safe harbor for the specified payment practice may result in any of the following:

"(A) An increase or decrease in access to health care services.

"(B) An increase or decrease in the quality of health care services.

"(C) An increase or decrease in patient freedom of choice among health care providers.

"(D) An increase or decrease in competition among health care providers.

"(E) An increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

"(F) An increase or decrease in the cost to Federal health care programs (as defined in section 1128B(f)).

"(G) An increase or decrease in the potential overutilization of health care services.

"(H) The existence or nonexistence of any potential financial benefit to a health care professional or provider which may vary based on their decisions of—

"(i) whether to order a health care item or service; or

"(ii) whether to arrange for a referral of health care items or services to a particular practitioner or provider.

"(I) Any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs (as so defined).

"(b) ADVISORY OPINIONS.—

"(1) ISSUANCE OF ADVISORY OPINIONS.—The Secretary, in consultation with the Attorney General, shall issue written advisory opinions as provided in this subsection.

"(2) MATTERS SUBJECT TO ADVISORY OPINIONS.—The Secretary shall issue advisory opinions as to the following matters:

"(A) What constitutes prohibited remuneration within the meaning of section 1128B(b).

"(B) Whether an arrangement or proposed arrangement satisfies the criteria set forth in section 1128B(b)(3) for activities which do not result in prohibited remuneration.

"(C) Whether an arrangement or proposed arrangement satisfies the criteria which the Secretary has established, or shall establish by regulation for activities which do not result in prohibited remuneration.

"(D) What constitutes an inducement to reduce or limit services to individuals entitled to benefits under title XVIII or title XIX within the meaning of section 1128B(b).

"(E) Whether any activity or proposed activity constitutes grounds for the imposition of a sanction under section 1128, 1128A, or 1128B.

"(3) MATTERS NOT SUBJECT TO ADVISORY OPINIONS.—Such advisory opinions shall not address the following matters:

"(A) Whether the fair market value shall be, or was paid or received for any goods, services or property.

"(B) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

"(4) EFFECT OF ADVISORY OPINIONS.—

"(A) BINDING AS TO SECRETARY AND PARTIES INVOLVED.—Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

"(B) FAILURE TO SEEK OPINION.—The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A, or 1128B.

"(5) REGULATIONS.—

"(A) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall issue regulations to carry out this section. Such regulations shall provide for—

"(i) the procedure to be followed by a party applying for an advisory opinion;

"(ii) the procedure to be followed by the Secretary in responding to a request for an advisory opinion;

"(iii) the interval in which the Secretary shall respond;

"(iv) the reasonable fee to be charged to the party requesting an advisory opinion; and

"(v) the manner in which advisory opinions will be made available to the public.

"(B) SPECIFIC CONTENTS.—Under the regulations promulgated pursuant to subparagraph (A)—

"(i) the Secretary shall be required to issue to a party requesting an advisory opinion by not later than 60 days after the request is received; and

"(ii) the fee charged to the party requesting an advisory opinion shall be equal to the costs incurred by the Secretary in responding to the request.

"(6) APPLICATION OF SUBSECTION.—This subsection shall apply to requests for advisory opinions made on or after the date which is 6 months after the date of enactment of this section and before the date which is 4 years after such date of enactment.

"(c) SPECIAL FRAUD ALERTS.—

"(1) IN GENERAL.—

"(A) REQUEST FOR SPECIAL FRAUD ALERTS.—Any person may present, at any time, a request to the Inspector General for a notice which informs the public of practices which the Inspector General considers to be suspect or of particular concern under the Medicare program under title XVIII or a State health care program, as defined in section 1128(h) (in this subsection referred to as a 'special fraud alert').

"(B) ISSUANCE AND PUBLICATION OF SPECIAL FRAUD ALERTS.—Upon receipt of a request described in subparagraph (A), the Inspector General shall investigate the subject matter of the request to determine whether a special fraud alert should be issued. If appropriate, the Inspector General shall issue a special fraud alert in response to the request. All special fraud alerts issued pursuant to this subparagraph shall be published in the Federal Register.

"(2) CRITERIA FOR SPECIAL FRAUD ALERTS.—In determining whether to issue a special fraud alert upon a request described in paragraph (1), the Inspector General may consider—

"(A) whether and to what extent the practices that would be identified in the special fraud alert may result in any of the consequences described in subsection (a)(2); and

"(B) the volume and frequency of the conduct that would be identified in the special fraud alert.".

Subtitle B—Revisions to Current Sanctions for Fraud and Abuse

<< 42 USCA § 1320a–7 >>

SEC. 211. MANDATORY EXCLUSION FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS.

(a) INDIVIDUAL CONVICTED OF FELONY RELATING TO HEALTH CARE FRAUD.—

(1) IN GENERAL.—Section 1128(a) (42 U.S.C. 1320a–7(a)) is amended by adding at the end the following new paragraph:

"(3) FELONY CONVICTION RELATING TO HEALTH CARE FRAUD.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.".

(2) CONFORMING AMENDMENT.—Paragraph (1) of section 1128(b) (42 U.S.C. 1320a–7(b)) is amended to read as follows:

"(1) CONVICTION RELATING TO FRAUD.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law—

"(A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

"(i) in connection with the delivery of a health care item or service, or

"(ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a)(1)) operated by or financed in whole or in part by any Federal, State, or local government agency; or

"(B) of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a health care program) operated by or financed in whole or in part by any Federal, State, or local government agency.".

(b) INDIVIDUAL CONVICTED OF FELONY RELATING TO CONTROLLED SUBSTANCE.—

(1) IN GENERAL.—Section 1128(a) (42 U.S.C. 1320a–7(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

"(4) FELONY CONVICTION RELATING TO CONTROLLED SUBSTANCE.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.".

(2) CONFORMING AMENDMENT.—Section 1128(b)(3) (42 U.S.C. 1320a–7(b)(3)) is amended—

(A) in the heading, by striking "CONVICTION" and inserting "MISDEMEANOR CONVICTION"; and

(B) by striking "criminal offense" and inserting "criminal offense consisting of a misdemeanor".

<< 42 USCA § 1320a–7 >>

SEC. 212. ESTABLISHMENT OF MINIMUM PERIOD OF EXCLUSION FOR CERTAIN INDIVIDUALS AND ENTITIES SUBJECT TO PERMISSIVE EXCLUSION FROM MEDICARE AND STATE HEALTH CARE PROGRAMS.

Section 1128(c)(3) (42 U.S.C. 1320a–7(c)(3)) is amended by adding at the end the following new subparagraphs:

"(D) In the case of an exclusion of an individual or entity under paragraph (1), (2), or (3) of subsection (b), the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances or that a longer period is appropriate because of aggravating circumstances.

"(E) In the case of an exclusion of an individual or entity under subsection (b)(4) or (b)(5), the period of the exclusion shall not be less than the period during which the individual's or entity's license to provide health care is revoked, suspended, or surrendered, or the individual or the entity is excluded or suspended from a Federal or State health care program.

"(F) In the case of an exclusion of an individual or entity under subsection (b)(6)(B), the period of the exclusion shall be not less than 1 year.".

<< 42 USCA § 1320a–7 >>

SEC. 213. PERMISSIVE EXCLUSION OF INDIVIDUALS WITH OWNERSHIP OR CONTROL INTEREST IN SANCTIONED ENTITIES.

Section 1128(b) (42 U.S.C. 1320a–7(b)) is amended by adding at the end the following new paragraph:

"(15) INDIVIDUALS CONTROLLING A SANCTIONED ENTITY.—

(A) Any individual—

"(i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know (as defined in section 1128A(i)(6)) of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or

"(ii) who is an officer or managing employee (as defined in section 1126(b)) of such an entity.

"(B) For purposes of subparagraph (A), the term 'sanctioned entity' means an entity—

"(i) that has been convicted of any offense described in subsection (a) or in paragraph (1), (2), or (3) of this subsection; or

"(ii) that has been excluded from participation under a program under title XVIII or under a State health care program.".

<< 42 USCA § 1320c–5 >>

SEC. 214. SANCTIONS AGAINST PRACTITIONERS AND PERSONS FOR FAILURE TO COMPLY WITH STATUTORY OBLIGATIONS.

(a) MINIMUM PERIOD OF EXCLUSION FOR PRACTITIONERS AND PERSONS FAILING TO MEET STATUTORY OBLIGATIONS.—

(1) IN GENERAL.—The second sentence of section 1156(b)(1) (42 U.S.C. 1320c–5(b)(1)) is amended by striking "may prescribe)" and inserting "may prescribe, except that such period may not be less than 1 year)".

(2) CONFORMING AMENDMENT.—Section 1156(b)(2) (42 U.S.C. 1320c–5(b)(2)) is amended by striking "shall remain" and inserting "shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain".

(b) REPEAL OF "UNWILLING OR UNABLE" CONDITION FOR IMPOSITION OF SANCTION.—Section 1156(b)(1) (42 U.S.C. 1320c–5(b)(1)) is amended—

(1) in the second sentence, by striking "and determines" and all that follows through "such obligations,"; and

(2) by striking the third sentence.

SEC. 215. INTERMEDIATE SANCTIONS FOR MEDICARE HEALTH MAINTENANCE ORGANIZATIONS.

<< 42 USCA § 1395mm >>

(a) APPLICATION OF INTERMEDIATE SANCTIONS FOR ANY PROGRAM VIOLATIONS.—

(1) IN GENERAL.—Section 1876(i)(1) (42 U.S.C. 1395mm(i)(1)) is amended by striking "the Secretary may terminate" and all that follows and inserting "in accordance with procedures established under paragraph (9), the Secretary may at any time

terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization—

"(A) has failed substantially to carry out the contract;

"(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

"(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f).".

(2) OTHER INTERMEDIATE SANCTIONS FOR MISCELLANEOUS PROGRAM VIOLATIONS.—Section 1876(i)(6) (42 U.S.C. 1395mm(i)(6)) is amended by adding at the end the following new subparagraph:

"(C) In the case of an eligible organization for which the Secretary makes a determination under paragraph (1), the basis of which is not described in subparagraph (A), the Secretary may apply the following intermediate sanctions:

"(i) Civil money penalties of not more than $25,000 for each determination under paragraph (1) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

"(ii) Civil money penalties of not more than $10,000 for each week beginning after the initiation of procedures by the Secretary under paragraph (9) during which the deficiency that is the basis of a determination under paragraph (1) exists.

"(iii) Suspension of enrollment of individuals under this section after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.".

(3) PROCEDURES FOR IMPOSING SANCTIONS.—Section 1876(i) (42 U.S.C. 1395mm(i)) is amended by adding at the end the following new paragraph:

"(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which—

"(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1) and the organization fails to develop or implement such a plan;

"(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an organization has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to the organization's attention;

"(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

"(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.".

(4) CONFORMING AMENDMENTS.—Section 1876(i)(6)(B) (42 U.S.C. 1395mm(i)(6)(B)) is amended by striking the second sentence.

(b) AGREEMENTS WITH PEER REVIEW ORGANIZATIONS.—Section 1876(i)(7)(A) (42 U.S.C. 1395mm(i)(7)(A)) is amended by striking "an agreement" and inserting "a written agreement".

<< 42 USCA § 1395mm NOTE >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to contract years beginning on or after January 1, 1997.

SEC. 216. ADDITIONAL EXCEPTION TO ANTI–KICKBACK PENALTIES FOR RISK-SHARING ARRANGEMENTS.

<< 42 USCA § 1320a–7b >>

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)) is amended—

(1) by striking "and" at the end of subparagraph (D);

(2) by striking the period at the end of subparagraph (E) and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

"(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible

organization under section 1876 or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide.".

<< 42 USCA § 1320a–7b NOTE >>

(b) NEGOTIATED RULEMAKING FOR RISK–SHARING EXCEPTION.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter 3 of chapter 5 of title 5, United States Code, standards relating to the exception for risk-sharing arrangements to the antikickback penalties described in section 1128B(b)(3)(F) of the Social Security Act, as added by subsection (a).

(B) FACTORS TO CONSIDER.—In establishing standards relating to the exception for risk-sharing arrangements to the anti-kickback penalties under subparagraph (A), the Secretary—

(i) shall consult with the Attorney General and representatives of the hospital, physician, other health practitioner, and health plan communities, and other interested parties; and

(ii) shall take into account—

(I) the level of risk appropriate to the size and type of arrangement;

(II) the frequency of assessment and distribution of incentives;

(III) the level of capital contribution; and

(IV) the extent to which the risk-sharing arrangement provides incentives to control the cost and quality of health care services.

(2) PUBLICATION OF NOTICE.—In carrying out the rule-making process under this subsection, the Secretary shall publish the notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this Act.

(3) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under paragraph (2), and for purposes of this subsection, the "target date for publication" (referred to in section 564(a)(5) of such title) shall be January 1, 1997.

(4) ABBREVIATED PERIOD FOR SUBMISSION OF COMMENTS.—In applying section 564(c) of such title under this subsection, "15 days" shall be substituted for "30 days".

(5) APPOINTMENT OF NEGOTIATED RULEMAKING COMMITTEE AND FACILITATOR.—The Secretary shall provide for—

(A) the appointment of a negotiated rulemaking committee under section 565(a) of such title by not later than 30 days after the end of the comment period provided for under section 564(c) of such title (as shortened under paragraph (4)), and

(B) the nomination of a facilitator under section 566(c) of such title by not later than 10 days after the date of appointment of the committee.

(6) PRELIMINARY COMMITTEE REPORT.—The negotiated rule-making committee appointed under paragraph (5) shall report to the Secretary, by not later than October 1, 1996, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before one month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress toward such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this subsection through such other methods as the Secretary may provide.

(7) FINAL COMMITTEE REPORT.—If the committee is not terminated under paragraph (6), the rulemaking committee shall submit a report containing a proposed rule by not later than one month before the target publication date.

(8) INTERIM, FINAL EFFECT.—The Secretary shall publish a rule under this subsection in the Federal Register by not later than the target publication date. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 60 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications of entities to be certified as provider-sponsored organizations pursuant to such rules and consistent with this subsection.

(9) PUBLICATION OF RULE AFTER PUBLIC COMMENT.—The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target publication date.

<< 42 USCA § 1320a–7b NOTE >>

(c) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to written agreements entered into on or after January 1, 1997, without regard to whether regulations have been issued to implement such amendments.

<< 42 USCA § 1320a–7b >>

SEC. 217. CRIMINAL PENALTY FOR FRAUDULENT DISPOSITION OF ASSETS IN ORDER TO OBTAIN MEDICAID BENEFITS.

Section 1128B(a) (42 U.S.C. 1320a–7b(a)) is amended—

(1) by striking "or" at the end of paragraph (4);

(2) by adding "or" at the end of paragraph (5); and

(3) by inserting after paragraph (5) the following new paragraph:

"(6) knowingly and willfully disposes of assets (including by any transfer in trust) in order for an individual to become eligible for medical assistance under a State plan under title XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c),".

<< 42 USCA §§ 1320a–7 NOTE, 1320a–7b nt, 1320c–5 nt, 1395mm nt >>

SEC. 218. EFFECTIVE DATE.

Except as otherwise provided, the amendments made by this subtitle shall take effect January 1, 1997.

Subtitle C—Data Collection

SEC. 221. ESTABLISHMENT OF THE HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM.

(a) IN GENERAL.—Title XI (42 U.S.C. 1301 et seq.), as amended by sections 201 and 205, is amended by inserting after section 1128D the following new section:

<< 42 USCA § 1320a–7e >>

"HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM

"SEC. 1128E. (a) GENERAL PURPOSE.—Not later than January 1, 1997, the Secretary shall establish a national health care fraud and abuse data collection program for the reporting of final adverse actions (not including settlements in which no findings of liability have been made) against health care providers, suppliers, or practitioners as required by subsection (b), with access as set forth in subsection (c), and shall maintain a database of the information collected under this section.

"(b) REPORTING OF INFORMATION.—

"(1) IN GENERAL.—Each Government agency and health plan shall report any final adverse action (not including settlements in which no findings of liability have been made) taken against a health care provider, supplier, or practitioner.

"(2) INFORMATION TO BE REPORTED.—The information to be reported under paragraph (1) includes:

"(A) The name and TIN (as defined in section 7701(a)(41) of the Internal Revenue Code of 1986) of any health care provider, supplier, or practitioner who is the subject of a final adverse action.

"(B) The name (if known) of any health care entity with which a health care provider, supplier, or practitioner, who is the subject of a final adverse action, is affiliated or associated.

"(C) The nature of the final adverse action and whether such action is on appeal.

"(D) A description of the acts or omissions and injuries upon which the final adverse action was based, and such other information as the Secretary determines by regulation is required for appropriate interpretation of information reported under this section.

"(3) CONFIDENTIALITY.—In determining what information is required, the Secretary shall include procedures to assure that the privacy of individuals receiving health care services is appropriately protected.

"(4) TIMING AND FORM OF REPORTING.—The information required to be reported under this subsection shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date specified by the Secretary.

"(5) TO WHOM REPORTED.—The information required to be reported under this subsection shall be reported to the Secretary.

"(c) DISCLOSURE AND CORRECTION OF INFORMATION.—

"(1) DISCLOSURE.—With respect to the information about final adverse actions (not including settlements in which no findings of liability have been made) reported to the Secretary under this section with respect to a health care provider, supplier, or practitioner, the Secretary shall, by regulation, provide for—

"(A) disclosure of the information, upon request, to the health care provider, supplier, or licensed practitioner, and

"(B) procedures in the case of disputed accuracy of the information.

"(2) CORRECTIONS.—Each Government agency and health plan shall report corrections of information already reported about any final adverse action taken against a health care provider, supplier, or practitioner, in such form and manner that the Secretary prescribes by regulation.

"(d) ACCESS TO REPORTED INFORMATION.—

"(1) AVAILABILITY.—The information in the database maintained under this section shall be available to Federal and State government agencies and health plans pursuant to procedures that the Secretary shall provide by regulation.

"(2) FEES FOR DISCLOSURE.—The Secretary may establish or approve reasonable fees for the disclosure of information in such database (other than with respect to requests by Federal agencies). The amount of such a fee shall be sufficient to recover the full costs of operating the database. Such fees shall be available to the Secretary or, in the Secretary's discretion to the agency designated under this section to cover such costs.

"(e) PROTECTION FROM LIABILITY FOR REPORTING.—No person or entity, including the agency designated by the Secretary in subsection (b)(5) shall be held liable in any civil action with respect to any report made as required by this section, without knowledge of the falsity of the information contained in the report.

"(f) COORDINATION WITH NATIONAL PRACTITIONER DATA BANK.—The Secretary shall implement this section in such a manner as to avoid duplication with the reporting requirements established for the National Practitioner Data Bank under the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.).

"(g) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

"(1) FINAL ADVERSE ACTION.—

"(A) IN GENERAL.—The term 'final adverse action' includes:

"(i) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service.

"(ii) Federal or State criminal convictions related to the delivery of a health care item or service.

"(iii) Actions by Federal or State agencies responsible for the licensing and certification of health care providers, suppliers, and licensed health care practitioners, including—

"(I) formal or official actions, such as revocation or suspension of a license (and the length of any such suspension), reprimand, censure or probation,

"(II) any other loss of license or the right to apply for, or renew, a license of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender, non-renewability, or otherwise, or

"(III) any other negative action or finding by such Federal or State agency that is publicly available information.

"(iv) Exclusion from participation in Federal or State health care programs (as defined in sections 1128B(f) and 1128(h), respectively).

"(v) Any other adjudicated actions or decisions that the Secretary shall establish by regulation.

"(B) EXCEPTION.—The term does not include any action with respect to a malpractice claim.

"(2) PRACTITIONER.—The terms 'licensed health care practitioner', 'licensed practitioner', and 'practitioner' mean, with respect to a State, an individual who is licensed or otherwise authorized by the State to provide health care services (or any individual who, without authority holds himself or herself out to be so licensed or authorized).

"(3) GOVERNMENT AGENCY.—The term 'Government agency' shall include:

"(A) The Department of Justice.

"(B) The Department of Health and Human Services.

"(C) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the Department of Defense and the Veterans' Administration.

"(D) State law enforcement agencies.

"(E) State medicaid fraud control units.

"(F) Federal or State agencies responsible for the licensing and certification of health care providers and licensed health care practitioners.

"(4) HEALTH PLAN.—The term 'health plan' has the meaning given such term by section 1128C(c).

"(5) DETERMINATION OF CONVICTION.—For purposes of paragraph (1), the existence of a conviction shall be determined under paragraph (4) of section 1128(i).".

<< 42 USCA § 1395u >>

(b) IMPROVED PREVENTION IN ISSUANCE OF MEDICARE PROVIDER NUMBERS.—Section 1842(r) (42 U.S.C. 1395u(r)) is amended by adding at the end the following new sentence: "Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.".

Subtitle D—Civil Monetary Penalties

SEC. 231. SOCIAL SECURITY ACT CIVIL MONETARY PENALTIES.

<< 42 USCA § 1320a–7a >>

(a) GENERAL CIVIL MONETARY PENALTIES.—Section 1128A (42 U.S.C. 1320a–7a) is amended as follows:

(1) In the third sentence of subsection (a), by striking "programs under title XVIII" and inserting "Federal health care programs (as defined in section 1128B(f)(1))".

(2) In subsection (f)—

(A) by redesignating paragraph (3) as paragraph (4); and

(B) by inserting after paragraph (2) the following new paragraph:

"(3) With respect to amounts recovered arising out of a claim under a Federal health care program (as defined in section 1128B(f)), the portion of such amounts as is determined to have been paid by the program shall be repaid to the program, and the portion of such amounts attributable to the amounts recovered under this section by reason of the amendments made by the Health Insurance Portability and Accountability Act of 1996 (as estimated by the Secretary) shall be deposited into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C).".

(3) In subsection (i)—

(A) in paragraph (2), by striking "title V, XVIII, XIX, or XX of this Act" and inserting "a Federal health care program (as defined in section 1128B(f))",

(B) in paragraph (4), by striking "a health insurance or medical services program under title XVIII or XIX of this Act" and inserting "a Federal health care program (as so defined)", and

(C) in paragraph (5), by striking "title V, XVIII, XIX, or XX" and inserting "a Federal health care program (as so defined)".

(4) By adding at the end the following new subsection:

"(m)(1) For purposes of this section, with respect to a Federal health care program not contained in this Act, references to the Secretary in this section shall be deemed to be references to the Secretary or Administrator of the department or agency with jurisdiction over such program and references to the Inspector General of the Department of Health and Human Services in this section shall be deemed to be references to the Inspector General of the applicable department or agency.

"(2)(A) The Secretary and Administrator of the departments and agencies referred to in paragraph (1) may include in any action pursuant to this section, claims within the jurisdiction of other Federal departments or agencies as long as the following conditions are satisfied:

"(i) The case involves primarily claims submitted to the Federal health care programs of the department or agency initiating the action.

"(ii) The Secretary or Administrator of the department or agency initiating the action gives notice and an opportunity to participate in the investigation to the Inspector General of the department or agency with primary jurisdiction over the Federal health care programs to which the claims were submitted.

"(B) If the conditions specified in subparagraph (A) are fulfilled, the Inspector General of the department or agency initiating the action is authorized to exercise all powers granted under the Inspector General Act of 1978 (5 U.S.C.App.) with respect to the claims submitted to the other departments or agencies to the same manner and extent as provided in that Act with respect to claims submitted to such departments or agencies.".

(b) EXCLUDED INDIVIDUAL RETAINING OWNERSHIP OR CONTROL INTEREST IN PARTICIPATING ENTITY.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)) is amended—

(1) by striking "or" at the end of paragraph (1)(D);

(2) by striking ", or" at the end of paragraph (2) and inserting a semicolon;

(3) by striking the semicolon at the end of paragraph (3) and inserting "; or"; and

(4) by inserting after paragraph (3) the following new paragraph:

"(4) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a program under title XVIII or a State health care program in accordance with this subsection or under section 1128 and who, at the time of a violation of this subsection—

"(A) retains a direct or indirect ownership or control interest in an entity that is participating in a program under title XVIII or a State health care program, and who knows or should know of the action constituting the basis for the exclusion; or

"(B) is an officer or managing employee (as defined in section 1126(b)) of such an entity;".

(c) MODIFICATIONS OF AMOUNTS OF PENALTIES AND ASSESSMENTS.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)), as amended by subsection (b), is amended in the matter following paragraph (4)—

(1) by striking "$2,000" and inserting "$10,000";

(2) by inserting "; in cases under paragraph (4), $10,000 for each day the prohibited relationship occurs" after "false or misleading information was given"; and

(3) by striking "twice the amount" and inserting "3 times the amount".

(d) CLARIFICATION OF LEVEL OF KNOWLEDGE REQUIRED FOR IMPOSITION OF CIVIL MONETARY PENALTIES.—

(1) IN GENERAL.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)) is amended—

(A) in paragraphs (1) and (2), by inserting "knowingly" before "presents" each place it appears; and

(B) in paragraph (3), by striking "gives" and inserting "knowingly gives or causes to be given".

(2) DEFINITION OF STANDARD.—Section 1128A(i) (42 U.S.C. 1320a–7a(i)), as amended by subsection (h)(2), is amended by adding at the end the following new paragraph:

"(7) The term 'should know' means that a person, with respect to information—

"(A) acts in deliberate ignorance of the truth or falsity of the information; or

"(B) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.".

(e) CLAIM FOR ITEM OR SERVICE BASED ON INCORRECT CODING OR MEDICALLY UNNECESSARY SERVICES.—Section 1128A(a)(1) (42 U.S.C. 1320a–7a(a)(1)), as amended by subsection (b), is amended—

(1) in subparagraph (A) by striking "claimed," and inserting "claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,";

(2) in subparagraph (C), by striking "or" at the end;

(3) in subparagraph (D), by striking the semicolon and inserting ", or"; and

(4) by inserting after subparagraph (D) the following new subparagraph:

"(E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary;".

(f) SANCTIONS AGAINST PRACTITIONERS AND PERSONS FOR FAILURE TO COMPLY WITH STATUTORY OBLIGATIONS.—Section 1156(b)(3) (42 U.S.C. 1320c–5(b)(3)) is amended by striking "the actual or estimated cost" and inserting "up to $10,000 for each instance".

<< 42 USCA § 1395mm >>

(g) PROCEDURAL PROVISIONS.—Section 1876(i)(6) (42 U.S.C. 1395mm(i)(6)), as amended by section 215(a)(2), is amended by adding at the end the following new subparagraph:

"(D) The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under subparagraph (B)(i) or (C)(i) in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a).".

<< 42 USCA § 1320a–7a >>

(h) PROHIBITION AGAINST OFFERING INDUCEMENTS TO INDIVIDUALS ENROLLED UNDER PROGRAMS OR PLANS.—

(1) OFFER OF REMUNERATION.—Section 1128A(a) (42 U.S.C. 1320a–7a(a)), as amended by subsection (b), is amended —

(A) by striking "or" at the end of paragraph (3);

(B) by striking the semicolon at the end of paragraph (4) and inserting "; or"; and

(C) by inserting after paragraph (4) the following new paragraph:

"(5) offers to or transfers remuneration to any individual eligible for benefits under title XVIII of this Act, or under a State health care program (as defined in section 1128(h)) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVIII, or a State health care program (as so defined);".

(2) REMUNERATION DEFINED.—Section 1128A(i) (42 U.S.C. 1320a–7a(i)) is amended by adding at the end the following new paragraph:

"(6) The term 'remuneration' includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term 'remuneration' does not include—

"(A) the waiver of coinsurance and deductible amounts by a person, if—

"(i) the waiver is not offered as part of any advertisement or solicitation;

"(ii) the person does not routinely waive coinsurance or deductible amounts; and

"(iii) the person—

"(I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need;

"(II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts; or

"(III) provides for any permissible waiver as specified in section 1128B(b)(3) or in regulations issued by the Secretary;

"(B) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and as long as the differentials meet the standards as defined in regulations promulgated by the Secretary not later than 180 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996; or

"(C) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated.".

<< 42 USCA §§ 1320a–7a NOTE, 1320c–5 nt, 1395mm nt >>

(i) EFFECTIVE DATE.—The amendments made by this section shall apply to acts or omissions occurring on or after January 1, 1997.

SEC. 232. PENALTY FOR FALSE CERTIFICATION FOR HOME HEALTH SERVICES.

<< 42 USCA § 1320a–7a >>

(a) IN GENERAL.—Section 1128A(b) (42 U.S.C. 1320a–7a(b)) is amended by adding at the end the following new paragraph:

"(3)(A) Any physician who executes a document described in subparagraph (B) with respect to an individual knowing that all of the requirements referred to in such subparagraph are not met with respect to the individual shall be subject to a civil monetary penalty of not more than the greater of—

"(i) $5,000, or

"(ii) three times the amount of the payments under title XVIII for home health services which are made pursuant to such certification.

"(B) A document described in this subparagraph is any document that certifies, for purposes of title XVIII, that an individual meets the requirements of section 1814(a)(2)(C) or 1835(a)(2)(A) in the case of home health services furnished to the individual.".

<< 42 USCA § 1320a–7a NOTE >>

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to certifications made on or after the date of the enactment of this Act.

Subtitle E—Revisions to Criminal Law

SEC. 241. DEFINITIONS RELATING TO FEDERAL HEALTH CARE OFFENSE.

<< 18 USCA § 24 >>

(a) IN GENERAL.—Chapter 1 of title 18, United States Code, is amended by adding at the end the following:

"§ 24. Definitions relating to Federal health care offense

"(a) As used in this title, the term 'Federal health care offense' means a violation of, or a criminal conspiracy to violate—

"(1) section 669, 1035, 1347, or 1518 of this title;

"(2) section 287, 371, 664, 666, 1001, 1027, 1341, 1343, or 1954 of this title, if the violation or conspiracy relates to a health care benefit program.

"(b) As used in this title, the term 'health care benefit program' means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.".

<< 18 USCA Ch. 1 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 2 of title 18, United States Code, is amended by inserting after the item relating to section 23 the following new item:

"24. Definitions relating to Federal health care offense.".

SEC. 242. HEALTH CARE FRAUD.

(a) OFFENSE.—

(1) IN GENERAL.—Chapter 63 of title 18, United States Code, is amended by adding at the end the following:

<< 18 USCA § 1347 >>

"§ 1347. Health care fraud

"Whoever knowingly and willfully executes, or attempts to execute, a scheme or artifice—

"(1) to defraud any health care benefit program; or

"(2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program,

in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 10 years, or both. If the violation results in serious bodily injury (as defined in section 1365 of this title), such person shall be fined under this title or imprisoned not more than 20 years, or both; and if the violation results in death, such person shall be fined under this title, or imprisoned for any term of years or for life, or both.".

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 63 of title 18, United States Code, is amended by adding at the end the following:

<< 18 USCA Ch. 63 >>

"1347. Health care fraud.".

<< 42 USCA § 1395i NOTE >>

(b) CRIMINAL FINES DEPOSITED IN FEDERAL HOSPITAL INSURANCE TRUST FUND.—The Secretary of the Treasury shall deposit into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C) of the Social Security Act (42 U.S.C. 1395i) an amount equal to the criminal fines imposed under section 1347 of title 18, United States Code (relating to health care fraud).

SEC. 243. THEFT OR EMBEZZLEMENT.

<< 18 USCA § 669 >>

(a) IN GENERAL.—Chapter 31 of title 18, United States Code, is amended by adding at the end the following:

"§ 669. Theft or embezzlement in connection with health care

"(a) Whoever knowingly and willfully embezzles, steals, or otherwise without authority converts to the use of any person other than the rightful owner, or intentionally misapplies any of the moneys, funds, securities, premiums, credits, property, or other assets of a health care benefit program, shall be fined under this title or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of $100 the defendant shall be fined under this title or imprisoned not more than one year, or both.

"(b) As used in this section, the term 'health care benefit program' has the meaning given such term in section 24(b) of this title.".

<< 18 USCA Ch. 31 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 31 of title 18, United States Code, is amended by adding at the end the following:

"669. Theft or embezzlement in connection with health care.".

SEC. 244. FALSE STATEMENTS.

<< 18 USCA § 1035 >>

(a) IN GENERAL.—Chapter 47 of title 18, United States Code, is amended by adding at the end the following:

"§ 1035. False statements relating to health care matters

"(a) Whoever, in any matter involving a health care benefit program, knowingly and willfully—

"(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or

"(2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry,

in connection with the delivery of or payment for health care benefits, items, or services, shall be fined under this title or imprisoned not more than 5 years, or both.

"(b) As used in this section, the term 'health care benefit program' has the meaning given such term in section 24(b) of this title.".

<< 18 USCA Ch. 47 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 47 of title 18, United States Code, is amended by adding at the end the following new item:

"1035. False statements relating to health care matters.".

SEC. 245. OBSTRUCTION OF CRIMINAL INVESTIGATIONS OF HEALTH CARE OFFENSES.

<< 18 USCA § 1518 >>

(a) IN GENERAL.—Chapter 73 of title 18, United States Code, is amended by adding at the end the following:

"§ 1518. Obstruction of criminal investigations of health care offenses

"(a) Whoever willfully prevents, obstructs, misleads, delays or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a Federal health care offense to a criminal investigator shall be fined under this title or imprisoned not more than 5 years, or both.

"(b) As used in this section the term 'criminal investigator' means any individual duly authorized by a department, agency, or armed force of the United States to conduct or engage in investigations for prosecutions for violations of health care offenses.".

<< 18 USCA Ch. 73 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 73 of title 18, United States Code, is amended by adding at the end the following new item:

"1518. Obstruction of criminal investigations of health care offenses.".

<< 18 USCA § 1956 >>

SEC. 246. LAUNDERING OF MONETARY INSTRUMENTS.

Section 1956(c)(7) of title 18, United States Code, is amended by adding at the end the following:

"(F) Any act or activity constituting an offense involving a Federal health care offense.".

<< 18 USCA § 1345 >>

SEC. 247. INJUNCTIVE RELIEF RELATING TO HEALTH CARE OFFENSES.

(a) IN GENERAL.—Section 1345(a)(1) of title 18, United States Code, is amended—

(1) by striking "or" at the end of subparagraph (A);

(2) by inserting "or" at the end of subparagraph (B); and

(3) by adding at the end the following:

"(C) committing or about to commit a Federal health care offense.".

(b) FREEZING OF ASSETS.—Section 1345(a)(2) of title 18, United States Code, is amended by inserting "or a Federal health care offense" after "title)".

SEC. 248. AUTHORIZED INVESTIGATIVE DEMAND PROCEDURES.

<< 18 USCA § 3486 >>

(a) IN GENERAL.—Chapter 223 of title 18, United States Code, is amended by adding after section 3485 the following:

"§ 3486. Authorized investigative demand procedures

"(a) AUTHORIZATION.—(1) In any investigation relating to any act or activity involving a Federal health care offense, the Attorney General or the Attorney General's designee may issue in writing and cause to be served a subpoena—

"(A) requiring the production of any records (including any books, papers, documents, electronic media, or other objects or tangible things), which may be relevant to an authorized law enforcement inquiry, that a person or legal entity may possess or have care, custody, or control; or

"(B) requiring a custodian of records to give testimony concerning the production and authentication of such records.

"(2) A subpoena under this subsection shall describe the objects required to be produced and prescribe a return date within a reasonable period of time within which the objects can be assembled and made available.

"(3) The production of records shall not be required under this section at any place more than 500 miles distant from the place where the subpoena for the production of such records is served.

"(4) Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the courts of the United States.

"(b) SERVICE.—A subpoena issued under this section may be served by any person who is at least 18 years of age and is designated in the subpoena to serve it. Service upon a natural person may be made by personal delivery of the subpoena to him. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpoena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpoena entered on a true copy thereof by the person serving it shall be proof of service.

"(c) ENFORCEMENT.—In the case of contumacy by or refusal to obey a subpoena issued to any person, the Attorney General may invoke the aid of any court of the United States within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which he carries on business or may be found, to compel compliance with the subpoena. The court may issue an order requiring the subpoenaed person to appear before the Attorney General to produce records, if so ordered, or to give testimony concerning the production and authentication of such records. Any failure to obey the order of the court may be punished by the court as a contempt thereof. All process in any such case may be served in any judicial district in which such person may be found.

"(d) IMMUNITY FROM CIVIL LIABILITY.—Notwithstanding any Federal, State, or local law, any person, including officers, agents, and employees, receiving a summons under this section, who complies in good faith with the summons and thus produces the materials sought, shall not be liable in any court of any State or the United States to any customer or other person for such production or for nondisclosure of that production to the customer.

"(e) LIMITATION ON USE.—(1) Health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual who is the subject of the information unless the action or investigation arises out of and is directly related to receipt of health care or payment for health care or action involving a fraudulent claim related to health; or if authorized by an appropriate order of a court of competent jurisdiction, granted after application showing good cause therefor.

"(2) In assessing good cause, the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services.

"(3) Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.".

<< 18 USCA Ch. 223 >>

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of chapter 223 of title 18, United States Code, is amended by inserting after the item relating to section 3485 the following new item:

"3486. Authorized investigative demand procedures.".

<< 18 USCA § 1510 >>

(c) CONFORMING AMENDMENT.—Section 1510(b)(3)(B) of title 18, United States Code, is amended by inserting "or a Department of Justice subpoena (issued under section 3486 of title 18)," after "subpoena".

SEC. 249. FORFEITURES FOR FEDERAL HEALTH CARE OFFENSES.

<< 18 USCA § 982 >>

(a) IN GENERAL.—Section 982(a) of title 18, United States Code, is amended by adding after paragraph (5) the following new paragraph:

"(6) The court, in imposing sentence on a person convicted of a Federal health care offense, shall order the person to forfeit property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense.".

(b) CONFORMING AMENDMENT.—Section 982(b)(1)(A) of title 18, United States Code, is amended by inserting "or (a)(6)" after "(a)(1)".

<< 42 USCA § 1395i NOTE >>

(c) PROPERTY FORFEITED DEPOSITED IN FEDERAL HOSPITAL INSURANCE TRUST FUND.—

(1) IN GENERAL.—After the payment of the costs of asset forfeiture has been made and after all restoration payments (if any) have been made, and notwithstanding any other provision of law, the Secretary of the Treasury shall deposit into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C) of the Social Security Act, as added by section 301(b), an amount equal to the net amount realized from the forfeiture of property by reason of a Federal health care offense pursuant to section 982(a)(6) of title 18, United States Code.

(2) COSTS OF ASSET FORFEITURE.—For purposes of paragraph (1), the term "payment of the costs of asset forfeiture" means—

(A) the payment, at the discretion of the Attorney General, of any expenses necessary to seize, detain, inventory, safeguard, maintain, advertise, sell, or dispose of property under seizure, detention, or forfeited, or of any other necessary expenses incident to the seizure, detention, forfeiture, or disposal of such property, including payment for—

(i) contract services;

(ii) the employment of outside contractors to operate and manage properties or provide other specialized services necessary to dispose of such properties in an effort to maximize the return from such properties; and

(iii) reimbursement of any Federal, State, or local agency for any expenditures made to perform the functions described in this subparagraph;

(B) at the discretion of the Attorney General, the payment of awards for information or assistance leading to a civil or criminal forfeiture involving any Federal agency participating in the Health Care Fraud and Abuse Control Account;

(C) the compromise and payment of valid liens and mortgages against property that has been forfeited, subject to the discretion of the Attorney General to determine the validity of any such lien or mortgage and the amount of payment to be made, and the employment of attorneys and other personnel skilled in State real estate law as necessary;

(D) payment authorized in connection with remission or mitigation procedures relating to property forfeited; and

(E) the payment of State and local property taxes on forfeited real property that accrued between the date of the violation giving rise to the forfeiture and the date of the forfeiture order.

(3) RESTORATION PAYMENT.—Notwithstanding any other provision of law, if the Federal health care offense referred to in paragraph (1) resulted in a loss to an employee welfare benefit plan within the meaning of section 3(1) of the Employee Retirement Income Security Act of 1974, the Secretary of the Treasury shall transfer to such employee welfare benefit plan,

from the amount realized from the forfeiture of property referred to in paragraph (1), an amount equal to such loss. For purposes of paragraph (1), the term "restoration payment" means the amount transferred to an employee welfare benefit plan pursuant to this paragraph.

<< 29 USCA § 1136 NOTE >>

SEC. 250. RELATION TO ERISA AUTHORITY.

Nothing in this subtitle shall be construed as affecting the authority of the Secretary of Labor under section 506(b) of the Employee Retirement Income Security Act of 1974, including the Secretary's authority with respect to violations of title 18, United States Code (as amended by this subtitle).

Subtitle F—Administrative Simplification

<< 42 USCA § 1320d NOTE >>

SEC. 261. PURPOSE.

It is the purpose of this subtitle to improve the Medicare program under title XVIII of the Social Security Act, the medicaid program under title XIX of such Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.

SEC. 262. ADMINISTRATIVE SIMPLIFICATION.

(a) IN GENERAL.—Title XI (42 U.S.C. 1301 et seq.) is amended by adding at the end the following:

<< 42 USCA Ch. 7 >>

"PART C—ADMINISTRATIVE SIMPLIFICATION

<< 42 USCA § 1320d >>

"DEFINITIONS

"SEC. 1171. For purposes of this part:

"(1) CODE SET.—The term 'code set' means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

"(2) HEALTH CARE CLEARINGHOUSE.—The term 'health care clearinghouse' means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.

"(3) HEALTH CARE PROVIDER.—The term 'health care provider' includes a provider of services (as defined in section 1861(u)), a provider of medical or other health services (as defined in section 1861(s)), and any other person furnishing health care services or supplies.

"(4) HEALTH INFORMATION.—The term 'health information' means any information, whether oral or recorded in any form or medium, that—

"(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

"(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

"(5) HEALTH PLAN.—The term 'health plan' means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 2791 of the Public Health Service Act). Such term includes the following, and any combination thereof:

"(A) A group health plan (as defined in section 2791(a) of the Public Health Service Act), but only if the plan—

"(i) has 50 or more participants (as defined in section 3(7) of the Employee Retirement Income Security Act of 1974); or

"(ii) is administered by an entity other than the employer who established and maintains the plan.

"(B) A health insurance issuer (as defined in section 2791(b) of the Public Health Service Act).

"(C) A health maintenance organization (as defined in section 2791(b) of the Public Health Service Act).

"(D) Part A or part B of the Medicare program under title XVIII.

"(E) The medicaid program under title XIX.

"(F) A Medicare supplemental policy (as defined in section 1882(g)(1)).

"(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

"(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

"(I) The health care program for active military personnel under title 10, United States Code.

"(J) The veterans health care program under chapter 17 of title 38, United States Code.

"(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10, United States Code.

"(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

"(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code.

"(6) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term 'individually identifiable health information' means any information, including demographic information collected from an individual, that—

"(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

"(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

"(i) identifies the individual; or

"(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

"(7) STANDARD.—The term 'standard', when used with reference to a data element of health information or a transaction referred to in section 1173(a)(1), means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1172 through 1174.

"(8) STANDARD SETTING ORGANIZATION.—The term 'standard setting organization' means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part.

<< 42 USCA § 1320d–1 >>

"GENERAL REQUIREMENTS FOR ADOPTION OF STANDARDS

"SEC. 1172. (a) APPLICABILITY.—Any standard adopted under this part shall apply, in whole or in part, to the following persons:

"(1) A health plan.

"(2) A health care clearinghouse.

"(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1173(a)(1).

"(b) REDUCTION OF COSTS.—Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

"(c) ROLE OF STANDARD SETTING ORGANIZATIONS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

"(2) SPECIAL RULES.—

"(A) DIFFERENT STANDARDS.—The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if—

"(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

"(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.

"(B) NO STANDARD BY STANDARD SETTING ORGANIZATION.—If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part—

"(i) paragraph (1) shall not apply; and

"(ii) subsection (f) shall apply.

"(3) CONSULTATION REQUIREMENT.—

"(A) IN GENERAL.—A standard may not be adopted under this part unless—

"(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

"(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f), consulted with each of the organizations described in subparagraph (B) before adopting the standard.

"(B) ORGANIZATIONS DESCRIBED.—The organizations referred to in subparagraph (A) are the following:

"(i) The National Uniform Billing Committee.

"(ii) The National Uniform Claim Committee.

"(iii) The Workgroup for Electronic Data Interchange.

"(iv) The American Dental Association.

"(d) IMPLEMENTATION SPECIFICATIONS.—The Secretary shall establish specifications for implementing each of the standards adopted under this part.

"(e) PROTECTION OF TRADE SECRETS.—Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

"(f) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

"(g) APPLICATION TO MODIFICATIONS OF STANDARDS.—This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1174(b) in the same manner as it applies to an initial standard adopted under section 1174(a).

<< 42 USCA § 1320d–2 >>

"STANDARDS FOR INFORMATION TRANSACTIONS AND DATA ELEMENTS

"SEC. 1173. (a) STANDARDS TO ENABLE ELECTRONIC EXCHANGE.—

"(1) IN GENERAL.—The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for—

"(A) the financial and administrative transactions described in paragraph (2); and

"(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs.

"(2) TRANSACTIONS.—The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

"(A) Health claims or equivalent encounter information.

"(B) Health claims attachments.

"(C) Enrollment and disenrollment in a health plan.

"(D) Eligibility for a health plan.

"(E) Health care payment and remittance advice.

"(F) Health plan premium payments.

"(G) First report of injury.

"(H) Health claim status.

"(I) Referral certification and authorization.

"(3) ACCOMMODATION OF SPECIFIC PROVIDERS.—The standards adopted by the Secretary under paragraph (1) shall accommodate the needs of different types of health care providers.

"(b) UNIQUE HEALTH IDENTIFIERS.—

"(1) IN GENERAL.—The Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out the preceding sentence for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

"(2) USE OF IDENTIFIERS.—The standards adopted under paragraph (1) shall specify the purposes for which a unique health identifier may be used.

"(c) CODE SETS.—

"(1) IN GENERAL.—The Secretary shall adopt standards that—

"(A) select code sets for appropriate data elements for the transactions referred to in subsection (a)(1) from among the code sets that have been developed by private and public entities; or

"(B) establish code sets for such data elements if no code sets for the data elements have been developed.

"(2) DISTRIBUTION.—The Secretary shall establish efficient and low-cost procedures for distribution (including electronic distribution) of code sets and modifications made to such code sets under section 1174(b).

"(d) SECURITY STANDARDS FOR HEALTH INFORMATION.—

"(1) SECURITY STANDARDS.—The Secretary shall adopt security standards that—

"(A) take into account—

"(i) the technical capabilities of record systems used to maintain health information;

"(ii) the costs of security measures;

"(iii) the need for training persons who have access to health information;

"(iv) the value of audit trails in computerized record systems; and

"(v) the needs and capabilities of small health care providers and rural health care providers (as such providers are defined by the Secretary); and

"(B) ensure that a health care clearinghouse, if it is part of a larger organization, has policies and security procedures which isolate the activities of the health care clearinghouse with respect to processing information in a manner that prevents unauthorized access to such information by such larger organization.

"(2) SAFEGUARDS.—Each person described in section 1172(a) who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards—

"(A) to ensure the integrity and confidentiality of the information;

"(B) to protect against any reasonably anticipated—

"(i) threats or hazards to the security or integrity of the information; and

"(ii) unauthorized uses or disclosures of the information; and

"(C) otherwise to ensure compliance with this part by the officers and employees of such person.

"(e) ELECTRONIC SIGNATURE.—

"(1) STANDARDS.—The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1).

"(2) EFFECT OF COMPLIANCE.—Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signatures with respect to the transactions referred to in subsection (a)(1).

"(f) TRANSFER OF INFORMATION AMONG HEALTH PLANS.—The Secretary shall adopt standards for transferring among health plans appropriate standard data elements needed for the coordination of benefits, the sequential processing of claims, and other data elements for individuals who have more than one health plan.

<< 42 USCA § 1320d–3 >>

"TIMETABLES FOR ADOPTION OF STANDARDS

"SEC. 1174. (a) INITIAL STANDARDS.—The Secretary shall carry out section 1173 not later than 18 months after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, except that standards relating to claims attachments shall be adopted not later than 30 months after such date.

"(b) ADDITIONS AND MODIFICATIONS TO STANDARDS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1173, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance.

"(2) SPECIAL RULES.—

"(A) FIRST 12–MONTH PERIOD.—Except with respect to additions and modifications to code sets under subparagraph (B), the Secretary may not adopt any modification to a standard adopted under this part during the 12–month period beginning on the date the standard is initially adopted, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.

"(B) ADDITIONS AND MODIFICATIONS TO CODE SETS.—

"(i) IN GENERAL.—The Secretary shall ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets.

"(ii) ADDITIONAL RULES.—If a code set is modified under this subsection, the modified code set shall include instructions on how data elements of health information that were encoded prior to the modification may be converted or translated so as to preserve the informational value of the data elements that existed before the modification. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption and cost of complying with such modification.

<< 42 USCA § 1320d–4 >>

"REQUIREMENTS

"SEC. 1175. (a) CONDUCT OF TRANSACTIONS BY PLANS.—

"(1) IN GENERAL.—If a person desires to conduct a transaction referred to in section 1173(a)(1) with a health plan as a standard transaction—

"(A) the health plan may not refuse to conduct such transaction as a standard transaction;

"(B) the insurance plan may not delay such transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction; and

"(C) the information transmitted and received in connection with the transaction shall be in the form of standard data elements of health information.

"(2) SATISFACTION OF REQUIREMENTS.—A health plan may satisfy the requirements under paragraph (1) by—

"(A) directly transmitting and receiving standard data elements of health information; or

"(B) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse, and receiving standard data elements through the health care clearinghouse.

"(3) TIMETABLE FOR COMPLIANCE.—Paragraph (1) shall not be construed to require a health plan to comply with any standard, implementation specification, or modification to a standard or specification adopted or established by the Secretary under sections 1172 through 1174 at any time prior to the date on which the plan is required to comply with the standard or specification under subsection (b).

"(b) COMPLIANCE WITH STANDARDS.—

"(1) INITIAL COMPLIANCE.—

"(A) IN GENERAL.—Not later than 24 months after the date on which an initial standard or implementation specification is adopted or established under sections 1172 and 1173, each person to whom the standard or implementation specification applies shall comply with the standard or specification.

"(B) SPECIAL RULE FOR SMALL HEALTH PLANS.—In the case of a small health plan, paragraph (1) shall be applied by substituting '36 months' for '24 months'. For purposes of this subsection, the Secretary shall determine the plans that qualify as small health plans.

"(2) COMPLIANCE WITH MODIFIED STANDARDS.—If the Secretary adopts a modification to a standard or implementation specification under this part, each person to whom the standard or implementation specification applies shall comply with the modified standard or implementation specification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification. The time determined appropriate under the preceding sentence may not be earlier than the last day of the 180–day period beginning on the date such modification is adopted. The Secretary may extend the time for compliance for small health plans, if the Secretary determines that such extension is appropriate.

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit any person from complying with a standard or specification by—

"(A) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse; or

"(B) receiving standard data elements through a health care clearinghouse.

<< 42 USCA § 1320d–5 >>

"GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

"SEC. 1176. (a) GENERAL PENALTY.—

"(1) IN GENERAL.—Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part a penalty of not more than $100 for each such violation, except that the total amount imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.

"(2) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A.

"(b) LIMITATIONS.—

"(1) OFFENSES OTHERWISE PUNISHABLE.—A penalty may not be imposed under subsection (a) with respect to an act if the act constitutes an offense punishable under section 1177.

"(2) NONCOMPLIANCE NOT DISCOVERED.—A penalty may not be imposed under subsection (a) with respect to a provision of this part if it is established to the satisfaction of the Secretary that the person liable for the penalty did not know, and by exercising reasonable diligence would not have known, that such person violated the provision.

"(3) FAILURES DUE TO REASONABLE CAUSE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), a penalty may not be imposed under subsection (a) if—

"(i) the failure to comply was due to reasonable cause and not to willful neglect; and

"(ii) the failure to comply is corrected during the 30–day period beginning on the first date the person liable for the penalty knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

"(B) EXTENSION OF PERIOD.—

"(i) NO PENALTY.—The period referred to in subparagraph (A)(ii) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

"(ii) ASSISTANCE.—If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A)(ii). Such assistance shall be provided in any manner determined appropriate by the Secretary.

"(4) REDUCTION.—In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

<< 42 USCA § 1320d–6 >>

"WRONGFUL DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

"SEC. 1177. (a) OFFENSE.—A person who knowingly and in violation of this part—

"(1) uses or causes to be used a unique health identifier;

"(2) obtains individually identifiable health information relating to an individual; or

"(3) discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b).

"(b) PENALTIES.—A person described in subsection (a) shall—

"(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

"(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and

"(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

<< 42 USCA § 1320d–7 >>

"EFFECT ON STATE LAW

"SEC. 1178. (a) GENERAL EFFECT.—

"(1) GENERAL RULE.—Except as provided in paragraph (2), a provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

"(2) EXCEPTIONS.—A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall not supersede a contrary provision of State law, if the provision of State law—

"(A) is a provision the Secretary determines—

"(i) is necessary—

"(I) to prevent fraud and abuse;

"(II) to ensure appropriate State regulation of insurance and health plans;

"(III) for State reporting on health care delivery or costs; or

"(IV) for other purposes; or

"(ii) addresses controlled substances; or

"(B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

"(b) PUBLIC HEALTH.—Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

"(c) STATE REGULATORY REPORTING.—Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

<< 42 USCA § 1320d–8 >>

"PROCESSING PAYMENT TRANSACTIONS BY FINANCIAL INSTITUTIONS

"SEC. 1179. To the extent that an entity is engaged in activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978), or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

"(1) The use or disclosure of information by the entity for authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care, where such payment is made by any means, including a credit, debit, or other payment card, an account, check, or electronic funds transfer.

"(2) The request for, or the use or disclosure of, information by the entity with respect to a payment described in paragraph (1)—

"(A) for transferring receivables;

"(B) for auditing;

"(C) in connection with—
"(i) a customer dispute; or
"(ii) an inquiry from, or to, a customer;
"(D) in a communication to a customer of the entity regarding the customer's transactions, payment card, account, check, or electronic funds transfer;
"(E) for reporting to consumer reporting agencies; or
"(F) for complying with—
"(i) a civil or criminal subpoena; or
"(ii) a Federal or State law regulating the entity.".

(b) CONFORMING AMENDMENTS.—

<< 42 USCA § 1395cc >>

(1) REQUIREMENT FOR MEDICARE PROVIDERS.—Section 1866(a)(1) (42 U.S.C. 1395cc(a)(1)) is amended—
(A) by striking "and" at the end of subparagraph (P);
(B) by striking the period at the end of subparagraph (Q) and inserting "; and"; and
(C) by inserting immediately after subparagraph (Q) the following new subparagraph:
"(R) to contract only with a health care clearinghouse (as defined in section 1171) that meets each standard and implementation specification adopted or established under part C of title XI on or after the date on which the health care clearinghouse is required to comply with the standard or specification.".

<< 42 USCA Ch. 7 >>

(2) TITLE HEADING.—Title XI (42 U.S.C. 1301 et seq.) is amended by striking the title heading and inserting the following:

"TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION".

<< 42 USCA § 242k >>

SEC. 263. CHANGES IN MEMBERSHIP AND DUTIES OF NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS.

Section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)) is amended—
(1) in paragraph (1), by striking "16" and inserting "18";
(2) by amending paragraph (2) to read as follows:
"(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.";
(3) by redesignating paragraphs (3) through (5) as paragraphs (4) through (6), respectively, and inserting after paragraph (2) the following:
"(3) Of the members of the Committee—
"(A) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;
"(B) 1 shall be appointed, not later than 60 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and
"(C) 16 shall be appointed by the Secretary.";
(4) by amending paragraph (5) (as so redesignated) to read as follows:

"(5) The Committee—

"(A) shall assist and advise the Secretary—

"(i) to delineate statistical problems bearing on health and health services which are of national or international interest;

"(ii) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

"(iii) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (I) within the Department of Health and Human Services, (II) by all programs administered or funded by the Secretary, including the Federal–State–local cooperative health statistics system referred to in subsection (e), and (III) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;

"(iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

"(v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

"(vi) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;

"(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

"(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act;

"(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

"(C) shall report to the Secretary not later than 4 years after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange; and

"(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act."; and

(5) by adding at the end the following:

"(7) Not later than 1 year after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

"(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

"(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

"(C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.

"(D) Any problems that exist with respect to implementation of such part.

"(E) The extent to which timetables under such part are being met.".

<< 42 USCA § 1320d–2 >>

SEC. 264. RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION.

(a) IN GENERAL.—Not later than the date that is 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Labor and Human Resources and the Committee on Finance of the Senate and the Committee on Commerce and the Committee on Ways and Means of the House of Representatives detailed recommendations on standards with respect to the privacy of individually identifiable health information.

(b) SUBJECTS FOR RECOMMENDATIONS.—The recommendations under subsection (a) shall address at least the following:

(1) The rights that an individual who is a subject of individually identifiable health information should have.

(2) The procedures that should be established for the exercise of such rights.

(3) The uses and disclosures of such information that should be authorized or required.

(c) REGULATIONS.—

(1) IN GENERAL.—If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by the date that is 36 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than the date that is 42 months after the date of the enactment of this Act. Such regulations shall address at least the subjects described in subsection (b).

(2) PREEMPTION.—A regulation promulgated under paragraph (1) shall not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation.

(d) CONSULTATION.—In carrying out this section, the Secretary of Health and Human Services shall consult with—

(1) the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)); and

(2) the Attorney General.

Subtitle G—Duplication and Coordination of Medicare–Related Plans

SEC. 271. DUPLICATION AND COORDINATION OF MEDICARE–RELATED PLANS.

<< 42 USCA § 1395ss >>

(a) TREATMENT OF CERTAIN HEALTH INSURANCE POLICIES AS NONDUPLICATIVE.—Section 1882(d)(3)(A) (42 U.S.C. 1395ss(d)(3)(A)) is amended—

(1) in clause (iii), by striking "clause (i)" and inserting "clause (i)(II)"; and

(2) by adding at the end the following:

"(iv) For purposes of this subparagraph, a health insurance policy (other than a Medicare supplemental policy) providing for benefits which are payable to or on behalf of an individual without regard to other health benefit coverage of such individual is not considered to 'duplicate' any health benefits under this title, under title XIX, or under a health insurance policy, and subclauses (I) and (III) of clause (i) do not apply to such a policy.

"(v) For purposes of this subparagraph, a health insurance policy (or a rider to an insurance contract which is not a health insurance policy) is not considered to 'duplicate' health benefits under this title or under another health insurance policy if it—

"(I) provides health care benefits only for long-term care, nursing home care, home health care, or community-based care, or any combination thereof,

"(II) coordinates against or excludes items and services available or paid for under this title or under another health insurance policy, and

"(III) for policies sold or issued on or after the end of the 90–day period beginning on the date of enactment of the Health Insurance Portability and Accountability Act of 1996 discloses such coordination or exclusion in the policy's outline of coverage.

For purposes of this clause, the terms 'coordinates' and 'coordination' mean, with respect to a policy in relation to health benefits under this title or under another health insurance policy, that the policy under its terms is secondary to, or excludes from payment, items and services to the extent available or paid for under this title or under another health insurance policy.

"(vi)(I) An individual entitled to benefits under part A or enrolled under part B of this title who is applying for a health insurance policy (other than a policy described in subclause (III)) shall be furnished a disclosure statement described in clause (vii) for the type of policy being applied for. Such statement shall be furnished as a part of (or together with) the application for such policy.

"(II) Whoever issues or sells a health insurance policy (other than a policy described in subclause (III)) to an individual described in subclause (I) and fails to furnish the appropriate disclosure statement as required under such subclause shall be

fined under title 18, United States Code, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $25,000 (or $15,000 in the case of a person other than the issuer of the policy) for each such violation.

"(III) A policy described in this subclause (to which subclauses (I) and (II) do not apply) is a Medicare supplemental policy or a health insurance policy identified under 60 Federal Register 30880 (June 12, 1995) as a policy not required to have a disclosure statement.

"(IV) Any reference in this section to the revised NAIC model regulation (referred to in subsection (m)(1)(A)) is deemed a reference to such regulation as revised by section 171(m)(2) of the Social Security Act Amendments of 1994 (Public Law 103–432) and as modified by substituting, for the disclosure required under section 16D(2), disclosure under subclause (I) of an appropriate disclosure statement under clause (vii).

"(vii) The disclosure statement described in this clause for a type of policy is the statement specified under subparagraph (D) of this paragraph (as in effect before the date of the enactment of the Health Insurance Portability and Accountability Act of 1996) for that type of policy, as revised as follows:

"(I) In each statement, amend the second line to read as follows:

'THIS IS NOT MEDICARE SUPPLEMENT INSURANCE'.

"(II) In each statement, strike the third line and insert the following: 'Some health care services paid for by Medicare may also trigger the payment of benefits under this policy.'.

"(III) In each statement not described in subclause (V), strike the boldface matter that begins 'This insurance' and all that follows up to the next paragraph that begins 'Medicare'.

"(IV) In each statement not described in subclause (V), insert before the boxed matter (that states 'Before You Buy This Insurance') the following: 'This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance.'.

"(V) In a statement relating to policies providing both nursing home and non-institutional coverage, to policies providing nursing home benefits only, or policies providing home care benefits only, amend the sentence that begins 'Federal law' to read as follows: 'Federal law requires us to inform you that in certain situations this insurance may pay for some care also covered by Medicare.'.

"(viii)(I) Subject to subclause (II), nothing in this subparagraph shall restrict or preclude a State's ability to regulate health insurance policies, including any health insurance policy that is described in clause (iv), (v), or (vi)(III).

"(II) A State may not declare or specify, in statute, regulation, or otherwise, that a health insurance policy (other than a Medicare supplemental policy) or rider to an insurance contract which is not a health insurance policy, that is described in clause (iv), (v), or (vi)(III) and that is sold, issued, or renewed to an individual entitled to benefits under part A or enrolled under part B 'duplicates' health benefits under this title or under a Medicare supplemental policy.".

(b) CONFORMING AMENDMENTS.—Section 1882(d)(3) (42 U.S.C. 1395ss(d)(3)) is amended—

(1) in subparagraph (C)—

(A) by striking "with respect to (i)" and inserting "with respect to", and

(B) by striking ", (ii) the sale" and all that follows up to the period at the end; and

(2) by striking subparagraph (D).

<< 42 USCA § 1395ss NOTE >>

(c) TRANSITIONAL PROVISION.—

(1) NO PENALTIES.—Subject to paragraph (3), no criminal or civil money penalty may be imposed under section 1882(d)(3)(A) of the Social Security Act for any act or omission that occurred during the transition period (as defined in paragraph (4)) and that relates to any health insurance policy that is described in clause (iv) or (v) of such section (as amended by subsection (a)).

(2) LIMITATION ON LEGAL ACTION.—Subject to paragraph (3), no legal action shall be brought or continued in any Federal or State court insofar as such action—

(A) includes a cause of action which arose, or which is based on or evidenced by any act or omission which occurred, during the transition period; and

(B) relates to the application of section 1882(d)(3)(A) of the Social Security Act to any act or omission with respect to the sale, issuance, or renewal of any health insurance policy that is described in clause (iv) or (v) of such section (as amended by subsection (a)).

(3) DISCLOSURE CONDITION.—In the case of a policy described in clause (iv) of section 1882(d)(3)(A) of the Social Security Act that is sold or issued on or after the effective date of statements under section 171(d)(3)(C) of the Social Security Act Amendments of 1994 and before the end of the 30–day period beginning on the date of the enactment of this Act, paragraphs (1) and (2) shall only apply if disclosure was made in accordance with section 1882(d)(3)(C)(ii) of the Social Security Act (as in effect before the date of the enactment of this Act).

(4) TRANSITION PERIOD.—In this subsection, the term "transition period" means the period beginning on November 5, 1991, and ending on the date of the enactment of this Act.

<< 42 USCA § 1395ss NOTE >>

(d) EFFECTIVE DATE.—(1) Except as provided in this subsection, the amendment made by subsection (a) shall be effective as if included in the enactment of section 4354 of the Omnibus Budget Reconciliation Act of 1990.

(2)(A) Clause (vi) of section 1882(d)(3)(A) of the Social Security Act, as added by subsection (a), shall only apply to individuals applying for—

(i) a health insurance policy described in section 1882(d)(3)(A)(iv) of such Act (as added by subsection (a)), after the date of the enactment of this Act, or

(ii) another health insurance policy after the end of the 30–day period beginning on the date of the enactment of this Act.

(B) A seller or issuer of a health insurance policy may substitute, for the disclosure statement described in clause (vii) of such section, the statement specified under section 1882(d)(3)(D) of the Social Security Act (as in effect before the date of the enactment of this Act), without the revision specified in such clause.

TITLE III—TAX–RELATED HEALTH PROVISIONS

SEC. 300. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

Subtitle A—Medical Savings Accounts

SEC. 301. MEDICAL SAVINGS ACCOUNTS.

<< 26 USCA § 220 >>

<< 26 USCA § 221 >>

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 (relating to additional itemized deductions for individuals) is amended by redesignating section 220 as section 221 and by inserting after section 219 the following new section:

<< 26 USCA § 220 >>

"SEC. 220. MEDICAL SAVINGS ACCOUNTS.

"(a) DEDUCTION ALLOWED.—In the case of an individual who is an eligible individual for any month during the taxable year, there shall be allowed as a deduction for the taxable year an amount equal to the aggregate amount paid in cash during such taxable year by such individual to a medical savings account of such individual.

"(b) LIMITATIONS.—

"(1) IN GENERAL.—The amount allowable as a deduction under subsection (a) to an individual for the taxable year shall not exceed the sum of the monthly limitations for months during such taxable year that the individual is an eligible individual.

"(2) MONTHLY LIMITATION.—The monthly limitation for any month is the amount equal to $^{1}/_{12}$ of—

"(A) in the case of an individual who has self-only coverage under thehigh deductible health plan as of the first day of such month, 65 percent of the annual deductible under such coverage, and

"(B) in the case of an individual who has family coverage under the high deductible health plan as of the first day of such month, 75 percent of the annual deductible under such coverage.

"(3) SPECIAL RULE FOR MARRIED INDIVIDUALS.—In the case of individuals who are married to each other, if either spouse has family coverage—

"(A) both spouses shall be treated as having only such family coverage (and if such spouses each have family coverage under different plans, as having the family coverage with the lowest annual deductible), and

"(B) the limitation under paragraph (1) (after the application of subparagraph (A) of this paragraph) shall be divided equally between them unless they agree on a different division.

"(4) DEDUCTION NOT TO EXCEED COMPENSATION.—

"(A) EMPLOYEES.—The deduction allowed under subsection (a) for contributions as an eligible individual described in subclause (I) of subsection (c)(1)(A)(iii) shall not exceed such individual's wages, salaries, tips, and other employee compensation which are attributable to such individual's employment by the employer referred to in such subclause.

"(B) SELF–EMPLOYED INDIVIDUALS.—The deduction allowed under subsection (a) for contributions as an eligible individual described in subclause (II) of subsection (c)(1)(A)(iii) shall not exceed such individual's earned income (as defined in section 401(c)(1)) derived by the taxpayer from the trade or business with respect to which the high deductible health plan is established.

"(C) COMMUNITY PROPERTY LAWS NOT TO APPLY.—The limitations under this paragraph shall be determined without regard to community property laws.

"(5) COORDINATION WITH EXCLUSION FOR EMPLOYER CONTRIBUTIONS.—No deduction shall be allowed under this section for any amount paid for any taxable year to a medical savings account of an individual if—

"(A) any amount is contributed to any medical savings account of such individual for such year which is excludable from gross income under section 106(b), or

"(B) if such individual's spouse is covered under the high deductible health plan covering such individual, any amount is contributed for such year to any medical savings account of such spouse which is so excludable.

"(6) DENIAL OF DEDUCTION TO DEPENDENTS.—No deduction shall be allowed under this section to any individual with respect to whom a deduction under section 151 is allowable to another taxpayer for a taxable year beginning in the calendar year in which such individual's taxable year begins.

"(c) DEFINITIONS.—For purposes of this section—

"(1) ELIGIBLE INDIVIDUAL.—

"(A) IN GENERAL.—The term 'eligible individual' means, with respect to any month, any individual if—

"(i) such individual is covered under a high deductible health plan as of the 1st day of such month,

"(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

"(I) which is not a high deductible health plan, and

"(II) which provides coverage for any benefit which is covered under the high deductible health plan, and

"(iii)(I) the high deductible health plan covering such individual is established and maintained by the employer of such individual or of the spouse of such individual and such employer is a small employer, or

"(II) such individual is an employee (within the meaning of section 401(c)(1)) or the spouse of such an employee and the high deductible health plan covering such individual is not established or maintained by any employer of such individual or spouse.

"(B) CERTAIN COVERAGE DISREGARDED.—Subparagraph (A)(ii) shall be applied without regard to—

"(i) coverage for any benefit provided by permitted insurance, and

"(ii) coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

"(C) CONTINUED ELIGIBILITY OF EMPLOYEE AND SPOUSE ESTABLISHING MEDICAL SAVINGS ACCOUNTS.—If, while an employer is a small employer—

"(i) any amount is contributed to a medical savings account of an individual who is an employee of such employer or the spouse of such an employee, and

"(ii) such amount is excludable from gross income under section 106(b) or allowable as a deduction under this section,

such individual shall not cease to meet the requirement of subparagraph (A)(iii)(I) by reason of such employer ceasing to be a small employer so long as such employee continues to be an employee of such employer.

"(D) LIMITATIONS ON ELIGIBILITY.—

"For limitations on number of taxpayers who are eligible to have medical savings accounts, see subsection (i).

"(2) HIGH DEDUCTIBLE HEALTH PLAN.—

"(A) IN GENERAL.—The term 'high deductible health plan' means a health plan—

"(i) in the case of self-only coverage, which has an annual deductible which is not less than $1,500 and not more than $2,250,

"(ii) in the case of family coverage, which has an annual deductible which is not less than $3,000 and not more than $4,500, and

"(iii) the annual out-of-pocket expenses required to be paid under the plan (other than for premiums) for covered benefits does not exceed—

"(I) $3,000 for self-only coverage, and

"(II) $5,500 for family coverage.

"(B) SPECIAL RULES.—

"(i) EXCLUSION OF CERTAIN PLANS.—Such term does not include a health plan if substantially all of its coverage is coverage described in paragraph (1)(B).

"(ii) SAFE HARBOR FOR ABSENCE OF PREVENTIVE CARE DEDUCTIBLE.—A plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care if the absence of a deductible for such care is required by State law.

"(3) PERMITTED INSURANCE.—The term 'permitted insurance' means—

"(A) Medicare supplemental insurance,

"(B) insurance if substantially all of the coverage provided under such insurance relates to—

"(i) liabilities incurred under workers' compensation laws,

"(ii) tort liabilities,

"(iii) liabilities relating to ownership or use of property, or

"(iv) such other similar liabilities as the Secretary may specify by regulations,

"(C) insurance for a specified disease or illness, and

"(D) insurance paying a fixed amount per day (or other period) of hospitalization.

"(4) SMALL EMPLOYER.—

"(A) IN GENERAL.—The term 'small employer' means, with respect to any calendar year, any employer if such employer employed an average of 50 or fewer employees on business days during either of the 2 preceding calendar years. For purposes of the preceding sentence, a preceding calendar year may be taken into account only if the employer was in existence throughout such year.

"(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the 1st preceding calendar year, the determination under subparagraph (A) shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

"(C) CERTAIN GROWING EMPLOYERS RETAIN TREATMENT AS SMALL EMPLOYER.—The term 'small employer' includes, with respect to any calendar year, any employer if—

"(i) such employer met the requirement of subparagraph (A) (determined without regard to subparagraph (B)) for any preceding calendar year after 1996,

"(ii) any amount was contributed to the medical savings account of any employee of such employer with respect to coverage of such employee under a high deductible health plan of such employer during such preceding calendar year and such amount was excludable from gross income under section 106(b) or allowable as a deduction under this section, and

"(iii) such employer employed an average of 200 or fewer employees on business days during each preceding calendar year after 1996.

"(D) SPECIAL RULES.—

"(i) CONTROLLED GROUPS.—For purposes of this paragraph, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as 1 employer.

"(ii) PREDECESSORS.—Any reference in this paragraph to an employer shall include a reference to any predecessor of such employer.

"(5) FAMILY COVERAGE.—The term 'family coverage' means any coverage other than self-only coverage.

"(d) MEDICAL SAVINGS ACCOUNT.—For purposes of this section—

"(1) MEDICAL SAVINGS ACCOUNT.—The term 'medical savings account' means a trust created or organized in the United States exclusively for the purpose of paying the qualified medical expenses of the account holder, but only if the written governing instrument creating the trust meets the following requirements:

"(A) Except in the case of a rollover contribution described in subsection (f)(5), no contribution will be accepted—

"(i) unless it is in cash, or

"(ii) to the extent such contribution, when added to previous contributions to the trust for the calendar year, exceeds 75 percent of the highest annual limit deductible permitted under subsection (c)(2)(A)(ii) for such calendar year.

"(B) The trustee is a bank (as defined in section 408(n)), an insurance company (as defined in section 816), or another person who demonstrates to the satisfaction of the Secretary that the manner in which such person will administer the trust will be consistent with the requirements of this section.

"(C) No part of the trust assets will be invested in life insurance contracts.

"(D) The assets of the trust will not be commingled with other property except in a common trust fund or common investment fund.

"(E) The interest of an individual in the balance in his account is nonforfeitable.

"(2) QUALIFIED MEDICAL EXPENSES.—

"(A) IN GENERAL.—The term 'qualified medical expenses' means, with respect to an account holder, amounts paid by such holder for medical care (as defined in section 213(d)) for such individual, the spouse of such individual, and any dependent (as defined in section 152) of such individual, but only to the extent such amounts are not compensated for by insurance or otherwise.

"(B) HEALTH INSURANCE MAY NOT BE PURCHASED FROM ACCOUNT.—

"(i) IN GENERAL.—Subparagraph (A) shall not apply to any payment for insurance.

"(ii) EXCEPTIONS.—Clause (i) shall not apply to any expense for coverage under—

"(I) a health plan during any period of continuation coverage required under any Federal law,

"(II) a qualified long-term care insurance contract (as defined in section 7702B(b)), or

"(III) a health plan during a period in which the individual is receiving unemployment compensation under any Federal or State law.

"(C) MEDICAL EXPENSES OF INDIVIDUALS WHO ARE NOT ELIGIBLE INDIVIDUALS.—Subparagraph (A) shall apply to an amount paid by an account holder for medical care of an individual who is not an eligible individual for the month in which the expense for such care is incurred only if no amount is contributed (other than a rollover contribution) to any medical savings account of such account holder for the taxable year which includes such month. This subparagraph shall not apply to any expense for coverage described in subclause (I) or (III) of subparagraph (B)(ii).

"(3) ACCOUNT HOLDER.—The term 'account holder' means the individual on whose behalf the medical savings account was established.

"(4) CERTAIN RULES TO APPLY.—Rules similar to the following rules shall apply for purposes of this section:

"(A) Section 219(d)(2) (relating to no deduction for rollovers).

"(B) Section 219(f)(3) (relating to time when contributions deemed made).

"(C) Except as provided in section 106(b), section 219(f)(5) (relating to employer payments).

"(D) Section 408(g) (relating to community property laws).

"(E) Section 408(h) (relating to custodial accounts).

"(e) TAX TREATMENT OF ACCOUNTS.—

"(1) IN GENERAL.—A medical savings account is exempt from taxation under this subtitle unless such account has ceased to be a medical savings account. Notwithstanding the preceding sentence, any such account is subject to the taxes imposed by section 511 (relating to imposition of tax on unrelated business income of charitable, etc. organizations).

"(2) ACCOUNT TERMINATIONS.—Rules similar to the rules of paragraphs (2) and (4) of section 408(e) shall apply to medical savings accounts, and any amount treated as distributed under such rules shall be treated as not used to pay qualified medical expenses.

"(f) TAX TREATMENT OF DISTRIBUTIONS.—

"(1) AMOUNTS USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a medical savings account which is used exclusively to pay qualified medical expenses of any account holder shall not be includible in gross income.

"(2) INCLUSION OF AMOUNTS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Any amount paid or distributed out of a medical savings account which is not used exclusively to pay the qualified medical expenses of the account holder shall be included in the gross income of such holder.

"(3) EXCESS CONTRIBUTIONS RETURNED BEFORE DUE DATE OF RETURN.—

"(A) IN GENERAL.—If any excess contribution is contributed for a taxable year to any medical savings account of an individual, paragraph (2) shall not apply to distributions from the medical savings accounts of such individual (to the extent such distributions do not exceed the aggregate excess contributions to all such accounts of such individual for such year) if—

"(i) such distribution is received by the individual on or before the last day prescribed by law (including extensions of time) for filing such individual's return for such taxable year, and

"(ii) such distribution is accompanied by the amount of net income attributable to such excess contribution.

Any net income described in clause (ii) shall be included in the gross income of the individual for the taxable year in which it is received.

"(B) EXCESS CONTRIBUTION.—For purposes of subparagraph (A), the term 'excess contribution' means any contribution (other than a rollover contribution) which is neither excludable from gross income under section 106(b) nor deductible under this section.

"(4) ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—

"(A) IN GENERAL.—The tax imposed by this chapter on the account holder for any taxable year in which there is a payment or distribution from a medical savings account of such holder which is includible in gross income under paragraph (2) shall be increased by 15 percent of the amount which is so includible.

"(B) EXCEPTION FOR DISABILITY OR DEATH.—Subparagraph (A) shall not apply if the payment or distribution is made after the account holder becomes disabled within the meaning of section 72(m)(7) or dies.

"(C) EXCEPTION FOR DISTRIBUTIONS AFTER MEDICARE ELIGIBILITY.—Subparagraph (A) shall not apply to any payment or distribution after the date on which the account holder attains the age specified in section 1811 of the Social Security Act.

"(5) ROLLOVER CONTRIBUTION.—An amount is described in this paragraph as a rollover contribution if it meets the requirements of subparagraphs (A) and (B).

"(A) IN GENERAL.—Paragraph (2) shall not apply to any amount paid or distributed from a medical savings account to the account holder to the extent the amount received is paid into a medical savings account for the benefit of such holder not later than the 60th day after the day on which the holder receives the payment or distribution.

"(B) LIMITATION.—This paragraph shall not apply to any amount described in subparagraph (A) received by an individual from a medical savings account if, at any time during the 1–year period ending on the day of such receipt, such individual received any other amount described in subparagraph (A) from a medical savings account which was not includible in the individual's gross income because of the application of this paragraph.

"(6) COORDINATION WITH MEDICAL EXPENSE DEDUCTION.—For purposes of determining the amount of the deduction under section 213, any payment or distribution out of a medical savings account for qualified medical expenses shall not be treated as an expense paid for medical care.

"(7) TRANSFER OF ACCOUNT INCIDENT TO DIVORCE.—The transfer of an individual's interest in a medical savings account to an individual's spouse or former spouse under a divorce or separation instrument described in subparagraph (A) of section 71(b)(2) shall not be considered a taxable transfer made by such individual notwithstanding any other provision of this subtitle, and such interest shall, after such transfer, be treated as a medical savings account with respect to which such spouse is the account holder.

"(8) TREATMENT AFTER DEATH OF ACCOUNT HOLDER.—

"(A) TREATMENT IF DESIGNATED BENEFICIARY IS SPOUSE.—If the account holder's surviving spouse acquires such holder's interest in a medical savings account by reason of being the designated beneficiary of such account at the death of the account holder, such medical savings account shall be treated as if the spouse were the account holder.

"(B) OTHER CASES.—

"(i) IN GENERAL.—If, by reason of the death of the account holder, any person acquires the account holder's interest in a medical savings account in a case to which subparagraph (A) does not apply—

"(I) such account shall cease to be a medical savings account as of the date of death, and

"(II) an amount equal to the fair market value of the assets in such account on such date shall be includible if such person is not the estate of such holder, in such person's gross income for the taxable year which includes such date, or if such person is the estate of such holder, in such holder's gross income for the last taxable year of such holder.

"(ii) SPECIAL RULES.—

"(I) REDUCTION OF INCLUSION FOR PRE–DEATH EXPENSES.—The amount includible in gross income under clause (i) by any person (other than the estate) shall be reduced by the amount of qualified medical expenses which were incurred by the decedent before the date of the decedent's death and paid by such person within 1 year after such date.

"(II) DEDUCTION FOR ESTATE TAXES.—An appropriate deduction shall be allowed under section 691(c) to any person (other than the decedent or the decedent's spouse) with respect to amounts included in gross income under clause (i) by such person.

"(g) COST–OF–LIVING ADJUSTMENT.—In the case of any taxable year beginning in a calendar year after 1998, each dollar amount in subsection (c)(2) shall be increased by an amount equal to—

"(1) such dollar amount, multiplied by

"(2) the cost-of-living adjustment determined under section 1(f)(3) for the calendar year in which such taxable year begins by substituting 'calendar year 1997' for 'calendar year 1992' in subparagraph (B) thereof.

If any increase under the preceding sentence is not a multiple of $50, such increase shall be rounded to the nearest multiple of $50.

"(h) REPORTS.—The Secretary may require the trustee of a medical savings account to make such reports regarding such account to the Secretary and to the account holder with respect to contributions, distributions, and such other matters as the Secretary determines appropriate. The reports required by this subsection shall be filed at such time and in such manner and furnished to such individuals at such time and in such manner as may be required by the Secretary.

"(i) LIMITATION ON NUMBER OF TAXPAYERS HAVING MEDICAL SAVINGS ACCOUNTS.—

"(1) IN GENERAL.—Except as provided in paragraph (5), no individual shall be treated as an eligible individual for any taxable year beginning after the cut-off year unless—

"(A) such individual was an active MSA participant for any taxable year ending on or before the close of the cut-off year, or

"(B) such individual first became an active MSA participant for a taxable year ending after the cut-off year by reason of coverage under a high deductible health plan of an MSA-participating employer.

"(2) CUT–OFF YEAR.—For purposes of paragraph (1), the term 'cut-off year' means the earlier of—

"(A) calendar year 2000, or

"(B) the first calendar year before 2000 for which the Secretary determines under subsection (j) that the numerical limitation for such year has been exceeded.

"(3) ACTIVE MSA PARTICIPANT.—For purposes of this subsection—

"(A) IN GENERAL.—The term 'active MSA participant' means, with respect to any taxable year, any individual who is the account holder of any medical savings account into which any contribution was made which was excludable from gross income under section 106(b), or allowable as a deduction under this section, for such taxable year.

"(B) SPECIAL RULE FOR CUT–OFF YEARS BEFORE 2000.—In the case of a cut-off year before 2000—

"(i) an individual shall not be treated as an eligible individual for any month of such year or an active MSA participant under paragraph (1)(A) unless such individual is, on or before the cut-off date, covered under a high deductible health plan, and

"(ii) an employer shall not be treated as an MSA-participating employer unless the employer, on or before the cut-off date, offered coverage under a high deductible health plan to any employee.

"(C) CUT–OFF DATE.—For purposes of subparagraph (B)—

"(i) IN GENERAL.—Except as otherwise provided in this subparagraph, the cut-off date is October 1 of the cut-off year.

"(ii) EMPLOYEES WITH ENROLLMENT PERIODS AFTER OCTOBER 1.—In the case of an individual described in subclause (I) of subsection (c)(1)(A)(iii), if the regularly scheduled enrollment period for health plans of the individual's employer occurs during the last 3 months of the cut-off year, the cut-off date is December 31 of the cut-off year.

"(iii) SELF–EMPLOYED INDIVIDUALS.—In the case of an individual described in subclause (II) of subsection (c)(1)(A)(iii), the cut-off date is November 1 of the cut-off year.

"(iv) SPECIAL RULES FOR 1997.—If 1997 is a cut-off year by reason of subsection (j)(1)(A)—

"(I) each of the cut-off dates under clauses (i) and (iii) shall be 1 month earlier than the date determined without regard to this clause, and

"(II) clause (ii) shall be applied by substituting '4 months' for '3 months'.

"(4) MSA–PARTICIPATING EMPLOYER.—For purposes of this subsection, the term 'MSA-participating employer' means any small employer if—

"(A) such employer made any contribution to the medical savings account of any employee during the cut-off year or any preceding calendar year which was excludable from gross income under section 106(b), or

"(B) at least 20 percent of the employees of such employer who are eligible individuals for any month of the cut-off year by reason of coverage under a high deductible health plan of such employer each made a contribution of at least $100 to their medical savings accounts for any taxable year ending with or within the cut-off year which was allowable as a deduction under this section.

"(5) ADDITIONAL ELIGIBILITY AFTER CUT–OFF YEAR.—If the Secretary determines under subsection (j)(2)(A) that the numerical limit for the calendar year following a cut-off year described in paragraph (2)(B) has not been exceeded—

"(A) this subsection shall not apply to any otherwise eligible individual who is covered under a high deductible health plan during the first 6 months of the second calendar year following the cut-off year (and such individual shall be treated as an active MSA participant for purposes of this subsection if a contribution is made to any medical savings account with respect to such coverage), and

"(B) any employer who offers coverage under a high deductible health plan to any employee during such 6–month period shall be treated as an MSA-participating employer for purposes of this subsection if the requirements of paragraph (4) are met with respect to such coverage.

For purposes of this paragraph, subsection (j)(2)(A) shall be applied for 1998 by substituting '750,000' for '600,000'.

"(j) DETERMINATION OF WHETHER NUMERICAL LIMITS ARE EXCEEDED.—

"(1) DETERMINATION OF WHETHER LIMIT EXCEEDED FOR 1997.—The numerical limitation for 1997 is exceeded if, based on the reports required under paragraph (4), the number of medical savings accounts established as of—

"(A) April 30, 1997, exceeds 375,000, or

"(B) June 30, 1997, exceeds 525,000.

"(2) DETERMINATION OF WHETHER LIMIT EXCEEDED FOR 1998 OR 1999.—

"(A) IN GENERAL.—The numerical limitation for 1998 or 1999 is exceeded if the sum of—

"(i) the number of MSA returns filed on or before April 15 of such calendar year for taxable years ending with or within the preceding calendar year, plus

"(ii) the Secretary's estimate (determined on the basis of the returns described in clause (i)) of the number of MSA returns for such taxable years which will be filed after such date,

exceeds 600,000 (750,000 in the case of 1999). For purposes of the preceding sentence, the term 'MSA return' means any return on which any exclusion is claimed under section 106(b) or any deduction is claimed under this section.

"(B) ALTERNATIVE COMPUTATION OF LIMITATION.—The numerical limitation for 1998 or 1999 is also exceeded if the sum of—

"(i) 90 percent of the sum determined under subparagraph (A) for such calendar year, plus

"(ii) the product of 2.5 and the number of medical savings accounts established during the portion of such year preceding July 1 (based on the reports required under paragraph (4)) for taxable years beginning in such year,

exceeds 750,000.

"(3) PREVIOUSLY UNINSURED INDIVIDUALS NOT INCLUDED IN DETERMINATION.—

"(A) IN GENERAL.—The determination of whether any calendar year is a cut-off year shall be made by not counting the medical savings account of any previously uninsured individual.

"(B) PREVIOUSLY UNINSURED INDIVIDUAL.—For purposes of this subsection, the term 'previously uninsured individual' means, with respect to any medical savings account, any individual who had no health plan coverage (other than coverage referred to in subsection (c)(1)(B)) at any time during the 6–month period before the date such individual's coverage under the high deductible health plan commences.

"(4) REPORTING BY MSA TRUSTEES.—

"(A) IN GENERAL.—Not later than August 1 of 1997, 1998, and 1999, each person who is the trustee of a medical savings account established before July 1 of such calendar year shall make a report to the Secretary (in such form and manner as the Secretary shall specify) which specifies—

"(i) the number of medical savings accounts established before such July 1 (for taxable years beginning in such calendar year) of which such person is the trustee,

"(ii) the name and TIN of the account holder of each such account, and

"(iii) the number of such accounts which are accounts of previously uninsured individuals.

"(B) ADDITIONAL REPORT FOR 1997.—Not later than June 1, 1997, each person who is the trustee of a medical savings account established before May 1, 1997, shall make an additional report described in subparagraph (A) but only with respect to accounts established before May 1, 1997.

"(C) PENALTY FOR FAILURE TO FILE REPORT.—The penalty provided in section 6693(a) shall apply to any report required by this paragraph, except that—

"(i) such section shall be applied by substituting '$25' for '$50', and

"(ii) the maximum penalty imposed on any trustee shall not exceed $5,000.

"(D) AGGREGATION OF ACCOUNTS.—To the extent practicable, in determining the number of medical savings accounts on the basis of the reports under this paragraph, all medical savings accounts of an individual shall be treated as 1 account and all accounts of individuals who are married to each other shall be treated as 1 account.

"(5) DATE OF MAKING DETERMINATIONS.—Any determination under this subsection that a calendar year is a cut-off year shall be made by the Secretary and shall be published not later than October 1 of such year.".

<< 26 USCA § 62 >>

(b) DEDUCTION ALLOWED WHETHER OR NOT INDIVIDUAL ITEMIZES OTHER DEDUCTIONS.—Subsection (a) of section 62 is amended by inserting after paragraph (15) the following new paragraph:

"(16) MEDICAL SAVINGS ACCOUNTS.—The deduction allowed by section 220.".

(c) EXCLUSIONS FOR EMPLOYER CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

<< 26 USCA § 106 >>

(1) EXCLUSION FROM INCOME TAX.—The text of section 106 (relating to contributions by employer to accident and health plans) is amended to read as follows:

"(a) GENERAL RULE.—Except as otherwise provided in this section, gross income of an employee does not include employer-provided coverage under an accident or health plan.

"(b) CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—

"(1) IN GENERAL.—In the case of an employee who is an eligible individual, amounts contributed by such employee's employer to any medical savings account of such employee shall be treated as employer-provided coverage for medical expenses under an accident or health plan to the extent such amounts do not exceed the limitation under section 220(b)(1) (determined without regard to this subsection) which is applicable to such employee for such taxable year.

"(2) NO CONSTRUCTIVE RECEIPT.—No amount shall be included in the gross income of any employee solely because the employee may choose between the contributions referred to in paragraph (1) and employer contributions to another health plan of the employer.

"(3) SPECIAL RULE FOR DEDUCTION OF EMPLOYER CONTRIBUTIONS.—Any employer contribution to a medical savings account, if otherwise allowable as a deduction under this chapter, shall be allowed only for the taxable year in which paid.

"(4) EMPLOYER MSA CONTRIBUTIONS REQUIRED TO BE SHOWN ON RETURN.—Every individual required to file a return under section 6012 for the taxable year shall include on such return the aggregate amount contributed by employers to the medical savings accounts of such individual or such individual's spouse for such taxable year.

"(5) MSA CONTRIBUTIONS NOT PART OF COBRA COVERAGE.—Paragraph (1) shall not apply for purposes of section 4980B.

"(6) DEFINITIONS.—For purposes of this subsection, the terms 'eligible individual' and 'medical savings account' have the respective meanings given to such terms by section 220.

"(7) CROSS REFERENCE.—

"For penalty on failure by employer to make comparable contributions to the medical savings accounts of comparable employees, see section 4980E.".

(2) EXCLUSION FROM EMPLOYMENT TAXES.—

<< 26 USCA § 3231 >>

(A) RAILROAD RETIREMENT TAX.—Subsection (e) of section 3231 is amended by adding at the end the following new paragraph:

"(10) MEDICAL SAVINGS ACCOUNT CONTRIBUTIONS.—The term 'compensation' shall not include any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(b).".

<< 26 USCA § 3306 >>

(B) UNEMPLOYMENT TAX.—Subsection (b) of section 3306 is amended by striking "or" at the end of paragraph (15), by striking the period at the end of paragraph (16) and inserting "; or", and by inserting after paragraph (16) the following new paragraph:

"(17) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(b).".

<< 26 USCA § 3401 >>

(C) WITHHOLDING TAX.—Subsection (a) of section 3401 is amended by striking "or" at the end of paragraph (19), by striking the period at the end of paragraph (20) and inserting "; or", and by inserting after paragraph (20) the following new paragraph:

"(21) any payment made to or for the benefit of an employee if at the time of such payment it is reasonable to believe that the employee will be able to exclude such payment from income under section 106(b)."

<< 26 USCA § 6051 >>

(3) EMPLOYER CONTRIBUTIONS REQUIRED TO BE SHOWN ON W–2.—Subsection (a) of section 6051 is amended by striking "and" at the end of paragraph (9), by striking the period at the end of paragraph (10) and inserting ", and", and by inserting after paragraph (10) the following new paragraph:

"(11) the amount contributed to any medical savings account (as defined in section 220(d)) of such employee or such employee's spouse.".

(4) PENALTY FOR FAILURE OF EMPLOYER TO MAKE COMPARABLE MSA CONTRIBUTIONS.—

<< 26 USCA § 4980E >>

(A) IN GENERAL.—Chapter 43 is amended by adding after section 4980D the following new section:

"SEC. 4980E. FAILURE OF EMPLOYER TO MAKE COMPARABLE MEDICAL SAVINGS ACCOUNT CONTRIBUTIONS.

"(a) GENERAL RULE.—In the case of an employer who makes a contribution to the medical savings account of any employee with respect to coverage under a high deductible health plan of the employer during a calendar year, there is hereby imposed a tax on the failure of such employer to meet the requirements of subsection (d) for such calendar year.

"(b) AMOUNT OF TAX.—The amount of the tax imposed by subsection (a) on any failure for any calendar year is the amount equal to 35 percent of the aggregate amount contributed by the employer to medical savings accounts of employees for taxable years of such employees ending with or within such calendar year.

"(c) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that the payment of such tax would be excessive relative to the failure involved.

"(d) EMPLOYER REQUIRED TO MAKE COMPARABLE MSA CONTRIBUTIONS FOR ALL PARTICIPATING EMPLOYEES.—

"(1) IN GENERAL.—An employer meets the requirements of this subsection for any calendar year if the employer makes available comparable contributions to the medical savings accounts of all comparable participating employees for each coverage period during such calendar year.

"(2) COMPARABLE CONTRIBUTIONS.—

"(A) IN GENERAL.—For purposes of paragraph (1), the term 'comparable contributions' means contributions—

"(i) which are the same amount, or

"(ii) which are the same percentage of the annual deductible limit under the high deductible health plan covering the employees.

"(B) PART–YEAR EMPLOYEES.—In the case of an employee who is employed by the employer for only a portion of the calendar year, a contribution to the medical savings account of such employee shall be treated as comparable if it is an amount which bears the same ratio to the comparable amount (determined without regard to this subparagraph) as such portion bears to the entire calendar year.

"(3) COMPARABLE PARTICIPATING EMPLOYEES.—For purposes of paragraph (1), the term 'comparable participating employees' means all employees—

"(A) who are eligible individuals covered under any high deductible health plan of the employer, and

"(B) who have the same category of coverage.

For purposes of subparagraph (B), the categories of coverage are self-only and family coverage.

"(4) PART–TIME EMPLOYEES.—

"(A) IN GENERAL.—Paragraph (3) shall be applied separately with respect to part-time employees and other employees.

"(B) PART–TIME EMPLOYEE.—For purposes of subparagraph (A), the term 'part-time employee' means any employee who is customarily employed for fewer than 30 hours per week.

"(e) CONTROLLED GROUPS.—For purposes of this section, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as 1 employer.

"(f) DEFINITIONS.—Terms used in this section which are also used in section 220 have the respective meanings given such terms in section 220.".

<< 26 USCA Ch. 43 >>

(B) CLERICAL AMENDMENT.—The table of sections for chapter 43 is amended by adding after the item relating to section 4980D the following new item:

"Sec. 4980E. Failure of employer to make comparable medical savings account contributions.".

<< 26 USCA § 125 >>

(d) MEDICAL SAVINGS ACCOUNT CONTRIBUTIONS NOT AVAILABLE UNDER CAFETERIA PLANS.—Subsection (f) of section 125 of such Code is amended by inserting "106(b)," before "117".

<< 26 USCA § 4973 >>

(e) TAX ON EXCESS CONTRIBUTIONS.—Section 4973 (relating to tax on excess contributions to individual retirement accounts, certain section 403(b) contracts, and certain individual retirement annuities) is amended—

(1) by inserting "MEDICAL SAVINGS ACCOUNTS," after "ACCOUNTS," in the heading of such section,

(2) by striking "or" at the end of paragraph (1) of subsection (a),

(3) by redesignating paragraph (2) of subsection (a) as paragraph (3) and by inserting after paragraph (1) the following:

"(2) a medical savings account (within the meaning of section 220(d)), or", and

(4) by adding at the end the following new subsection:

"(d) EXCESS CONTRIBUTIONS TO MEDICAL SAVINGS ACCOUNTS.—For purposes of this section, in the case of medical savings accounts (within the meaning of section 220(d)), the term 'excess contributions' means the sum of—

"(1) the aggregate amount contributed for the taxable year to the accounts (other than rollover contributions described in section 220(f)(5)) which is neither excludable from gross income under section 106(b) nor allowable as a deduction under section 220 for such year, and

"(2) the amount determined under this subsection for the preceding taxable year, reduced by the sum of—

"(A) the distributions out of the accounts which were included in gross income under section 220(f)(2), and

"(B) the excess (if any) of—

"(i) the maximum amount allowable as a deduction under section 220(b)(1) (determined without regard to section 106(b)) for the taxable year, over

"(ii) the amount contributed to the accounts for the taxable year.

For purposes of this subsection, any contribution which is distributed out of the medical savings account in a distribution to which section 220(f)(3) applies shall be treated as an amount not contributed.".

<< 26 USCA § 4975 >>

(f) TAX ON PROHIBITED TRANSACTIONS.—

(1) Section 4975 (relating to tax on prohibited transactions) is amended by adding at the end of subsection (c) the following new paragraph:

"(4) SPECIAL RULE FOR MEDICAL SAVINGS ACCOUNTS.—An individual for whose benefit a medical savings account (within the meaning of section 220(d)) is established shall be exempt from the tax imposed by this section with respect to any transaction concerning such account (which would otherwise be taxable under this section) if, with respect to such transaction, the account ceases to be a medical savings account by reason of the application of section 220(e)(2) to such account.".

(2) Paragraph (1) of section 4975(e) is amended to read as follows:

"(1) PLAN.—For purposes of this section, the term 'plan' means—

"(A) a trust described in section 401(a) which forms a part of a plan, or a plan described in section 403(a), which trust or plan is exempt from tax under section 501(a),

"(B) an individual retirement account described in section 408(a),

"(C) an individual retirement annuity described in section 408(b),

"(D) a medical savings account described in section 220(d), or

"(E) a trust, plan, account, or annuity which, at any time, has been determined by the Secretary to be described in any preceding subparagraph of this paragraph.".

<< 26 USCA § 6693 >>

(g) FAILURE TO PROVIDE REPORTS ON MEDICAL SAVINGS ACCOUNTS.—

(1) Subsection (a) of section 6693 (relating to failure to provide reports on individual retirement accounts or annuities) is amended to read as follows:

"(a) REPORTS.—

"(1) IN GENERAL.—If a person required to file a report under a provision referred to in paragraph (2) fails to file such report at the time and in the manner required by such provision, such person shall pay a penalty of $50 for each failure unless it is shown that such failure is due to reasonable cause.

"(2) PROVISIONS.—The provisions referred to in this paragraph are—

"(A) subsections (i) and (l) of section 408 (relating to individual retirement plans), and

"(B) section 220(h) (relating to medical savings accounts).".

<< 26 USCA § 848 >>

(h) EXCEPTION FROM CAPITALIZATION OF POLICY ACQUISITION EXPENSES.—Subparagraph (B) of section 848(e)(1) (defining specified insurance contract) is amended by striking "and" at the end of clause (ii), by striking the period at the end of clause (iii) and inserting ", and", and by adding at the end the following new clause:

"(iv) any contract which is a medical savings account (as defined in section 220(d)).".

<< 26 USCA Ch. 1 >>

(i) CLERICAL AMENDMENT.—The table of sections for part VII of subchapter B of chapter 1 is amended by striking the last item and inserting the following:

"Sec. 220. Medical savings accounts.

"Sec. 221. Cross reference.".

<< 26 USCA §§ 62 NOTE, 106 nt, 125 nt, 220 nt, 848 nt, 3231 nt, 3306 nt, 3401 nt, 4973 nt, 4975 nt, 6051 nt, 6693 nt >>

<< 26 USCA § 4980E nt >>

(j) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1996.

<< 26 USCA § 220 NOTE >>

(k) MONITORING OF PARTICIPATION IN MEDICAL SAVINGS ACCOUNTS.—The Secretary of the Treasury or his delegate shall—

(1) during 1997, 1998, 1999, and 2000, regularly evaluate the number of individuals who are maintaining medical savings accounts and the reduction in revenues to the United States by reason of such accounts, and

(2) provide such reports of such evaluations to Congress as such Secretary determines appropriate.

<< 26 USCA § 220 NOTE >>

(l) STUDY OF EFFECTS OF MEDICAL SAVINGS ACCOUNTS ON SMALL GROUP MARKET.—The Comptroller General of the United States shall enter into a contract with an organization with expertise in health economics, health insurance markets, and actuarial science to conduct a comprehensive study regarding the effects of medical savings accounts in the small group market on—

(1) selection, including adverse selection,

(2) health costs, including any impact on premiums of individuals with comprehensive coverage,

(3) use of preventive care,

(4) consumer choice,

(5) the scope of coverage of high deductible plans purchased in conjunction with such accounts, and

(6) other relevant items.

A report on the results of the study conducted under this subsection shall be submitted to the Congress no later than January 1, 1999.

Subtitle B—Increase in Deduction for Health Insurance Costs of Self–Employed Individuals

SEC. 311. INCREASE IN DEDUCTION FOR HEALTH INSURANCE COSTS OF SELF–EMPLOYED INDIVIDUALS.

<< 26 USCA § 162 >>

(a) IN GENERAL.—Paragraph (1) of section 162(l) is amended to read as follows:

"(1) ALLOWANCE OF DEDUCTION.—

"(A) IN GENERAL.—In the case of an individual who is an employee within the meaning of section 401(c)(1), there shall be allowed as a deduction under this section an amount equal to the applicable percentage of the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer, his spouse, and dependents.

"(B) APPLICABLE PERCENTAGE.—For purposes of subparagraph (A), the applicable percentage shall be determined under the following table:

"For taxable years beginning in calendar year—	**The applicable percentage is—**
1997	40 percent
1998 through 2002	45 percent
2003	50 percent
2004	60 percent
2005	70 percent
2006 or thereafter	80 percent.".

<< 26 USCA § 104 >>

(b) EXCLUSION FOR AMOUNTS RECEIVED UNDER CERTAIN SELF–INSURED PLANS.—Paragraph (3) of section 104(a) is amended by inserting "(or through an arrangement having the effect of accident or health insurance)" after "health insurance".

<< 26 USCA §§ 104 NOTE, 162 nt >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1996.

Subtitle C—Long–Term Care Services and Contracts

PART I—GENERAL PROVISIONS

SEC. 321. TREATMENT OF LONG–TERM CARE INSURANCE.

<< 26 USCA § 7702B >>

(a) GENERAL RULE.—Chapter 79 (relating to definitions) is amended by inserting after section 7702A the following new section:

"SEC. 7702B. TREATMENT OF QUALIFIED LONG–TERM CARE INSURANCE.

"(a) IN GENERAL.—For purposes of this title—

"(1) a qualified long-term care insurance contract shall be treated as an accident and health insurance contract,

"(2) amounts (other than policyholder dividends, as defined in section 808, or premium refunds) received under a qualified long-term care insurance contract shall be treated as amounts received for personal injuries and sickness and shall be treated as reimbursement for expenses actually incurred for medical care (as defined in section 213(d)),

"(3) any plan of an employer providing coverage under a qualified long-term care insurance contract shall be treated as an accident and health plan with respect to such coverage,

"(4) except as provided in subsection (e)(3), amounts paid for a qualified long-term care insurance contract providing the benefits described in subsection (b)(2)(A) shall be treated as payments made for insurance for purposes of section 213(d)(1)(D), and

"(5) a qualified long-term care insurance contract shall be treated as a guaranteed renewable contract subject to the rules of section 816(e).

"(b) QUALIFIED LONG–TERM CARE INSURANCE CONTRACT.—For purposes of this title—

"(1) IN GENERAL.—The term 'qualified long-term care insurance contract' means any insurance contract if—

"(A) the only insurance protection provided under such contract is coverage of qualified long-term care services,

"(B) such contract does not pay or reimburse expenses incurred for services or items to the extent that such expenses are reimbursable under title XVIII of the Social Security Act or would be so reimbursable but for the application of a deductible or coinsurance amount,

"(C) such contract is guaranteed renewable,

"(D) such contract does not provide for a cash surrender value or other money that can be—

"(i) paid, assigned, or pledged as collateral for a loan, or

"(ii) borrowed,

other than as provided in subparagraph (E) or paragraph (2)(C),

"(E) all refunds of premiums, and all policyholder dividends or similar amounts, under such contract are to be applied as a reduction in future premiums or to increase future benefits, and

"(F) such contract meets the requirements of subsection (g).

"(2) SPECIAL RULES.—

"(A) PER DIEM, ETC. PAYMENTS PERMITTED.—A contract shall not fail to be described in subparagraph (A) or (B) of paragraph (1) by reason of payments being made on a per diem or other periodic basis without regard to the expenses incurred during the period to which the payments relate.

"(B) SPECIAL RULES RELATING TO MEDICARE.—

"(i) Paragraph (1)(B) shall not apply to expenses which are reimbursable under title XVIII of the Social Security Act only as a secondary payor.

"(ii) No provision of law shall be construed or applied so as to prohibit the offering of a qualified long-term care insurance contract on the basis that the contract coordinates its benefits with those provided under such title.

"(C) REFUNDS OF PREMIUMS.—Paragraph (1)(E) shall not apply to any refund on the death of the insured, or on a complete surrender or cancellation of the contract, which cannot exceed the aggregate premiums paid under the contract. Any refund on a complete surrender or cancellation of the contract shall be includible in gross income to the extent that any deduction or exclusion was allowable with respect to the premiums.

"(c) QUALIFIED LONG–TERM CARE SERVICES.—For purposes of this section—

"(1) IN GENERAL.—The term 'qualified long-term care services' means necessary diagnostic, preventive, therapeutic, curing, treating, mitigating, and rehabilitative services, and maintenance or personal care services, which—

"(A) are required by a chronically ill individual, and

"(B) are provided pursuant to a plan of care prescribed by a licensed health care practitioner.

"(2) CHRONICALLY ILL INDIVIDUAL.—

"(A) IN GENERAL.—The term 'chronically ill individual' means any individual who has been certified by a licensed health care practitioner as—

"(i) being unable to perform (without substantial assistance from another individual) at least 2 activities of daily living for a period of at least 90 days due to a loss of functional capacity,

"(ii) having a level of disability similar (as determined under regulations prescribed by the Secretary in consultation with the Secretary of Health and Human Services) to the level of disability described in clause (i), or

"(iii) requiring substantial supervision to protect such individual from threats to health and safety due to severe cognitive impairment.

Such term shall not include any individual otherwise meeting the requirements of the preceding sentence unless within the preceding 12–month period a licensed health care practitioner has certified that such individual meets such requirements.

"(B) ACTIVITIES OF DAILY LIVING.—For purposes of subparagraph (A), each of the following is an activity of daily living:

"(i) Eating.

"(ii) Toileting.

"(iii) Transferring.

"(iv) Bathing.

"(v) Dressing.

"(vi) Continence.

A contract shall not be treated as a qualified long-term care insurance contract unless the determination of whether an individual is a chronically ill individual takes into account at least 5 of such activities.

"(3) MAINTENANCE OR PERSONAL CARE SERVICES.—The term 'maintenance or personal care services' means any care the primary purpose of which is the provision of needed assistance with any of the disabilities as a result of which the individual is a chronically ill individual (including the protection from threats to health and safety due to severe cognitive impairment).

"(4) LICENSED HEALTH CARE PRACTITIONER.—The term 'licensed health care practitioner' means any physician (as defined in section 1861(r)(1) of the Social Security Act) and any registered professional nurse, licensed social worker, or other individual who meets such requirements as may be prescribed by the Secretary.

"(d) AGGREGATE PAYMENTS IN EXCESS OF LIMITS.—

"(1) IN GENERAL.—If the aggregate of—

"(A) the periodic payments received for any period under all qualified long-term care insurance contracts which are treated as made for qualified long-term care services for an insured, and

"(B) the periodic payments received for such period which are treated under section 101(g) as paid by reason of the death of such insured,

exceeds the per diem limitation for such period, such excess shall be includible in gross income without regard to section 72. A payment shall not be taken into account under subparagraph (B) if the insured is a terminally ill individual (as defined in section 101(g)) at the time the payment is received.

"(2) PER DIEM LIMITATION.—For purposes of paragraph (1), the per diem limitation for any period is an amount equal to the excess (if any) of—

"(A) the greater of—

"(i) the dollar amount in effect for such period under paragraph (4), or

"(ii) the costs incurred for qualified long-term care services provided for the insured for such period, over

"(B) the aggregate payments received as reimbursements (through insurance or otherwise) for qualified long-term care services provided for the insured during such period.

"(3) AGGREGATION RULES.—For purposes of this subsection—

"(A) all persons receiving periodic payments described in paragraph (1) with respect to the same insured shall be treated as 1 person, and

"(B) the per diem limitation determined under paragraph (2) shall be allocated first to the insured and any remaining limitation shall be allocated among the other such persons in such manner as the Secretary shall prescribe.

"(4) DOLLAR AMOUNT.—The dollar amount in effect under this subsection shall be $175 per day (or the equivalent amount in the case of payments on another periodic basis).

"(5) INFLATION ADJUSTMENT.—In the case of a calendar year after 1997, the dollar amount contained in paragraph (4) shall be increased at the same time and in the same manner as amounts are increased pursuant to section 213(d)(10).

"(6) PERIODIC PAYMENTS.—For purposes of this subsection, the term 'periodic payment' means any payment (whether on a periodic basis or otherwise) made without regard to the extent of the costs incurred by the payee for qualified long-term care services.

"(e) TREATMENT OF COVERAGE PROVIDED AS PART OF A LIFE INSURANCE CONTRACT.—Except as otherwise provided in regulations prescribed by the Secretary, in the case of any long-term care insurance coverage (whether or not qualified) provided by a rider on or as part of a life insurance contract—

"(1) IN GENERAL.—This section shall apply as if the portion of the contract providing such coverage is a separate contract.

"(2) APPLICATION OF 7702.—Section 7702(c)(2) (relating to the guideline premium limitation) shall be applied by increasing the guideline premium limitation with respect to a life insurance contract, as of any date—

"(A) by the sum of any charges (but not premium payments) against the life insurance contract's cash surrender value (within the meaning of section 7702(f)(2)(A)) for such coverage made to that date under the contract, less

"(B) any such charges the imposition of which reduces the premiums paid for the contract (within the meaning of section 7702(f)(1)).

"(3) APPLICATION OF SECTION 213.—No deduction shall be allowed under section 213(a) for charges against the life insurance contract's cash surrender value described in paragraph (2), unless such charges are includible in income as a result of the application of section 72(e)(10) and the rider is a qualified long-term care insurance contract under subsection (b).

"(4) PORTION DEFINED.—For purposes of this subsection, the term 'portion' means only the terms and benefits under a life insurance contract that are in addition to the terms and benefits under the contract without regard to long-term care insurance coverage.

"(f) TREATMENT OF CERTAIN STATE–MAINTAINED PLANS.—

"(1) IN GENERAL.—If—

"(A) an individual receives coverage for qualified long-term care services under a State long-term care plan, and

"(B) the terms of such plan would satisfy the requirements of subsection (b) were such plan an insurance contract,

such plan shall be treated as a qualified long-term care insurance contract for purposes of this title.

"(2) STATE LONG–TERM CARE PLAN.—For purposes of paragraph (1), the term 'State long-term care plan' means any plan—

"(A) which is established and maintained by a State or an instrumentality of a State,

"(B) which provides coverage only for qualified long-term care services, and

"(C) under which such coverage is provided only to—

"(i) employees and former employees of a State (or any political subdivision or instrumentality of a State),

"(ii) the spouses of such employees, and

"(iii) individuals bearing a relationship to such employees or spouses which is described in any of paragraphs (1) through (8) of section 152(a).".

<< 26 USCA § 807 >>

(b) RESERVE METHOD.—Clause (iii) of section 807(d)(3)(A) is amended by inserting "(other than a qualified long-term care insurance contract, as defined in section 7702B(b))" after "insurance contract".

(c) LONG–TERM CARE INSURANCE NOT PERMITTED UNDER CAFETERIA PLANS OR FLEXIBLE SPENDING ARRANGEMENTS.—

<< 26 USCA § 125 >>

(1) CAFETERIA PLANS.—Section 125(f) is amended by adding at the end the following new sentence: "Such term shall not include any product which is advertised, marketed, or offered as long-term care insurance.".

<< 26 USCA § 106 >>

(2) FLEXIBLE SPENDING ARRANGEMENTS.—Section 106 (relating to contributions by employer to accident and health plans), as amended by section 301(c), is amended by adding at the end the following new subsection:

"(c) INCLUSION OF LONG–TERM CARE BENEFITS PROVIDED THROUGH FLEXIBLE SPENDING ARRANGEMENTS.—

"(1) IN GENERAL.—Effective on and after January 1, 1997, gross income of an employee shall include employer-provided coverage for qualified long-term care services (as defined in section 7702B(c)) to the extent that such coverage is provided through a flexible spending or similar arrangement.

"(2) FLEXIBLE SPENDING ARRANGEMENT.—For purposes of this subsection, a flexible spending arrangement is a benefit program which provides employees with coverage under which—

"(A) specified incurred expenses may be reimbursed (subject to reimbursement maximums and other reasonable conditions), and

"(B) the maximum amount of reimbursement which is reasonably available to a participant for such coverage is less than 500 percent of the value of such coverage.

In the case of an insured plan, the maximum amount reasonably available shall be determined on the basis of the underlying coverage."

(d) CONTINUATION COVERAGE RULES NOT TO APPLY.—

<< 26 USCA § 4980B >>

(1) Paragraph (2) of section 4980B(g) is amended by adding at the end the following new sentence: "Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c))."

<< 29 USCA § 1167 >>

(2) Paragraph (1) of section 607 of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following new sentence: "Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c) of such Code)."

<< 42 USCA § 300bb–8 >>

(3) Paragraph (1) of section 2208 of the Public Health Service Act is amended by adding at the end the following new sentence: "Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c) of such Code)."

<< 26 USCA Ch. 79 >>

(e) CLERICAL AMENDMENT.—The table of sections for chapter 79 is amended by inserting after the item relating to section 7702A the following new item:

"Sec. 7702B. Treatment of qualified long-term care insurance.".

<< 26 USCA §§ 106 nt, 125 nt, 807 nt, 4980B nt >>

<< 26 USCA § 7702B NOTE >>

<< 29 USCA § 1167 nt >>

<< 42 USCA § 300bb–8 nt >>

(f) EFFECTIVE DATES.—

(1) GENERAL EFFECTIVE DATE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the amendments made by this section shall apply to contracts issued after December 31, 1996.

(B) RESERVE METHOD.—The amendment made by subsection (b) shall apply to contracts issued after December 31, 1997.

(2) CONTINUATION OF EXISTING POLICIES.—In the case of any contract issued before January 1, 1997, which met the long-term care insurance requirements of the State in which the contract was situsted at the time the contract was issued—

(A) such contract shall be treated for purposes of the Internal Revenue Code of 1986 as a qualified long-term care insurance contract (as defined in section 7702B(b) of such Code), and

(B) services provided under, or reimbursed by, such contract shall be treated for such purposes as qualified long-term care services (as defined in section 7702B(c) of such Code).

In the case of an individual who is covered on December 31, 1996, under a State long-term care plan (as defined in section 7702B(f)(2) of such Code), the terms of such plan on such date shall be treated for purposes of the preceding sentence as a contract issued on such date which met the long-term care insurance requirements of such State.

(3) EXCHANGES OF EXISTING POLICIES.—If, after the date of enactment of this Act and before January 1, 1998, a contract providing for long-term care insurance coverage is exchanged solely for a qualified long-term care insurance contract (as defined in section 7702B(b) of such Code), no gain or loss shall be recognized on the exchange. If, in addition to a qualified long-term care insurance contract, money or other property is received in the exchange, then any gain shall be recognized to the extent of the sum of the money and the fair market value of the other property received. For purposes of this paragraph, the cancellation of a contract providing for long-term care insurance coverage and reinvestment of the cancellation proceeds in a qualified long-term care insurance contract within 60 days thereafter shall be treated as an exchange.

(4) ISSUANCE OF CERTAIN RIDERS PERMITTED.—For purposes of applying sections 101(f), 7702, and 7702A of the Internal Revenue Code of 1986 to any contract—

(A) the issuance of a rider which is treated as a qualified long-term care insurance contract under section 7702B, and

(B) the addition of any provision required to conform any other long-term care rider to be so treated,

shall not be treated as a modification or material change of such contract.

(5) APPLICATION OF PER DIEM LIMITATION TO EXISTING CONTRACTS.—The amount of per diem payments made under a contract issued on or before July 31, 1996, with respect to an insured which are excludable from gross income by reason of section 7702B of the Internal Revenue Code of 1986 (as added by this section) shall not be reduced under subsection (d)(2)(B) thereof by reason of reimbursements received under a contract issued on or before such date. The preceding sentence shall cease to apply as of the date (after July 31, 1996) such contract is exchanged or there is any contract modification which results in an increase in the amount of such per diem payments or the amount of such reimbursements.

<< 26 USCA § 7702B NOTE >>

(g) LONG–TERM CARE STUDY REQUEST.—The Chairman of the Committee on Ways and Means of the House of Representatives and the Chairman of the Committee on Finance of the Senate shall jointly request the National Association of Insurance Commissioners, in consultation with representatives of the insurance industry and consumer organizations, to formulate, develop, and conduct a study to determine the marketing and other effects of per diem limits on certain types of long-term care policies. If the National Association of Insurance Commissioners agrees to the study request, the National Association of Insurance Commissioners shall report the results of its study to such committees not later than 2 years after accepting the request.

SEC. 322. QUALIFIED LONG–TERM CARE SERVICES TREATED AS MEDICAL CARE.

<< 26 USCA § 213 >>

(a) GENERAL RULE.—Paragraph (1) of section 213(d) (defining medical care) is amended by striking "or" at the end of subparagraph (B), by redesignating subparagraph (C) as subparagraph (D), and by inserting after subparagraph (B) the following new subparagraph:

"(C) for qualified long-term care services (as defined in section 7702B(c)), or".

(b) TECHNICAL AMENDMENTS.—

(1) Subparagraph (D) of section 213(d)(1) (as redesignated by subsection (a)) is amended by inserting before the period "or for any qualified long-term care insurance contract (as defined in section 7702B(b))".

(2)(A) Paragraph (1) of section 213(d) is amended by adding at the end the following new flush sentence:

"In the case of a qualified long-term care insurance contract (as defined in section 7702B(b)), only eligible long-term care premiums (as defined in paragraph (10)) shall be taken into account under subparagraph (D)."

<< 26 USCA § 162 >>

(B) Paragraph (2) of section 162(l) is amended by adding at the end the following new subparagraph:

"(C) LONG–TERM CARE PREMIUMS.—In the case of a qualified long-term care insurance contract (as defined in section 7702B(b)), only eligible long-term care premiums (as defined in section 213(d)(10)) shall be taken into account under paragraph (1)."

<< 26 USCA § 213 >>

(C) Subsection (d) of section 213 is amended by adding at the end the following new paragraphs:

"(10) ELIGIBLE LONG–TERM CARE PREMIUMS.—

"(A) IN GENERAL.—For purposes of this section, the term 'eligible long-term care premiums' means the amount paid during a taxable year for any qualified long-term care insurance contract (as defined in section 7702B(b)) covering an individual, to the extent such amount does not exceed the limitation determined under the following table:

"In the case of an individual with an attained age before the close of the taxable year of:	**The limitation is:**
40 or less	$ 200
More than 40 but not more than 50	375
More than 50 but not more than 60	750
More than 60 but not more than 70	2,000
More than 70	2,500.

"(B) INDEXING.—

"(i) IN GENERAL.—In the case of any taxable year beginning in a calendar year after 1997, each dollar amount contained in subparagraph (A) shall be increased by the medical care cost adjustment of such amount for such calendar year. If any increase determined under the preceding sentence is not a multiple of $10, such increase shall be rounded to the nearest multiple of $10.

"(ii) MEDICAL CARE COST ADJUSTMENT.—For purposes of clause (i), the medical care cost adjustment for any calendar year is the percentage (if any) by which—

"(I) the medical care component of the Consumer Price Index (as defined in section 1(f)(5)) for August of the preceding calendar year, exceeds

"(II) such component for August of 1996.

The Secretary shall, in consultation with the Secretary of Health and Human Services, prescribe an adjustment which the Secretary determines is more appropriate for purposes of this paragraph than the adjustment described in the preceding sentence, and the adjustment so prescribed shall apply in lieu of the adjustment described in the preceding sentence.

"(11) CERTAIN PAYMENTS TO RELATIVES TREATED AS NOT PAID FOR MEDICAL CARE.—An amount paid for a qualified long-term care service (as defined in section 7702B(c)) provided to an individual shall be treated as not paid for medical care if such service is provided—

"(A) by the spouse of the individual or by a relative (directly or through a partnership, corporation, or other entity) unless the service is provided by a licensed professional with respect to such service, or

"(B) by a corporation or partnership which is related (within the meaning of section 267(b) or 707(b)) to the individual.

For purposes of this paragraph, the term 'relative' means an individual bearing a relationship to the individual which is described in any of paragraphs (1) through (8) of section 152(a). This paragraph shall not apply for purposes of section 105(b) with respect to reimbursements through insurance.".

(3) Paragraph (6) of section 213(d) is amended—

(A) by striking "subparagraphs (A) and (B)" and inserting "subparagraphs (A), (B), and (C)", and

(B) by striking "paragraph (1)(C)" in subparagraph (A) and inserting "paragraph (1)(D)".

(4) Paragraph (7) of section 213(d) is amended by striking "subparagraphs (A) and (B)" and inserting "subparagraphs (A), (B), and (C)".

<< 26 USCA §§ 162 NOTE, 213 nt >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1996.

SEC. 323. REPORTING REQUIREMENTS.

<< 26 USCA § 6050Q >>

(a) IN GENERAL.—Subpart B of part III of subchapter A of chapter 61 is amended by adding at the end the following new section:

"SEC. 6050Q. CERTAIN LONG–TERM CARE BENEFITS.

"(a) REQUIREMENT OF REPORTING.—Any person who pays long-term care benefits shall make a return, according to the forms or regulations prescribed by the Secretary, setting forth—

"(1) the aggregate amount of such benefits paid by such person to any individual during any calendar year,

"(2) whether or not such benefits are paid in whole or in part on a per diem or other periodic basis without regard to the expenses incurred during the period to which the payments relate,

"(3) the name, address, and TIN of such individual, and

"(4) the name, address, and TIN of the chronically ill or terminally ill individual on account of whose condition such benefits are paid.

"(b) STATEMENTS TO BE FURNISHED TO PERSONS WITH RESPECT TO WHOM INFORMATION IS REQUIRED.—Every person required to make a return under subsection (a) shall furnish to each individual whose name is required to be set forth in such return a written statement showing—

"(1) the name of the person making the payments, and

"(2) the aggregate amount of long-term care benefits paid to the individual which are required to be shown on such return.

The written statement required under the preceding sentence shall be furnished to the individual on or before January 31 of the year following the calendar year for which the return under subsection (a) was required to be made.

"(c) LONG–TERM CARE BENEFITS.—For purposes of this section, the term 'long-term care benefit' means—

"(1) any payment under a product which is advertised, marketed, or offered as long-term care insurance, and

"(2) any payment which is excludable from gross income by reason of section 101(g).".

<< 26 USCA § 6724 >>

(b) PENALTIES.—

(1) Subparagraph (B) of section 6724(d)(1) is amended by redesignating clauses (ix) through (xiv) as clauses (x) through (xv), respectively, and by inserting after clause (viii) the following new clause:

"(ix) section 6050Q (relating to certain long-term care benefits),".

(2) Paragraph (2) of section 6724(d) is amended by redesignating subparagraphs (Q) through (T) as subparagraphs (R) through (U), respectively, and by inserting after subparagraph (P) the following new subparagraph:

"(Q) section 6050Q(b) (relating to certain long-term care benefits),".

<< 26 USCA Ch. 61 >>

(c) CLERICAL AMENDMENT.—The table of sections for subpart B of part III of subchapter A of chapter 61 is amended by adding at the end the following new item:

"Sec. 6050Q. Certain long-term care benefits.".

<< 26 USCA § 6050Q NOTE >>

<< 26 USCA § 6724 nt >>

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to benefits paid after December 31, 1996.

PART II—CONSUMER PROTECTION PROVISIONS

<< 26 USCA § 7702B >>

SEC. 325. POLICY REQUIREMENTS.

Section 7702B (as added by section 321) is amended by adding at the end the following new subsection:

"(g) CONSUMER PROTECTION PROVISIONS.—

"(1) IN GENERAL.—The requirements of this subsection are met with respect to any contract if the contract meets—

"(A) the requirements of the model regulation and model Act described in paragraph (2),

"(B) the disclosure requirement of paragraph (3), and

"(C) the requirements relating to nonforfeitability under paragraph (4).

"(2) REQUIREMENTS OF MODEL REGULATION AND ACT.—

"(A) IN GENERAL.—The requirements of this paragraph are met with respect to any contract if such contract meets—

"(i) MODEL REGULATION.—The following requirements of the model regulation:

"(I) Section 7A (relating to guaranteed renewal or noncancellability), and the requirements of section 6B of the model Act relating to such section 7A.

"(II) Section 7B (relating to prohibitions on limitations and exclusions).

"(III) Section 7C (relating to extension of benefits).

"(IV) Section 7D (relating to continuation or conversion of coverage).

"(V) Section 7E (relating to discontinuance and replacement of policies).

"(VI) Section 8 (relating to unintentional lapse).

"(VII) Section 9 (relating to disclosure), other than section 9F thereof.

"(VIII) Section 10 (relating to prohibitions against post-claims underwriting).

"(IX) Section 11 (relating to minimum standards).

"(X) Section 12 (relating to requirement to offer inflation protection), except that any requirement for a signature on a rejection of inflation protection shall permit the signature to be on an application or on a separate form.

"(XI) Section 23 (relating to prohibition against preexisting conditions and probationary periods in replacement policies or certificates).

"(ii) MODEL ACT.—The following requirements of the model Act:

"(I) Section 6C (relating to preexisting conditions).

"(II) Section 6D (relating to prior hospitalization).

"(B) DEFINITIONS.—For purposes of this paragraph—

"(i) MODEL PROVISIONS.—The terms 'model regulation' and 'model Act' mean the long-term care insurance model regulation, and the long-term care insurance model Act, respectively, promulgated by the National Association of Insurance Commissioners (as adopted as of January 1993).

"(ii) COORDINATION.—Any provision of the model regulation or model Act listed under clause (i) or (ii) of subparagraph (A) shall be treated as including any other provision of such regulation or Act necessary to implement the provision.

"(iii) DETERMINATION.—For purposes of this section and section 4980C, the determination of whether any requirement of a model regulation or the model Act has been met shall be made by the Secretary.

"(3) DISCLOSURE REQUIREMENT.—The requirement of this paragraph is met with respect to any contract if such contract meets the requirements of section 4980C(d).

"(4) NONFORFEITURE REQUIREMENTS.—

"(A) IN GENERAL.—The requirements of this paragraph are met with respect to any level premium contract, if the issuer of such contract offers to the policyholder, including any group policyholder, a nonforfeiture provision meeting the requirements of subparagraph (B).

"(B) REQUIREMENTS OF PROVISION.—The nonforfeiture provision required under subparagraph (A) shall meet the following requirements:

"(i) The nonforfeiture provision shall be appropriately captioned.

"(ii) The nonforfeiture provision shall provide for a benefit available in the event of a default in the payment of any premiums and the amount of the benefit may be adjusted subsequent to being initially granted only as necessary to reflect changes in claims, persistency, and interest as reflected in changes in rates for premium paying contracts approved by the Secretary for the same contract form.

"(iii) The nonforfeiture provision shall provide at least one of the following:

"(I) Reduced paid-up insurance.

"(II) Extended term insurance.

"(III) Shortened benefit period.

"(IV) Other similar offerings approved by the Secretary.

"(5) CROSS REFERENCE.—

"For coordination of the requirements of this subsection with State requirements, see section 4980C(f).".

SEC. 326. REQUIREMENTS FOR ISSUERS OF QUALIFIED LONG–TERM CARE INSURANCE CONTRACTS.

<< 26 USCA § 4980C >>

(a) IN GENERAL.—Chapter 43 is amended by adding at the end the following new section:

"SEC. 4980C. REQUIREMENTS FOR ISSUERS OF QUALIFIED LONG–TERM CARE INSURANCE CONTRACTS.

"(a) GENERAL RULE.—There is hereby imposed on any person failing to meet the requirements of subsection (c) or (d) a tax in the amount determined under subsection (b).

"(b) AMOUNT.—

"(1) IN GENERAL.—The amount of the tax imposed by subsection (a) shall be $100 per insured for each day any requirement of subsection (c) or (d) is not met with respect to each qualified long-term care insurance contract.

"(2) WAIVER.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that payment of the tax would be excessive relative to the failure involved.

"(c) RESPONSIBILITIES.—The requirements of this subsection are as follows:

"(1) REQUIREMENTS OF MODEL PROVISIONS.—

"(A) MODEL REGULATION.—The following requirements of the model regulation must be met:

"(i) Section 13 (relating to application forms and replacement coverage).

"(ii) Section 14 (relating to reporting requirements), except that the issuer shall also report at least annually the number of claims denied during the reporting period for each class of business (expressed as a percentage of claims denied), other than claims denied for failure to meet the waiting period or because of any applicable preexisting condition.

"(iii) Section 20 (relating to filing requirements for marketing).

"(iv) Section 21 (relating to standards for marketing), including inaccurate completion of medical histories, other than sections 21C(1) and 21C(6) thereof, except that—

"(I) in addition to such requirements, no person shall, in selling or offering to sell a qualified long-term care insurance contract, misrepresent a material fact; and

"(II) no such requirements shall include a requirement to inquire or identify whether a prospective applicant or enrollee for long-term care insurance has accident and sickness insurance.

"(v) Section 22 (relating to appropriateness of recommended purchase).

"(vi) Section 24 (relating to standard format outline of coverage).

"(vii) Section 25 (relating to requirement to deliver shopper's guide).

"(B) MODEL ACT.—The following requirements of the model Act must be met:

"(i) Section 6F (relating to right to return), except that such section shall also apply to denials of applications and any refund shall be made within 30 days of the return or denial.

"(ii) Section 6G (relating to outline of coverage).

"(iii) Section 6H (relating to requirements for certificates under group plans).

"(iv) Section 6I (relating to policy summary).

"(v) Section 6J (relating to monthly reports on accelerated death benefits).

"(vi) Section 7 (relating to incontestability period).

"(C) DEFINITIONS.—For purposes of this paragraph, the terms 'model regulation' and 'model Act' have the meanings given such terms by section 7702B(g)(2)(B).

"(2) DELIVERY OF POLICY.—If an application for a qualified long-term care insurance contract (or for a certificate under such a contract for a group) is approved, the issuer shall deliver to the applicant (or policyholder or certificateholder) the contract (or certificate) of insurance not later than 30 days after the date of the approval.

"(3) INFORMATION ON DENIALS OF CLAIMS.—If a claim under a qualified, long-term care insurance contract is denied, the issuer shall, within 60 days of the date of a written request by the policyholder or certificateholder (or representative)—

"(A) provide a written explanation of the reasons for the denial, and

"(B) make available all information directly relating to such denial.

"(d) DISCLOSURE.—The requirements of this subsection are met if the issuer of a long-term care insurance policy discloses in such policy and in the outline of coverage required under subsection (c)(1)(B)(ii) that the policy is intended to be a qualified long-term care insurance contract under section 7702B(b).

"(e) QUALIFIED LONG–TERM CARE INSURANCE CONTRACT DEFINED.—For purposes of this section, the term 'qualified long-term care insurance contract' has the meaning given such term by section 7702B.

"(f) COORDINATION WITH STATE REQUIREMENTS.—If a State imposes any requirement which is more stringent than the analogous requirement imposed by this section or section 7702B(g), the requirement imposed by this section or section 7702B(g) shall be treated as met if the more stringent State requirement is met.".

<< 26 USCA Ch. 43 >>

(b) CONFORMING AMENDMENT.—The table of sections for chapter 43 is amended by adding at the end the following new item:

"Sec. 4980C. Requirements for issuers of qualified long-term care insurance contracts.".

<< 26 USCA § 4980C NOTE >>

SEC. 327. EFFECTIVE DATES.

(a) IN GENERAL.—The provisions of, and amendments made by, this part shall apply to contracts issued after December 31, 1996. The provisions of section 321(f) (relating to transition rule) shall apply to such contracts.

(b) ISSUERS.—The amendments made by section 326 shall apply to actions taken after December 31, 1996.

Subtitle D—Treatment of Accelerated Death Benefits

SEC. 331. TREATMENT OF ACCELERATED DEATH BENEFITS BY RECIPIENT.

<< 26 USCA § 101 >>

(a) IN GENERAL.—Section 101 (relating to certain death benefits) is amended by adding at the end the following new subsection:

"(g) TREATMENT OF CERTAIN ACCELERATED DEATH BENEFITS.—

"(1) IN GENERAL.—For purposes of this section, the following amounts shall be treated as an amount paid by reason of the death of an insured:

"(A) Any amount received under a life insurance contract on the life of an insured who is a terminally ill individual.

"(B) Any amount received under a life insurance contract on the life of an insured who is a chronically ill individual.

"(2) TREATMENT OF VIATICAL SETTLEMENTS.—

"(A) IN GENERAL.—If any portion of the death benefit under a life insurance contract on the life of an insured described in paragraph (1) is sold or assigned to a viatical settlement provider, the amount paid for the sale or assignment of such portion shall be treated as an amount paid under the life insurance contract by reason of the death of such insured.

"(B) VIATICAL SETTLEMENT PROVIDER.—

"(i) IN GENERAL.—The term 'viatical settlement provider' means any person regularly engaged in the trade or business of purchasing, or taking assignments of, life insurance contracts on the lives of insureds described in paragraph (1) if—

"(I) such person is licensed for such purposes (with respect to insureds described in the same subparagraph of paragraph (1) as the insured) in the State in which the insured resides, or

"(II) in the case of an insured who resides in a State not requiring the licensing of such persons for such purposes with respect to such insured, such person meets the requirements of clause (ii) or (iii), whichever applies to such insured.

"(ii) TERMINALLY ILL INSUREDS.—A person meets the requirements of this clause with respect to an insured who is a terminally ill individual if such person—

"(I) meets the requirements of sections 8 and 9 of the Viatical Settlements Model Act of the National Association of Insurance Commissioners, and

"(II) meets the requirements of the Model Regulations of the National Association of Insurance Commissioners (relating to standards for evaluation of reasonable payments) in determining amounts paid by such person in connection with such purchases or assignments.

"(iii) CHRONICALLY ILL INSUREDS.—A person meets the requirements of this clause with respect to an insured who is a chronically ill individual if such person—

"(I) meets requirements similar to the requirements referred to in clause (ii)(I), and

"(II) meets the standards (if any) of the National Association of Insurance Commissioners for evaluating the reasonableness of amounts paid by such person in connection with such purchases or assignments with respect to chronically ill individuals.

"(3) SPECIAL RULES FOR CHRONICALLY ILL INSUREDS.—In the case of an insured who is a chronically ill individual —

"(A) IN GENERAL.—Paragraphs (1) and (2) shall not apply to any payment received for any period unless—

"(i) such payment is for costs incurred by the payee (not compensated for by insurance or otherwise) for qualified long-term care services provided for the insured for such period, and

"(ii) the terms of the contract giving rise to such payment satisfy—

"(I) the requirements of section 7702B(b)(1)(B), and

"(II) the requirements (if any) applicable under subparagraph (B).

For purposes of the preceding sentence, the rule of section 7702B(b)(2)(B) shall apply.

"(B) OTHER REQUIREMENTS.—The requirements applicable under this subparagraph are—

"(i) those requirements of section 7702B(g) and section 4980C which the Secretary specifies as applying to such a purchase, assignment, or other arrangement,

"(ii) standards adopted by the National Association of Insurance Commissioners which specifically apply to chronically ill individuals (and, if such standards are adopted, the analogous requirements specified under clause (i) shall cease to apply), and

"(iii) standards adopted by the State in which the policyholder resides (and if such standards are adopted, the analogous requirements specified under clause (i) and (subject to section 4980C(f)) standards under clause (ii), shall cease to apply).

"(C) PER DIEM PAYMENTS.—A payment shall not fail to be described in subparagraph (A) by reason of being made on a per diem or other periodic basis without regard to the expenses incurred during the period to which the payment relates.

"(D) LIMITATION ON EXCLUSION FOR PERIODIC PAYMENTS.—

"For limitation on amount of periodic payments which are treated as described in paragraph (1), see section 7702B(d).".

"(4) DEFINITIONS.—For purposes of this subsection—

"(A) TERMINALLY ILL INDIVIDUAL.—The term 'terminally ill individual' means an individual who has been certified by a physician as having an illness or physical condition which can reasonably be expected to result in death in 24 months or less after the date of the certification.

"(B) CHRONICALLY ILL INDIVIDUAL.—The term 'chronically ill individual' has the meaning given such term by section 7702B(c)(2); except that such term shall not include a terminally ill individual.

"(C) QUALIFIED LONG–TERM CARE SERVICES.—The term 'qualified long-term care services' has the meaning given such term by section 7702B(c).

"(D) PHYSICIAN.—The term 'physician' has the meaning given to such term by section 1861(r)(1) of the Social Security Act (42 U.S.C. 1395x(r)(1)).

"(5) EXCEPTION FOR BUSINESS–RELATED POLICIES.—This subsection shall not apply in the case of any amount paid to any taxpayer other than the insured if such taxpayer has an insurable interest with respect to the life of the insured by reason of the insured being a director, officer, or employee of the taxpayer or by reason of the insured being financially interested in any trade or business carried on by the taxpayer.".

<< 26 USCA § 101 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to amounts received after December 31, 1996.

SEC. 332. TAX TREATMENT OF COMPANIES ISSUING QUALIFIED ACCELERATED DEATH BENEFIT RIDERS.

<< 26 USCA § 818 >>

(a) QUALIFIED ACCELERATED DEATH BENEFIT RIDERS TREATED AS LIFE INSURANCE.—Section 818 (relating to other definitions and special rules) is amended by adding at the end the following new subsection:

"(g) QUALIFIED ACCELERATED DEATH BENEFIT RIDERS TREATED AS LIFE INSURANCE.—For purposes of this part—

"(1) IN GENERAL.—Any reference to a life insurance contract shall be treated as including a reference to a qualified accelerated death benefit rider on such contract.

"(2) QUALIFIED ACCELERATED DEATH BENEFIT RIDERS.—For purposes of this subsection, the term 'qualified accelerated death benefit rider' means any rider on a life insurance contract if the only payments under the rider are payments meeting the requirements of section 101(g).

"(3) EXCEPTION FOR LONG–TERM CARE RIDERS.—Paragraph (1) shall not apply to any rider which is treated as a long-term care insurance contract under section 7702B.".

(b) EFFECTIVE DATE.—

<< 26 USCA § 818 NOTE >>

(1) IN GENERAL.—The amendment made by this section shall take effect on January 1, 1997.

(2) ISSUANCE OF RIDER NOT TREATED AS MATERIAL CHANGE.—For purposes of applying sections 101(f), 7702, and 7702A of the Internal Revenue Code of 1986 to any contract—

(A) the issuance of a qualified accelerated death benefit rider (as defined in section 818(g) of such Code (as added by this Act)), and

(B) the addition of any provision required to conform an accelerated death benefit rider to the requirements of such section 818(g),

shall not be treated as a modification or material change of such contract.

Subtitle E—State Insurance Pools

SEC. 341. EXEMPTION FROM INCOME TAX FOR STATE–SPONSORED ORGANIZATIONS PROVIDING HEALTH COVERAGE FOR HIGH–RISK INDIVIDUALS.

<< 26 USCA § 501 >>

(a) IN GENERAL.—Subsection (c) of section 501 (relating to list of exempt organizations) is amended by adding at the end the following new paragraph:

"(26) Any membership organization if—

"(A) such organization is established by a State exclusively to provide coverage for medical care (as defined in section 213(d)) on a not-for-profit basis to individuals described in subparagraph (B) through—

"(i) insurance issued by the organization, or

"(ii) a health maintenance organization under an arrangement with the organization,

"(B) the only individuals receiving such coverage through the organization are individuals—

"(i) who are residents of such State, and

"(ii) who, by reason of the existence or history of a medical condition—

"(I) are unable to acquire medical care coverage for such condition through insurance or from a health maintenance organization, or

"(II) are able to acquire such coverage only at a rate which is substantially in excess of the rate for such coverage through the membership organization,

"(C) the composition of the membership in such organization is specified by such State, and

"(D) no part of the net earnings of the organization inures to the benefit of any private shareholder or individual.".

<< 26 USCA § 501 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 1996.

SEC. 342. EXEMPTION FROM INCOME TAX FOR STATE–SPONSORED WORKMEN'S COMPENSATION REINSURANCE ORGANIZATIONS.

<< 26 USCA § 501 >>

(a) IN GENERAL.—Subsection (c) of section 501 (relating to list of exempt organizations), as amended by section 341, is amended by adding at the end the following new paragraph:

"(27) Any membership organization if—

"(A) such organization is established before June 1, 1996, by a State exclusively to reimburse its members for losses arising under workmen's compensation acts,

"(B) such State requires that the membership of such organization consist of—

"(i) all persons who issue insurance covering workmen's compensation losses in such State, and

"(ii) all persons and governmental entities who self-insure against such losses, and

"(C) such organization operates as a non-profit organization by—

"(i) returning surplus income to its members or workmen's compensation policyholders on a periodic basis, and

"(ii) reducing initial premiums in anticipation of investment income.".

<< 26 USCA § 501 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years ending after the date of the enactment of this Act.

Subtitle F—Organizations Subject to Section 833

SEC. 351. ORGANIZATIONS SUBJECT TO SECTION 833.

<< 26 USCA § 833 >>

(a) IN GENERAL.—Section 833(c) (relating to organization to which section applies) is amended by adding at the end the following new paragraph:

"(4) TREATMENT AS EXISTING BLUE CROSS OR BLUE SHIELD ORGANIZATION.—

"(A) IN GENERAL.—Paragraph (2) shall be applied to an organization described in subparagraph (B) as if it were a Blue Cross or Blue Shield organization.

"(B) APPLICABLE ORGANIZATION.—An organization is described in this subparagraph if it—

"(i) is organized under, and governed by, State laws which are specifically and exclusively applicable to not-for-profit health insurance or health service type organizations, and

"(ii) is not a Blue Cross or Blue Shield organization or health maintenance organization.".

<< 26 USCA § 833 NOTE >>

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years ending after December 31, 1996.

Subtitle G—IRA Distributions to the Unemployed

SEC. 361. DISTRIBUTIONS FROM CERTAIN PLANS MAY BE USED WITHOUT ADDITIONAL TAX TO PAY FINANCIALLY DEVASTATING MEDICAL EXPENSES.

<< 26 USCA § 72 >>

(a) IN GENERAL.—Section 72(t)(3)(A) is amended by striking "(B),".

(b) DISTRIBUTIONS FOR PAYMENT OF HEALTH INSURANCE PREMIUMS OF CERTAIN UNEMPLOYED INDIVIDUALS.—Paragraph (2) of section 72(t) is amended by adding at the end the following new subparagraph:

"(D) DISTRIBUTIONS TO UNEMPLOYED INDIVIDUALS FOR HEALTH INSURANCE PREMIUMS.—

"(i) IN GENERAL.—Distributions from an individual retirement plan to an individual after separation from employment—

"(I) if such individual has received unemployment compensation for 12 consecutive weeks under any Federal or State unemployment compensation law by reason of such separation,

"(II) if such distributions are made during any taxable year during which such unemployment compensation is paid or the succeeding taxable year, and

"(III) to the extent such distributions do not exceed the amount paid during the taxable year for insurance described in section 213(d)(1)(D) with respect to the individual and the individual's spouse and dependents (as defined in section 152).

"(ii) DISTRIBUTIONS AFTER REEMPLOYMENT.—Clause (i) shall not apply to any distribution made after the individual has been employed for at least 60 days after the separation from employment to which clause (i) applies.

"(iii) SELF–EMPLOYED INDIVIDUALS.—To the extent provided in regulations, a self-employed individual shall be treated as meeting the requirements of clause (i)(I) if, under Federal or State law, the individual would have received unemployment compensation but for the fact the individual was self-employed.".

(c) CONFORMING AMENDMENT.—Subparagraph (B) of section 72(t)(2) is amended by striking "or (C)" and inserting ", (C), or (D)".

<< 26 USCA § 72 NOTE >>

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to distributions after December 31, 1996.

Subtitle H—Organ and Tissue Donation Information Included With Income Tax Refund Payments

<< 26 USCA § 6402 NOTE >>

SEC. 371. ORGAN AND TISSUE DONATION INFORMATION INCLUDED WITH INCOME TAX REFUND PAYMENTS.

(a) IN GENERAL.—The Secretary of the Treasury shall, to the extent practicable, include with the mailing of any payment of a refund of individual income tax made during the period beginning on February 1, 1997, and ending on June 30, 1997, a copy of the document described in subsection (b).

(b) TEXT OF DOCUMENT.—The Secretary of the Treasury shall, after consultation with the Secretary of Health and Human Services and organizations promoting organ and tissue (including eye) donation, prepare a document suitable for inclusion with individual income tax refund payments which—

(1) encourages organ and tissue donation;

(2) includes a detachable organ and tissue donor card; and

(3) urges recipients to—

(A) sign the organ and tissue donor card;

(B) discuss organ and tissue donation with family members and tell family members about the recipient's desire to be an organ and tissue donor if the occasion arises; and

(C) encourage family members to request or authorize organ and tissue donation if the occasion arises.

TITLE IV—APPLICATION AND ENFORCEMENT OF GROUP HEALTH PLAN REQUIREMENTS

Subtitle A—Application and Enforcement of Group Health Plan Requirements

SEC. 401. GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS.

(a) IN GENERAL.—The Internal Revenue Code of 1986 is amended by adding at the end the following new subtitle:

<< 26 USCA Ch. 100 >>

"Subtitle K—Group Health Plan Portability, Access, and Renewability Requirements

"Chapter 100. Group health plan portability, access, and renewability requirements.

"CHAPTER 100—GROUP HEALTH PLAN PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS

"Sec. 9801. Increased portability through limitation on preexisting condition exclusions.

"Sec. 9802. Prohibiting discrimination against individual participants and beneficiaries based on health status.

"Sec. 9803. Guaranteed renewability in multiemployer plans and certain multiple employer welfare arrangements.

<< 26 USCA § 9801 >>

“SEC. 9801. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

“(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

“(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6–month period ending on the enrollment date;

“(2) such exclusion extends for a period of not more than 12 months (or 18 months in the case of a late enrollee) after the enrollment date; and

“(3) the period of any such preexisting condition exclusion is reduced by the length of the aggregate of the periods of creditable coverage (if any) applicable to the participant or beneficiary as of the enrollment date.

“(b) DEFINITIONS.—For purposes of this section—

“(1) PREEXISTING CONDITION EXCLUSION.—

“(A) IN GENERAL.—The term ‘preexisting condition exclusion’ means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

“(B) TREATMENT OF GENETIC INFORMATION.—For purposes of this section, genetic information shall not be treated as a condition described in subsection (a)(1) in the absence of a diagnosis of the condition related to such information.

“(2) ENROLLMENT DATE.—The term ‘enrollment date’ means, with respect to an individual covered under a group health plan, the date of enrollment of the individual in the plan or, if earlier, the first day of the waiting period for such enrollment.

“(3) LATE ENROLLEE.—The term ‘late enrollee’ means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

“(A) the first period in which the individual is eligible to enroll under the plan, or

“(B) a special enrollment period under subsection (f).

“(4) WAITING PERIOD.—The term ‘waiting period’ means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

“(c) RULES RELATING TO CREDITING PREVIOUS COVERAGE.—

“(1) CREDITABLE COVERAGE DEFINED.—For purposes of this part, the term ‘creditable coverage’ means, with respect to an individual, coverage of the individual under any of the following:

“(A) A group health plan.

“(B) Health insurance coverage.

“(C) Part A or part B of title XVIII of the Social Security Act.

“(D) Title XIX of the Social Security Act, other than coverage consisting solely of benefits under section 1928.

“(E) Chapter 55 of title 10, United States Code.

“(F) A medical care program of the Indian Health Service or of a tribal organization.

“(G) A State health benefits risk pool.

“(H) A health plan offered under chapter 89 of title 5, United States Code.

“(I) A public health plan (as defined in regulations).

“(J) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 9805(c)).

"(2) NOT COUNTING PERIODS BEFORE SIGNIFICANT BREAKS IN COVERAGE.—

"(A) IN GENERAL.—A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group health plan, if, after such period and before the enrollment date, there was a 63–day period during all of which the individual was not covered under any creditable coverage.

"(B) WAITING PERIOD NOT TREATED AS A BREAK IN COVERAGE.—For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group health plan or is in an affiliation period shall not be taken into account in determining the continuous period under subparagraph (A).

"(C) AFFILIATION PERIOD.—

"(i) IN GENERAL.—For purposes of this section, the term 'affiliation period' means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. During such an affiliation period, the organization is not required to provide health care services or benefits and no premium shall be charged to the participant or beneficiary.

"(ii) BEGINNING.—Such period shall begin on the enrollment date.

"(iii) RUNS CONCURRENTLY WITH WAITING PERIODS.—Any such affiliation period shall run concurrently with any waiting period under the plan.

"(3) METHOD OF CREDITING COVERAGE.—

"(A) STANDARD METHOD.—Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3), a group health plan shall count a period of creditable coverage without regard to the specific benefits for which coverage is offered during the period.

"(B) ELECTION OF ALTERNATIVE METHOD.—A group health plan may elect to apply subsection (a)(3) based on coverage of any benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group health plan shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

"(C) PLAN NOTICE.—In the case of an election with respect to a group health plan under subparagraph (B), the plan shall—

"(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

"(ii) include in such statements a description of the effect of this election.

"(4) ESTABLISHMENT OF PERIOD.—Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

"(d) EXCEPTIONS.—

"(1) EXCLUSION NOT APPLICABLE TO CERTAIN NEWBORNS.—Subject to paragraph (4), a group health plan may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30–day period beginning with the date of birth, is covered under creditable coverage.

"(2) EXCLUSION NOT APPLICABLE TO CERTAIN ADOPTED CHILDREN.—Subject to paragraph (4), a group health plan may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30–day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

"(3) EXCLUSION NOT APPLICABLE TO PREGNANCY.—For purposes of this section, a group health plan may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

"(4) LOSS IF BREAK IN COVERAGE.—Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63–day period during all of which the individual was not covered under any creditable coverage.

"(e) CERTIFICATIONS AND DISCLOSURE OF COVERAGE.—

"(1) REQUIREMENT FOR CERTIFICATION OF PERIOD OF CREDITABLE COVERAGE.—

"(A) IN GENERAL.—A group health plan shall provide the certification described in subparagraph (B)—

"(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

"(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

"(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

"(B) CERTIFICATION.—The certification described in this subparagraph is a written certification of—

"(i) the period of creditable coverage of the individual under such plan and the coverage under such COBRA continuation provision, and

"(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

"(C) ISSUER COMPLIANCE.—To the extent that medical care under a group health plan consists of health insurance coverage offered in connection with the plan, the plan is deemed to have satisfied the certification requirement under this paragraph if the issuer provides for such certification in accordance with this paragraph.

"(2) DISCLOSURE OF INFORMATION ON PREVIOUS BENEFITS.—

"(A) IN GENERAL.—In the case of an election described in subsection (c)(3)(B) by a group health plan, if the plan enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

"(i) upon request of such plan, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan information on coverage of classes and categories of health benefits available under such entity's plan, and

"(ii) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

"(3) REGULATIONS.—The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

"(f) SPECIAL ENROLLMENT PERIODS.—

"(1) INDIVIDUALS LOSING OTHER COVERAGE.—A group health plan shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

"(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or individual.

"(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor (or the health insurance issuer offering health insurance coverage in connection with the plan) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

"(C) The employee's or dependent's coverage described in subparagraph (A)—

"(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

"(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

"(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

"(2) FOR DEPENDENT BENEFICIARIES.—

"(A) IN GENERAL.—If—

"(i) a group health plan makes coverage available with respect to a dependent of an individual,

"(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

"(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

"(B) DEPENDENT SPECIAL ENROLLMENT PERIOD.—The dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

"(i) the date dependent coverage is made available, or

"(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

"(C) NO WAITING PERIOD.—If an individual seeks coverage of a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

"(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

"(ii) in the case of a dependent's birth, as of the date of such birth; or

"(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

<< 26 USCA § 9802 >>

"SEC. 9802. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.

"(a) IN ELIGIBILITY TO ENROLL.—

"(1) IN GENERAL.—Subject to paragraph (2), a group health plan may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan based on any of the following factors in relation to the individual or a dependent of the individual:

"(A) Health status.

"(B) Medical condition (including both physical and mental illnesses).

"(C) Claims experience.

"(D) Receipt of health care.

"(E) Medical history.

"(F) Genetic information.

"(G) Evidence of insurability (including conditions arising out of acts of domestic violence).

"(H) Disability.

"(2) NO APPLICATION TO BENEFITS OR EXCLUSIONS.—To the extent consistent with section 9801, paragraph (1) shall not be construed—

"(A) to require a group health plan to provide particular benefits (or benefits with respect to a specific procedure, treatment, or service) other than those provided under the terms of such plan; or

"(B) to prevent such a plan from establishing limitations or restrictions on the amount, level, extent, or nature of the benefits or coverage for similarly situated individuals enrolled in the plan or coverage.

"(3) CONSTRUCTION.—For purposes of paragraph (1), rules for eligibility to enroll under a plan include rules defining any applicable waiting periods for such enrollment.

"(b) IN PREMIUM CONTRIBUTIONS.—

"(1) IN GENERAL.—A group health plan may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any factor described in subsection (a)(1) in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

"(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

"(A) to restrict the amount that an employer may be charged for coverage under a group health plan; or

"(B) to prevent a group health plan from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

<< 26 USCA § 9803 >>

"SEC. 9803. GUARANTEED RENEWABILITY IN MULTIEMPLOYER PLANS AND CERTAIN MULTIPLE EMPLOYER WELFARE ARRANGEMENTS.

"(a) IN GENERAL.—A group health plan which is a multiemployer plan (as defined in section 414(f)) or which is a multiple employer welfare arrangement may not deny an employer continued access to the same or different coverage under such plan, other than—

"(1) for nonpayment of contributions;

"(2) for fraud or other intentional misrepresentation of material fact by the employer;

"(3) for noncompliance with material plan provisions;

"(4) because the plan is ceasing to offer any coverage in a geographic area;

"(5) in the case of a plan that offers benefits through a network plan, because there is no longer any individual enrolled through the employer who lives, resides, or works in the service area of the network plan and the plan applies this paragraph uniformly without regard to the claims experience of employers or a factor described in section 9802(a)(1) in relation to such individuals or their dependents; or

"(6) for failure to meet the terms of an applicable collective bargaining agreement, to renew a collective bargaining or other agreement requiring or authorizing contributions to the plan, or to employ employees covered by such an agreement.

"(b) MULTIPLE EMPLOYER WELFARE ARRANGEMENT.—For purposes of subsection (a), the term 'multiple employer welfare arrangement' has the meaning given such term by section 3(40) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section.

<< 26 USCA § 9804 >>

"SEC. 9804. GENERAL EXCEPTIONS.

"(a) EXCEPTION FOR CERTAIN PLANS.—The requirements of this chapter shall not apply to—

"(1) any governmental plan, and

"(2) any group health plan for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees.

"(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(1).

"(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

"(1) LIMITED, EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(2) if the benefits—

"(A) are provided under a separate policy, certificate, or contract of insurance; or

"(B) are otherwise not an integral part of the plan.

"(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(3) if all of the following conditions are met:

"(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

"(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

"(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor.

"(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this chapter shall not apply to any group health plan in relation to its provision of excepted benefits described in section 9805(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

<< 26 USCA § 9805 >>

“SEC. 9805. DEFINITIONS.

“(a) GROUP HEALTH PLAN.—For purposes of this chapter, the term ‘group health plan’ has the meaning given to such term by section 5000(b)(1).

“(b) DEFINITIONS RELATING TO HEALTH INSURANCE.—For purposes of this chapter—

“(1) HEALTH INSURANCE COVERAGE.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), the term ‘health insurance coverage’ means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

“(B) NO APPLICATION TO CERTAIN EXCEPTED BENEFITS.—In applying subparagraph (A), excepted benefits described in subsection (c)(1) shall not be treated as benefits consisting of medical care.

“(2) HEALTH INSURANCE ISSUER.—The term ‘health insurance issuer’ means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section). Such term does not include a group health plan.

“(3) HEALTH MAINTENANCE ORGANIZATION.—The term ‘health maintenance organization’ means—

“(A) a federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a))),

“(B) an organization recognized under State law as a health maintenance organization, or

“(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

“(c) EXCEPTED BENEFITS.—For purposes of this chapter, the term ‘excepted benefits' means benefits under one or more (or any combination thereof) of the following:

“(1) BENEFITS NOT SUBJECT TO REQUIREMENTS.—

“(A) Coverage only for accident, or disability income insurance, or any combination thereof.

“(B) Coverage issued as a supplement to liability insurance.

“(C) Liability insurance, including general liability insurance and automobile liability insurance.

“(D) Workers' compensation or similar insurance.

“(E) Automobile medical payment insurance.

“(F) Credit-only insurance.

“(G) Coverage for on-site medical clinics.

“(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

“(2) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED SEPARATELY.—

“(A) Limited scope dental or vision benefits.

“(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

“(C) Such other similar, limited benefits as are specified in regulations.

“(3) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS INDEPENDENT, NONCOORDINATED BENEFITS.—

“(A) Coverage only for a specified disease or illness.

“(B) Hospital indemnity or other fixed indemnity insurance.

“(4) BENEFITS NOT SUBJECT TO REQUIREMENTS IF OFFERED AS SEPARATE INSURANCE POLICY.—Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act), coverage supplemental to the coverage provided under chapter 55 of title 10, United States Code, and similar supplemental coverage provided to coverage under a group health plan.

"(d) OTHER DEFINITIONS.—For purposes of this chapter—

"(1) COBRA CONTINUATION PROVISION.—The term 'COBRA continuation provision' means any of the following:

"(A) Section 4980B, other than subsection (f)(1) thereof insofar as it relates to pediatric vaccines.

"(B) Part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1161 et seq.), other than section 609 of such Act.

"(C) Title XXII of the Public Health Service Act.

"(2) GOVERNMENTAL PLAN.—The term 'governmental plan' has the meaning given such term by section 414(d).

"(3) MEDICAL CARE.—The term 'medical care' has the meaning given such term by section 213(d) determined without regard to—

"(A) paragraph (1)(C) thereof, and

"(B) so much of paragraph (1)(D) thereof as relates to qualified long-term care insurance.

"(4) NETWORK PLAN.—The term 'network plan' means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care are provided, in whole or in part, through a defined set of providers under contract with the issuer.

"(5) PLACED FOR ADOPTION DEFINED.—The term 'placement', or being 'placed', for adoption, in connection with any placement for adoption of a child with any person, means the assumption and retention by such person of a legal obligation for total or partial support of such child in anticipation of adoption of such child. The child's placement with such person terminates upon the termination of such legal obligation.

<< 26 USCA § 9806 >>

"SEC. 9806. REGULATIONS.

"The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this chapter. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this chapter.".

<< 26 USCA Ch. 1 >>

(b) CLERICAL AMENDMENT.—The table of subtitles of such Code is amended by adding at the end the following new item:

"Subtitle K. Group health plan portability, access, and renewability requirements.".

<< 26 USCA §§ 9801 NOTE, 9802 nt, 9803 nt, 9804 nt, 9805 nt, 9806 nt >>

(c) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to plan years beginning after June 30, 1997.

(2) DETERMINATION OF CREDITABLE COVERAGE.—

(A) PERIOD OF COVERAGE.—

(i) IN GENERAL.—Subject to clause (ii), no period before July 1, 1996, shall be taken into account under chapter 100 of the Internal Revenue Code of 1986 (as added by this section) in determining creditable coverage.

(ii) SPECIAL RULE FOR CERTAIN PERIODS.—The Secretary of the Treasury, consistent with section 104, shall provide for a process whereby individuals who need to establish creditable coverage for periods before July 1, 1996, and who would have such coverage credited but for clause (i) may be given credit for creditable coverage for such periods through the presentation of documents or other means.

(B) CERTIFICATIONS, ETC.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), subsection (e) of section 9801 of the Internal Revenue Code of 1986 (as added by this section) shall apply to events occurring after June 30, 1996.

(ii) NO CERTIFICATION REQUIRED TO BE PROVIDED BEFORE JUNE 1, 1997.—In no case is a certification required to be provided under such subsection before June 1, 1997.

(iii) CERTIFICATION ONLY ON WRITTEN REQUEST FOR EVENTS OCCURRING BEFORE OCTOBER 1, 1996.—In the case of an event occurring after June 30, 1996, and before October 1, 1996, a certification is not required to be provided under such subsection unless an individual (with respect to whom the certification is otherwise required to be made) requests such certification in writing.

(C) TRANSITIONAL RULE.—In the case of an individual who seeks to establish creditable coverage for any period for which certification is not required because it relates to an event occurring before June 30, 1996—

(i) the individual may present other credible evidence of such coverage in order to establish the period of creditable coverage; and

(ii) a group health plan and a health insurance issuer shall not be subject to any penalty or enforcement action with respect to the plan's or issuer's crediting (or not crediting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under the amendments made by this section.

(3) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—Except as provided in paragraph (2), in the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by this section shall not apply to plan years beginning before the later of—

(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(B) July 1, 1997.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this section shall not be treated as a termination of such collective bargaining agreement.

(4) TIMELY REGULATIONS.—The Secretary of the Treasury, consistent with section 104, shall first issue by not later than April 1, 1997, such regulations as may be necessary to carry out the amendments made by this section.

(5) LIMITATION ON ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this section, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before January 1, 1998, or, if later, the date of issuance of regulations referred to in paragraph (4), if the plan or issuer has sought to comply in good faith with such requirements.

SEC. 402. PENALTY ON FAILURE TO MEET CERTAIN GROUP HEALTH PLAN REQUIREMENTS.

<< 26 USCA § 4980D >>

(a) IN GENERAL.—Chapter 43 of the Internal Revenue Code of 1986 (relating to qualified pension, etc., plans) is amended by adding after section 4980C the following new section:

"SEC. 4980D. FAILURE TO MEET CERTAIN GROUP HEALTH PLAN REQUIREMENTS.

"(a) GENERAL RULE.—There is hereby imposed a tax on any failure of a group health plan to meet the requirements of chapter 100 (relating to group health plan portability, access, and renewability requirements).

"(b) AMOUNT OF TAX.—

"(1) IN GENERAL.—The amount of the tax imposed by subsection (a) on any failure shall be $100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

"(2) NONCOMPLIANCE PERIOD.—For purposes of this section, the term 'noncompliance period' means, with respect to any failure, the period—

"(A) beginning on the date such failure first occurs, and

"(B) ending on the date such failure is corrected.

"(3) MINIMUM TAX FOR NONCOMPLIANCE PERIOD WHERE FAILURE DISCOVERED AFTER NOTICE OF EXAMINATION.—Notwithstanding paragraphs (1) and (2) of subsection (c)—

"(A) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

"(i) which are not corrected before the date a notice of examination of income tax liability is sent to the employer, and

"(ii) which occurred or continued during the period under examination,

the amount of tax imposed by subsection (a) by reason of such failures with respect to such individual shall not be less than the lesser of $2,500 or the amount of tax which would be imposed by subsection (a) without regard to such paragraphs.

"(B) HIGHER MINIMUM TAX WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under subsection (e) for any year are more than de minimis, subparagraph (A) shall be applied by substituting '$15,000' for '$2,500' with respect to such person.

"(C) EXCEPTION FOR CHURCH PLANS.—This paragraph shall not apply to any failure under a church plan (as defined in section 414(e)).

"(c) LIMITATIONS ON AMOUNT OF TAX.—

"(1) TAX NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No tax shall be imposed by subsection (a) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such tax did not know, and exercising reasonable diligence would not have known, that such failure existed.

"(2) TAX NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No tax shall be imposed by subsection (a) on any failure if—

"(A) such failure was due to reasonable cause and not to willful neglect, and

"(B)(i) in the case of a plan other than a church plan (as defined in section 414(e)), such failure is corrected during the 30–day period beginning on the first date the person otherwise liable for such tax knew, or exercising reasonable diligence would have known, that such failure existed, and

"(ii) in the case of a church plan (as so defined), such failure is corrected before the close of the correction period (determined under the rules of section 414(e)(4)(C)).

"(3) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect—

"(A) SINGLE EMPLOYER PLANS.—

"(i) IN GENERAL.—In the case of failures with respect to plans other than specified multiple employer health plans, the tax imposed by subsection (a) for failures during the taxable year of the employer shall not exceed the amount equal to the lesser of—

"(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans, or

"(II) $500,000.

"(ii) TAXABLE YEARS IN THE CASE OF CERTAIN CONTROLLED GROUPS.—For purposes of this subparagraph, if not all persons who are treated as a single employer for purposes of this section have the same taxable year, the taxable years taken into account shall be determined under principles similar to the principles of section 1561.

"(B) SPECIFIED MULTIPLE EMPLOYER HEALTH PLANS.—

"(i) IN GENERAL.—In the case of failures with respect to a specified multiple employer health plan, the tax imposed by subsection (a) for failures during the taxable year of the trust forming part of such plan shall not exceed the amount equal to the lesser of—

"(I) 10 percent of the amount paid or incurred by such trust during such taxable year to provide medical care (as defined in section 9805(d)(3)) directly or through insurance, reimbursement, or otherwise, or

"(II) $500,000.

For purposes of the preceding sentence, all plans of which the same trust forms a part shall be treated as one plan.

"(ii) SPECIAL RULE FOR EMPLOYERS REQUIRED TO PAY TAX.—If an employer is assessed a tax imposed by subsection (a) by reason of a failure with respect to a specified multiple employer health plan, the limit shall be determined under subparagraph (A) (and not under this subparagraph) and as if such plan were not a specified multiple employer health plan.

"(4) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that the payment of such tax would be excessive relative to the failure involved.

"(d) TAX NOT TO APPLY TO CERTAIN INSURED SMALL EMPLOYER PLANS.—

"(1) IN GENERAL.—In the case of a group health plan of a small employer which provides health insurance coverage solely through a contract with a health insurance issuer, no tax shall be imposed by this section on the employer on any failure which is solely because of the health insurance coverage offered by such issuer.

"(2) SMALL EMPLOYER.—

"(A) IN GENERAL.—For purposes of paragraph (1), the term 'small employer' means, with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of the preceding sentence, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as one employer.

"(B) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

"(C) PREDECESSORS.—Any reference in this paragraph to an employer shall include a reference to any predecessor of such employer.

"(3) HEALTH INSURANCE COVERAGE; HEALTH INSURANCE ISSUER.—For purposes of paragraph (1), the terms 'health insurance coverage' and 'health insurance issuer' have the respective meanings given such terms by section 9805.

"(e) LIABILITY FOR TAX.—The following shall be liable for the tax imposed by subsection (a) on a failure:

"(1) Except as otherwise provided in this subsection, the employer.

"(2) In the case of a multiemployer plan, the plan.

"(3) In the case of a failure under section 9803 (relating to guaranteed renewability) with respect to a plan described in subsection (f)(2)(B), the plan.

"(f) DEFINITIONS.—For purposes of this section—

"(1) GROUP HEALTH PLAN.—The term 'group health plan' has the meaning given such term by section 9805(a).

"(2) SPECIFIED MULTIPLE EMPLOYER HEALTH PLAN.—The term 'specified multiple employer health plan' means a group health plan which is—

"(A) any multiemployer plan, or

"(B) any multiple employer welfare arrangement (as defined in section 3(40) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section).

"(3) CORRECTION.—A failure of a group health plan shall be treated as corrected if—

"(A) such failure is retroactively undone to the extent possible, and

"(B) the person to whom the failure relates is placed in a financial position which is as good as such person would have been in had such failure not occurred.".

<< 26 USCA Ch. 43 >>

(b) CLERICAL AMENDMENT.—The table of sections for chapter 43 of such Code is amended by adding after the item relating to section 4980C the following new item:

"Sec. 4980D. Failure to meet certain group health plan requirements.".

<< 26 USCA § 4980D NOTE >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to failures under chapter 100 of the Internal Revenue Code of 1986 (as added by section 401 of this Act).

Subtitle B—Clarification of Certain Continuation Coverage Requirements

SEC. 421. COBRA CLARIFICATIONS.

(a) PUBLIC HEALTH SERVICE ACT.—

<< 42 USCA § 300bb–2 >>

(1) PERIOD OF COVERAGE.—Section 2202(2) of the Public Health Service Act (42 U.S.C. 300bb–2(2)) is amended—

(A) in subparagraph (A)—

(i) by transferring the sentence immediately preceding clause (iv) so as to appear immediately following such clause (iv); and

(ii) in the last sentence (as so transferred)—

(I) by striking "an individual" and inserting "a qualified beneficiary";

(II) by striking "at the time of a qualifying event described in section 2203(2)" and inserting "at any time during the first 60 days of continuation coverage under this title";

(III) by striking "with respect to such event,"; and

(IV) by inserting "(with respect to all qualified beneficiaries)" after "29 months";

(B) in subparagraph (D)(i), by inserting before ", or" the following: "(other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of the Internal Revenue Code of 1986, part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, or title XXVII of this Act)"; and

(C) in subparagraph (E), by striking "at the time of a qualifying event described in section 2203(2)" and inserting "at any time during the first 60 days of continuation coverage under this title".

<< 42 USCA § 300bb–6 >>

(2) NOTICES.—Section 2206(3) of the Public Health Service Act (42 U.S.C. 300bb–6(3)) is amended by striking "at the time of a qualifying event described in section 2203(2)" and inserting "at any time during the first 60 days of continuation coverage under this title".

<< 42 USCA § 300bb–8 >>

(3) BIRTH OR ADOPTION OF A CHILD.—Section 2208(3)(A) of the Public Health Service Act (42 U.S.C. 300bb–8(3)(A)) is amended by adding at the end thereof the following new flush sentence:

"Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this title.".

(b) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

<< 29 USCA § 1162 >>

(1) PERIOD OF COVERAGE.—Section 602(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1162(2)) is amended—

(A) in the last sentence of subparagraph (A)—

(i) by striking "an individual" and inserting "a qualified beneficiary";

(ii) by striking "at the time of a qualifying event described in section 603(2)" and inserting "at any time during the first 60 days of continuation coverage under this part";

(iii) by striking "with respect to such event"; and

(iv) by inserting "(with respect to all qualified beneficiaries)" after "29 months";

(B) in subparagraph (D)(i), by inserting before ", or" the following: "(other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of the Internal Revenue Code of 1986, part 7 of this subtitle, or title XXVII of the Public Health Service Act)"; and

(C) in subparagraph (E), by striking "at the time of a qualifying event described in section 603(2)" and inserting "at any time during the first 60 days of continuation coverage under this part".

<< 29 USCA § 1166 >>

(2) NOTICES.—Section 606(a)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1166(a)(3)) is amended by striking "at the time of a qualifying event described in section 603(2)" and inserting "at any time during the first 60 days of continuation coverage under this part".

<< 29 USCA § 1167 >>

(3) BIRTH OR ADOPTION OF A CHILD.—Section 607(3)(A) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1167(3)) is amended by adding at the end thereof the following new flush sentence:

"Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this part.".

<< 26 USCA § 4980B >>

(c) INTERNAL REVENUE CODE OF 1986.—

(1) PERIOD OF COVERAGE.—Section 4980B(f)(2)(B) of the Internal Revenue Code of 1986 is amended—

(A) in the last sentence of clause (i)—

(i) by striking "at the time of a qualifying event described in paragraph (3)(B)" and inserting "at any time during the first 60 days of continuation coverage under this section";

(ii) by striking "with respect to such event"; and

(iii) by inserting "(with respect to all qualified beneficiaries)" after "29 months";

(B) in clause (iv)(I), by inserting before ", or" the following: "(other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of this title, part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, or title XXVII of the Public Health Service Act)"; and

(C) in clause (v), by striking "at the time of a qualifying event described in paragraph (3)(B)" and inserting "at any time during the first 60 days of continuation coverage under this section".

(2) NOTICES.—Section 4980B(f)(6)(C) of the Internal Revenue Code of 1986 is amended by striking "at the time of a qualifying event described in paragraph (3)(B)" and inserting "at any time during the first 60 days of continuation coverage under this section".

(3) BIRTH OR ADOPTION OF A CHILD.—Section 4980B(g)(1)(A) of the Internal Revenue Code of 1986 is amended by adding at the end thereof the following new flush sentence:

"Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this section.".

<< 26 USCA § 4980B NOTE >>

<< 29 USCA §§ 1162 nt, 1166 nt, 1167 nt >>

<< 42 USCA §§ 300bb–2 nt, 300bb–6 nt, 300bb–8 nt >>

(d) EFFECTIVE DATE.—The amendments made by this section shall become effective on January 1, 1997, regardless of whether the qualifying event occurred before, on, or after such date.

<< 26 USCA § 4980B NOTE >>

(e) NOTIFICATION OF CHANGES.—Not later than November 1, 1996, each group health plan (covered under title XXII of the Public Health Service Act, part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, and section 4980B(f) of the Internal Revenue Code of 1986) shall notify each qualified beneficiary who has elected continuation coverage under such title, part or section of the amendments made by this section.

TITLE V—REVENUE OFFSETS

SEC. 500. AMENDMENT OF 1986 CODE.

Except as otherwise expressly provided, whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Internal Revenue Code of 1986.

Subtitle A—Company–Owned Life Insurance

SEC. 501. DENIAL OF DEDUCTION FOR INTEREST ON LOANS WITH RESPECT TO COMPANY–OWNED LIFE INSURANCE.

<< 26 USCA § 264 >>

(a) IN GENERAL.—Paragraph (4) of section 264(a) is amended—

(1) by inserting ", or any endowment or annuity contracts owned by the taxpayer covering any individual," after "the life of any individual", and

(2) by striking all that follows "carried on by the taxpayer" and inserting a period.

(b) EXCEPTION FOR CONTRACTS RELATING TO KEY PERSONS; PERMISSIBLE INTEREST RATES.—Section 264 is amended—

(1) by striking "Any" in subsection (a)(4) and inserting "Except as provided in subsection (d), any", and

(2) by adding at the end the following new subsection:

"(d) SPECIAL RULES FOR APPLICATION OF SUBSECTION (a)(4).—

"(1) EXCEPTION FOR KEY PERSONS.—Subsection (a)(4) shall not apply to any interest paid or accrued on any indebtedness with respect to policies or contracts covering an individual who is a key person to the extent that the aggregate amount of such indebtedness with respect to policies and contracts covering such individual does not exceed $50,000.

"(2) INTEREST RATE CAP ON KEY PERSONS AND PRE–1986 CONTRACTS.—

"(A) IN GENERAL.—No deduction shall be allowed by reason of paragraph (1) or the last sentence of subsection (a) with respect to interest paid or accrued for any month beginning after December 31, 1995, to the extent the amount of such interest exceeds the amount which would have been determined if the applicable rate of interest were used for such month.

"(B) APPLICABLE RATE OF INTEREST.—For purposes of subparagraph (A)—

"(i) IN GENERAL.—The applicable rate of interest for any month is the rate of interest described as Moody's Corporate Bond Yield Average–Monthly Average Corporates as published by Moody's Investors Service, Inc., or any successor thereto, for such month.

"(ii) PRE–1986 CONTRACTS.—In the case of indebtedness on a contract purchased on or before June 20, 1986—

"(I) which is a contract providing a fixed rate of interest, the applicable rate of interest for any month shall be the Moody's rate described in clause (i) for the month in which the contract was purchased, or

"(II) which is a contract providing a variable rate of interest, the applicable rate of interest for any month in an applicable period shall be such Moody's rate for the third month preceding the first month in such period.

For purposes of subclause (II), the taxpayer shall elect an applicable period for such contract on its return of tax imposed by this chapter for its first taxable year ending on or after October 13, 1995. Such applicable period shall be for any number of months (not greater than 12) specified in the election and may not be changed by the taxpayer without the consent of the Secretary.

"(3) KEY PERSON.—For purposes of paragraph (1), the term 'key person' means an officer or 20–percent owner, except that the number of individuals who may be treated as key persons with respect to any taxpayer shall not exceed the greater of—

"(A) 5 individuals, or

"(B) the lesser of 5 percent of the total officers and employees of the taxpayer or 20 individuals.

"(4) 20–PERCENT OWNER.—For purposes of this subsection, the term '20–percent owner' means—

"(A) if the taxpayer is a corporation, any person who owns directly 20 percent or more of the outstanding stock of the corporation or stock possessing 20 percent or more of the total combined voting power of all stock of the corporation, or

"(B) if the taxpayer is not a corporation, any person who owns 20 percent or more of the capital or profits interest in the employer.

"(5) AGGREGATION RULES.—

"(A) IN GENERAL.—For purposes of paragraph (4)(A) and applying the $50,000 limitation in paragraph (1)—

"(i) all members of a controlled group shall be treated as one taxpayer, and

"(ii) such limitation shall be allocated among the members of such group in such manner as the Secretary may prescribe.

"(B) CONTROLLED GROUP.—For purposes of this paragraph, all persons treated as a single employer under subsection (a) or (b) of section 52 or subsection (m) or (o) of section 414 shall be treated as members of a controlled group.".

<< 26 USCA § 264 NOTE >>

(c) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by this section shall apply to interest paid or accrued after October 13, 1995.

(2) TRANSITION RULE FOR EXISTING INDEBTEDNESS.—

(A) IN GENERAL.—In the case of—

(i) indebtedness incurred before January 1, 1996, or

(ii) indebtedness incurred before January 1, 1997 with respect to any contract or policy entered into in 1994 or 1995,

the amendments made by this section shall not apply to qualified interest paid or accrued on such indebtedness after October 13, 1995, and before January 1, 1999.

(B) QUALIFIED INTEREST.—For purposes of subparagraph (A), the qualified interest with respect to any indebtedness for any month is the amount of interest (otherwise deductible) which would be paid or accrued for such month on such indebtedness if—

(i) in the case of any interest paid or accrued after December 31, 1995, indebtedness with respect to no more than 20,000 insured individuals were taken into account, and

(ii) the lesser of the following rates of interest were used for such month:

(I) The rate of interest specified under the terms of the indebtedness as in effect on October 13, 1995 (and without regard to modification of such terms after such date).

(II) The applicable percentage of the rate of interest described as Moody's Corporate Bond Yield Average–Monthly Average Corporates as published by Moody's Investors Service, Inc., or any successor thereto, for such month.

For purposes of clause (i), all persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 or subsection (m) or (o) of section 414 of such Code shall be treated as 1 person. Subclause (II) of clause (ii) shall not apply to any month before January 1, 1996.

(C) APPLICABLE PERCENTAGE.—For purposes of subparagraph (B), the applicable percentage is as follows:

For calendar year:	**The percentage is:**
1996	100 percent
1997	90 percent
1998	80 percent.

(3) SPECIAL RULE FOR GRANDFATHERED CONTRACTS.—This section shall not apply to any contract purchased on or before June 20, 1986, except that section 264(d)(2) of the Internal Revenue Code of 1986 shall apply to interest paid or accrued after October 13, 1995.

<< 26 USCA § 264 NOTE >>

(d) SPREAD OF INCOME INCLUSION ON SURRENDER, ETC. OF CONTRACTS.—

(1) IN GENERAL.—If any amount is received under any life insurance policy or endowment or annuity contract described in paragraph (4) of section 264(a) of the Internal Revenue Code of 1986—

(A) on the complete surrender, redemption, or maturity of such policy or contract during calendar year 1996, 1997, or 1998, or

(B) in full discharge during any such calendar year of the obligation under the policy or contract which is in the nature of a refund of the consideration paid for the policy or contract,

then (in lieu of any other inclusion in gross income) such amount shall be includible in gross income ratably over the 4–taxable year period beginning with the taxable year such amount would (but for this paragraph) be includible. The preceding sentence shall only apply to the extent the amount is includible in gross income for the taxable year in which the event described in subparagraph (A) or (B) occurs.

(2) SPECIAL RULES FOR APPLYING SECTION 264.—A contract shall not be treated as—

(A) failing to meet the requirement of section 264(c)(1) of the Internal Revenue Code of 1986, or

(B) a single premium contract under section 264(b)(1) of such Code,

solely by reason of an occurrence described in subparagraph (A) or (B) of paragraph (1) of this subsection or solely by reason of no additional premiums being received under the contract by reason of a lapse occurring after October 13, 1995.

(3) SPECIAL RULE FOR DEFERRED ACQUISITION COSTS.—In the case of the occurrence of any event described in subparagraph (A) or (B) of paragraph (1) of this subsection with respect to any policy or contract—

(A) section 848 of the Internal Revenue Code of 1986 shall not apply to the unamortized balance (if any) of the specified policy acquisition expenses attributable to such policy or contract immediately before the insurance company's taxable year in which such event occurs, and

(B) there shall be allowed as a deduction to such company for such taxable year under chapter 1 of such Code an amount equal to such unamortized balance.

Subtitle B—Treatment of Individuals Who Lose United States Citizenship

SEC. 511. REVISION OF INCOME, ESTATE, AND GIFT TAXES ON INDIVIDUALS WHO LOSE UNITED STATES CITIZENSHIP.

<< 26 USCA § 877 >>

(a) IN GENERAL.—Subsection (a) of section 877 is amended to read as follows:

"(a) TREATMENT OF EXPATRIATES.—

"(1) IN GENERAL.—Every nonresident alien individual who, within the 10–year period immediately preceding the close of the taxable year, lost United States citizenship, unless such loss did not have for one of its principal purposes the avoidance of taxes under this subtitle or subtitle B, shall be taxable for such taxable year in the manner provided in subsection (b) if the tax imposed pursuant to such subsection exceeds the tax which, without regard to this section, is imposed pursuant to section 871.

"(2) CERTAIN INDIVIDUALS TREATED AS HAVING TAX AVOIDANCE PURPOSE.—For purposes of paragraph (1), an individual shall be treated as having a principal purpose to avoid such taxes if—

"(A) the average annual net income tax (as defined in section 38(c)(1)) of such individual for the period of 5 taxable years ending before the date of the loss of United States citizenship is greater than $100,000, or

"(B) the net worth of the individual as of such date is $500,000 or more.

In the case of the loss of United States citizenship in any calendar year after 1996, such $100,000 and $500,000 amounts shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment determined under section 1(f)(3) for such calendar year by substituting '1994' for '1992' in subparagraph (B) thereof. Any increase under the preceding sentence shall be rounded to the nearest multiple of $1,000.".

(b) EXCEPTIONS.—

(1) IN GENERAL.—Section 877 is amended by striking subsection (d), by redesignating subsection (c) as subsection (d), and by inserting after subsection (b) the following new subsection:

"(c) TAX AVOIDANCE NOT PRESUMED IN CERTAIN CASES.—

"(1) IN GENERAL.—Subsection (a)(2) shall not apply to an individual if—

"(A) such individual is described in a subparagraph of paragraph (2) of this subsection, and

"(B) within the 1–year period beginning on the date of the loss of United States citizenship, such individual submits a ruling request for the Secretary's determination as to whether such loss has for one of its principal purposes the avoidance of taxes under this subtitle or subtitle B.

"(2) INDIVIDUALS DESCRIBED.—

"(A) DUAL CITIZENSHIP, ETC.—An individual is described in this subparagraph if—

"(i) the individual became at birth a citizen of the United States and a citizen of another country and continues to be a citizen of such other country, or

"(ii) the individual becomes (not later than the close of a reasonable period after loss of United States citizenship) a citizen of the country in which—

"(I) such individual was born,

"(II) if such individual is married, such individual's spouse was born, or

"(III) either of such individual's parents were born.

"(B) LONG–TERM FOREIGN RESIDENTS.—An individual is described in this subparagraph if, for each year in the 10–year period ending on the date of loss of United States citizenship, the individual was present in the United States for 30 days or less. The rule of section 7701(b)(3)(D)(ii) shall apply for purposes of this subparagraph.

"(C) RENUNCIATION UPON REACHING AGE OF MAJORITY.—An individual is described in this subparagraph if the individual's loss of United States citizenship occurs before such individual attains age 18½.

"(D) INDIVIDUALS SPECIFIED IN REGULATIONS.—An individual is described in this subparagraph if the individual is described in a category of individuals prescribed by regulation by the Secretary.".

(2) TECHNICAL AMENDMENT.—Paragraph (1) of section 877(b) of such Code is amended by striking "subsection (c)" and inserting "subsection (d)".

(c) TREATMENT OF PROPERTY DISPOSED OF IN NONRECOGNITION TRANSACTIONS; TREATMENT OF DISTRIBUTIONS FROM CERTAIN CONTROLLED FOREIGN CORPORATIONS.—Subsection (d) of section 877, as redesignated by subsection (b), is amended to read as follows:

"(d) SPECIAL RULES FOR SOURCE, ETC.—For purposes of subsection (b)—

"(1) SOURCE RULES.—The following items of gross income shall be treated as income from sources within the United States:

"(A) SALE OF PROPERTY.—Gains on the sale or exchange of property (other than stock or debt obligations) located in the United States.

"(B) STOCK OR DEBT OBLIGATIONS.—Gains on the sale or exchange of stock issued by a domestic corporation or debt obligations of United States persons or of the United States, a State or political subdivision thereof, or the District of Columbia.

"(C) INCOME OR GAIN DERIVED FROM CONTROLLED FOREIGN CORPORATION.—Any income or gain derived from stock in a foreign corporation but only—

"(i) if the individual losing United States citizenship owned (within the meaning of section 958(a)), or is considered as owning (by applying the ownership rules of section 958(b)), at any time during the 2–year period ending on the date of the loss of United States citizenship, more than 50 percent of—

"(I) the total combined voting power of all classes of stock entitled to vote of such corporation, or

"(II) the total value of the stock of such corporation, and

"(ii) to the extent such income or gain does not exceed the earnings and profits attributable to such stock which were earned or accumulated before the loss of citizenship and during periods that the ownership requirements of clause (i) are met.

"(2) GAIN RECOGNITION ON CERTAIN EXCHANGES.—

"(A) IN GENERAL.—In the case of any exchange of property to which this paragraph applies, notwithstanding any other provision of this title, such property shall be treated as sold for its fair market value on the date of such exchange, and any gain shall be recognized for the taxable year which includes such date.

"(B) EXCHANGES TO WHICH PARAGRAPH APPLIES.—This paragraph shall apply to any exchange during the 10–year period described in subsection (a) if—

"(i) gain would not (but for this paragraph) be recognized on such exchange in whole or in part for purposes of this subtitle,

"(ii) income derived from such property was from sources within the United States (or, if no income was so derived, would have been from such sources), and

"(iii) income derived from the property acquired in the exchange would be from sources outside the United States.

"(C) EXCEPTION.—Subparagraph (A) shall not apply if the individual enters into an agreement with the Secretary which specifies that any income or gain derived from the property acquired in the exchange (or any other property which has a basis determined in whole or part by reference to such property) during such 10–year period shall be treated as from sources within the United States. If the property transferred in the exchange is disposed of by the person acquiring such property, such agreement shall terminate and any gain which was not recognized by reason of such agreement shall be recognized as of the date of such disposition.

"(D) SECRETARY MAY EXTEND PERIOD.—To the extent provided in regulations prescribed by the Secretary, subparagraph (B) shall be applied by substituting the 15–year period beginning 5 years before the loss of United States citizenship for the 10–year period referred to therein.

"(E) SECRETARY MAY REQUIRE RECOGNITION OF GAIN IN CERTAIN CASES.—To the extent provided in regulations prescribed by the Secretary—

"(i) the removal of appreciated tangible personal property from the United States, and

"(ii) any other occurrence which (without recognition of gain) results in a change in the source of the income or gain from property from sources within the United States to sources outside the United States,

shall be treated as an exchange to which this paragraph applies.

"(3) SUBSTANTIAL DIMINISHING OF RISKS OF OWNERSHIP.—For purposes of determining whether this section applies to any gain on the sale or exchange of any property, the running of the 10–year period described in subsection (a) shall be suspended for any period during which the individual's risk of loss with respect to the property is substantially diminished by—

"(A) the holding of a put with respect to such property (or similar property),

"(B) the holding by another person of a right to acquire the property, or

"(C) a short sale or any other transaction.

"(4) TREATMENT OF PROPERTY CONTRIBUTED TO CONTROLLED FOREIGN CORPORATIONS.—

"(A) IN GENERAL.—If—

"(i) an individual losing United States citizenship contributes property to any corporation which, at the time of the contribution, is described in subparagraph (B), and

"(ii) income derived from such property was from sources within the United States (or, if no income was so derived, would have been from such sources),

during the 10–year period referred to in subsection (a), any income or gain on such property (or any other property which has a basis determined in whole or part by reference to such property) received or accrued by the corporation shall be treated as received or accrued directly by such individual and not by such corporation. The preceding sentence shall not apply to the extent the property has been treated under subparagraph (C) as having been sold by such corporation.

"(B) CORPORATION DESCRIBED.—A corporation is described in this subparagraph with respect to an individual if, were such individual a United States citizen—

"(i) such corporation would be a controlled foreign corporation (as defined in 957), and

"(ii) such individual would be a United States shareholder (as defined in section 951(b)) with respect to such corporation.

"(C) DISPOSITION OF STOCK IN CORPORATION.—If stock in the corporation referred to in subparagraph (A) (or any other stock which has a basis determined in whole or part by reference to such stock) is disposed of during the 10–year period referred to in subsection (a) and while the property referred to in subparagraph (A) is held by such corporation, a pro rata share of such property (determined on the basis of the value of such stock) shall be treated as sold by the corporation immediately before such disposition.

"(D) ANTI–ABUSE RULES.—The Secretary shall prescribe such regulations as may be necessary to prevent the avoidance of the purposes of this paragraph, including where—

"(i) the property is sold to the corporation, and

"(ii) the property taken into account under subparagraph (A) is sold by the corporation.

"(E) INFORMATION REPORTING.—The Secretary shall require such information reporting as is necessary to carry out the purposes of this paragraph.".

(d) CREDIT FOR FOREIGN TAXES IMPOSED ON UNITED STATES SOURCE INCOME.—

(1) Subsection (b) of section 877 is amended by adding at the end the following new sentence: "The tax imposed solely by reason of this section shall be reduced (but not below zero) by the amount of any income, war profits, and excess profits taxes (within the meaning of section 903) paid to any foreign country or possession of the United States on any income of the taxpayer on which tax is imposed solely by reason of this section."

(2) Subsection (a) of section 877, as amended by subsection (a), is amended by inserting "(after any reduction in such tax under the last sentence of such subsection)" after "such subsection".

(e) COMPARABLE ESTATE AND GIFT TAX TREATMENT.—

(1) ESTATE TAX.—

<< 26 USCA § 2107 >>

(A) IN GENERAL.—Subsection (a) of section 2107 is amended to read as follows:

"(a) TREATMENT OF EXPATRIATES.—

"(1) RATE OF TAX.—A tax computed in accordance with the table contained in section 2001 is hereby imposed on the transfer of the taxable estate, determined as provided in section 2106, of every decedent nonresident not a citizen of the United States if, within the 10–year period ending with the date of death, such decedent lost United States citizenship, unless such loss did not have for one of its principal purposes the avoidance of taxes under this subtitle or subtitle A.

"(2) CERTAIN INDIVIDUALS TREATED AS HAVING TAX AVOIDANCE PURPOSE.—

"(A) IN GENERAL.—For purposes of paragraph (1), an individual shall be treated as having a principal purpose to avoid such taxes if such individual is so treated under section 877(a)(2).

"(B) EXCEPTION.—Subparagraph (A) shall not apply to a decedent meeting the requirements of section 877(c)(1).".

(B) CREDIT FOR FOREIGN DEATH TAXES.—Subsection (c) of section 2107 is amended by redesignating paragraph (2) as paragraph (3) and by inserting after paragraph (1) the following new paragraph:

"(2) CREDIT FOR FOREIGN DEATH TAXES.—

"(A) IN GENERAL.—The tax imposed by subsection (a) shall be credited with the amount of any estate, inheritance, legacy, or succession taxes actually paid to any foreign country in respect of any property which is included in the gross estate solely by reason of subsection (b).

"(B) LIMITATION ON CREDIT.—The credit allowed by subparagraph (A) for such taxes paid to a foreign country shall not exceed the lesser of—

"(i) the amount which bears the same ratio to the amount of such taxes actually paid to such foreign country in respect of property included in the gross estate as the value of the property included in the gross estate solely by reason of subsection (b) bears to the value of all property subjected to such taxes by such foreign country, or

"(ii) such property's proportionate share of the excess of—

"(I) the tax imposed by subsection (a), over

"(II) the tax which would be imposed by section 2101 but for this section.

"(C) PROPORTIONATE SHARE.—For purposes of subparagraph (B), a property's proportionate share is the percentage of the value of the property which is included in the gross estate solely by reason of subsection (b) bears to the total value of the gross estate.".

(C) EXPANSION OF INCLUSION IN GROSS ESTATE OF STOCK OF FOREIGN CORPORATIONS.—Paragraph (2) of section 2107(b) is amended by striking "more than 50 percent of" and all that follows and inserting "more than 50 percent of—

"(A) the total combined voting power of all classes of stock entitled to vote of such corporation, or

"(B) the total value of the stock of such corporation,".

<< 26 USCA § 2501 >>

(2) GIFT TAX.—

(A) IN GENERAL.—Paragraph (3) of section 2501(a) is amended to read as follows:

"(3) EXCEPTION.—

"(A) CERTAIN INDIVIDUALS.—Paragraph (2) shall not apply in the case of a donor who, within the 10–year period ending with the date of transfer, lost United States citizenship, unless such loss did not have for one of its principal purposes the avoidance of taxes under this subtitle or subtitle A.

"(B) CERTAIN INDIVIDUALS TREATED AS HAVING TAX AVOIDANCE PURPOSE.—For purposes of subparagraph (A), an individual shall be treated as having a principal purpose to avoid such taxes if such individual is so treated under section 877(a)(2).

"(C) EXCEPTION FOR CERTAIN INDIVIDUALS.—Subparagraph (B) shall not apply to a decedent meeting the requirements of section 877(c)(1).

"(D) CREDIT FOR FOREIGN GIFT TAXES.—The tax imposed by this section solely by reason of this paragraph shall be credited with the amount of any gift tax actually paid to any foreign country in respect of any gift which is taxable under this section solely by reason of this paragraph.".

(f) COMPARABLE TREATMENT OF LAWFUL PERMANENT RESIDENTS WHO CEASE TO BE TAXED AS RESIDENTS.—

<< 26 USCA § 877 >>

(1) IN GENERAL.—Section 877 is amended by redesignating subsection (e) as subsection (f) and by inserting after subsection (d) the following new subsection:

"(e) COMPARABLE TREATMENT OF LAWFUL PERMANENT RESIDENTS WHO CEASE TO BE TAXED AS RESIDENTS.—

"(1) IN GENERAL.—Any long-term resident of the United States who—

"(A) ceases to be a lawful permanent resident of the United States (within the meaning of section 7701(b)(6)), or

"(B) commences to be treated as a resident of a foreign country under the provisions of a tax treaty between the United States and the foreign country and who does not waive the benefits of such treaty applicable to residents of the foreign country,

shall be treated for purposes of this section and sections 2107, 2501, and 6039F in the same manner as if such resident were a citizen of the United States who lost United States citizenship on the date of such cessation or commencement.

"(2) LONG–TERM RESIDENT.—For purposes of this subsection, the term 'long-term resident' means any individual (other than a citizen of the United States) who is a lawful permanent resident of the United States in at least 8 taxable years during the period of 15 taxable years ending with the taxable year during which the event described in subparagraph (A) or (B) of paragraph (1) occurs. For purposes of the preceding sentence, an individual shall not be treated as a lawful permanent resident for any taxable year if such individual is treated as a resident of a foreign country for the taxable year under the provisions of a tax treaty between the United States and the foreign country and does not waive the benefits of such treaty applicable to residents of the foreign country.

"(3) SPECIAL RULES.—

"(A) EXCEPTIONS NOT TO APPLY.—Subsection (c) shall not apply to an individual who is treated as provided in paragraph (1).

"(B) STEP–UP IN BASIS.—Solely for purposes of determining any tax imposed by reason of this subsection, property which was held by the long-term resident on the date the individual first became a resident of the United States shall be treated as having a basis on such date of not less than the fair market value of such property on such date. The preceding sentence shall not apply if the individual elects not to have such sentence apply. Such an election, once made, shall be irrevocable.

"(4) AUTHORITY TO EXEMPT INDIVIDUALS.—This subsection shall not apply to an individual who is described in a category of individuals prescribed by regulation by the Secretary.

"(5) REGULATIONS.—The Secretary shall prescribe such regulations as may be appropriate to carry out this subsection, including regulations providing for the application of this subsection in cases where an alien individual becomes a resident of the United States during the 10–year period after being treated as provided in paragraph (1).".

(2) CONFORMING AMENDMENTS.—

<< 26 USCA § 2107 >>

(A) Section 2107 is amended by striking subsection (d), by redesignating subsection (e) as subsection (d), and by inserting after subsection (d) (as so redesignated) the following new subsection:

"(e) CROSS REFERENCE.—

"For comparable treatment of long-term lawful permanent residents who ceased to be taxed as residents, see section 877(e).".

<< 26 USCA § 2501 >>

(B) Paragraph (3) of section 2501(a) (as amended by subsection (e)) is amended by adding at the end the following new subparagraph:

"(E) CROSS REFERENCE.—

"For comparable treatment of long-term lawful permanent residents who ceased to be taxed as residents, see section 877(e).".

<< 26 USCA §§ 877 NOTE, 2107 nt, 2501 nt >>

(g) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to—

(A) individuals losing United States citizenship (within the meaning of section 877 of the Internal Revenue Code of 1986) on or after February 6, 1995, and

(B) long-term residents of the United States with respect to whom an event described in subparagraph (A) or (B) of section 877(e)(1) of such Code occurs on or after February 6, 1995.

(2) RULING REQUESTS.—In no event shall the 1–year period referred to in section 877(c)(1)(B) of such Code, as amended by this section, expire before the date which is 90 days after the date of the enactment of this Act.

(3) SPECIAL RULE.—

(A) IN GENERAL.—In the case of an individual who performed an act of expatriation specified in paragraph (1), (2), (3), or (4) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(1)–(4)) before February 6, 1995, but who did not, on or before such date, furnish to the United States Department of State a signed statement of voluntary relinquishment of United States nationality confirming the performance of such act, the amendments made by this section and section 512 shall apply to such individual except that the 10–year period described in section 877(a) of such Code shall not expire before the end of the 10–year period beginning on the date such statement is so furnished.

(B) EXCEPTION.—Subparagraph (A) shall not apply if the individual establishes to the satisfaction of the Secretary of the Treasury that such loss of United States citizenship occurred before February 6, 1994.

SEC. 512. INFORMATION ON INDIVIDUALS LOSING UNITED STATES CITIZENSHIP.

<< 26 USCA § 6039F >>

(a) IN GENERAL.—Subpart A of part III of subchapter A of chapter 61 is amended by inserting after section 6039E the following new section:

"SEC. 6039F. INFORMATION ON INDIVIDUALS LOSING UNITED STATES CITIZENSHIP.

"(a) IN GENERAL.—Notwithstanding any other provision of law, any individual who loses United States citizenship (within the meaning of section 877(a)) shall provide a statement which includes the information described in subsection (b). Such statement shall be—

"(1) provided not later than the earliest date of any act referred to in subsection (c), and

"(2) provided to the person or court referred to in subsection (c) with respect to such act.

"(b) INFORMATION TO BE PROVIDED.—Information required under subsection (a) shall include—

"(1) the taxpayer's TIN,

"(2) the mailing address of such individual's principal foreign residence,

"(3) the foreign country in which such individual is residing,

"(4) the foreign country of which such individual is a citizen,

"(5) in the case of an individual having a net worth of at least the dollar amount applicable under section 877(a)(2)(B), information detailing the assets and liabilities of such individual, and

"(6) such other information as the Secretary may prescribe.

"(c) ACTS DESCRIBED.—For purposes of this section, the acts referred to in this subsection are—

"(1) the individual's renunciation of his United States nationality before a diplomatic or consular officer of the United States pursuant to paragraph (5) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(5)),

"(2) the individual's furnishing to the United States Department of State a signed statement of voluntary relinquishment of United States nationality confirming the performance of an act of expatriation specified in paragraph (1), (2), (3), or (4) of section 349(a) of the Immigration and Nationality Act (8 U.S.C. 1481(a)(1)–(4)),

"(3) the issuance by the United States Department of State of a certificate of loss of nationality to the individual, or

"(4) the cancellation by a court of the United States of a naturalized citizen's certificate of naturalization.

"(d) PENALTY.—Any individual failing to provide a statement required under subsection (a) shall be subject to a penalty for each year (of the 10–year period beginning on the date of loss of United States citizenship) during any portion of which such failure continues in an amount equal to the greater of—

"(1) 5 percent of the tax required to be paid under section 877 for the taxable year ending during such year, or

"(2) $1,000,

unless it is shown that such failure is due to reasonable cause and not to willful neglect.

"(e) INFORMATION TO BE PROVIDED TO SECRETARY.—Notwithstanding any other provision of law—

"(1) any Federal agency or court which collects (or is required to collect) the statement under subsection (a) shall provide to the Secretary—

"(A) a copy of any such statement, and

"(B) the name (and any other identifying information) of any individual refusing to comply with the provisions of subsection (a),

"(2) the Secretary of State shall provide to the Secretary a copy of each certificate as to the loss of American nationality under section 358 of the Immigration and Nationality Act which is approved by the Secretary of State, and

"(3) the Federal agency primarily responsible for administering the immigration laws shall provide to the Secretary the name of each lawful permanent resident of the United States (within the meaning of section 7701(b)(6)) whose status as such has been revoked or has been administratively or judicially determined to have been abandoned.

Notwithstanding any other provision of law, not later than 30 days after the close of each calendar quarter, the Secretary shall publish in the Federal Register the name of each individual losing United States citizenship (within the meaning of section 877(a)) with respect to whom the Secretary receives information under the preceding sentence during such quarter.

"(f) REPORTING BY LONG–TERM LAWFUL PERMANENT RESIDENTS WHO CEASE TO BE TAXED AS RESIDENTS.—In lieu of applying the last sentence of subsection (a), any individual who is required to provide a statement under this section by reason of section 877(e)(1) shall provide such statement with the return of tax imposed by chapter 1 for the taxable year during which the event described in such section occurs.

"(g) EXEMPTION.—The Secretary may by regulations exempt any class of individuals from the requirements of this section if he determines that applying this section to such individuals is not necessary to carry out the purposes of this section.".

<< 26 USCA Ch. 61 >>

(b) CLERICAL AMENDMENT.—The table of sections for such subpart A is amended by inserting after the item relating to section 6039E the following new item:

"Sec. 6039F. Information on individuals losing United States citizenship.".

<< 26 USCA § 6039F NOTE >>

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to—

(1) individuals losing United States citizenship (within the meaning of section 877 of the Internal Revenue Code of 1986) on or after February 6, 1995, and

(2) long-term residents of the United States with respect to whom an event described in subparagraph (A) or (B) of section 877(e)(1) of such Code occurs on or after such date.

In no event shall any statement required by such amendments be due before the 90th day after the date of the enactment of this Act.

SEC. 513. REPORT ON TAX COMPLIANCE BY UNITED STATES CITIZENS AND RESIDENTS LIVING ABROAD.

Not later than 90 days after the date of the enactment of this Act, the Secretary of the Treasury shall prepare and submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report—

(1) describing the compliance with subtitle A of the Internal Revenue Code of 1986 by citizens and lawful permanent residents of the United States (within the meaning of section 7701(b)(6) of such Code) residing outside the United States, and

(2) recommending measures to improve such compliance (including improved coordination between executive branch agencies).

Subtitle C—Repeal of Financial Institution Transition Rule to Interest Allocation Rules

<< 26 USCA § 864 NOTE >>

SEC. 521. REPEAL OF FINANCIAL INSTITUTION TRANSITION RULE TO INTEREST ALLOCATION RULES.

(a) IN GENERAL.—Paragraph (5) of section 1215(c) of the Tax Reform Act of 1986 (Public Law 99–514, 100 Stat. 2548) is hereby repealed.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendment made by this section shall apply to taxable years beginning after December 31, 1995.

(2) SPECIAL RULE.—In the case of the first taxable year beginning after December 31, 1995, the pre-effective date portion of the interest expense of the corporation referred to in such paragraph (5) of such section 1215(c) for such taxable year shall be allocated and apportioned without regard to such amendment. For purposes of the preceding sentence, the pre-effective date portion is the amount which bears the same ratio to the interest expense for such taxable year as the number of days during such taxable year before the date of the enactment of this Act bears to 366.

Approved August 21, 1996.

PL 104–191, 1996 HR 3103

End of Document


KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Limitation Recognized by Krafsur v. Davenport, 6th Cir.(Tenn.), Dec. 04, 2013


KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 5. Government Organization and Employees (Refs & Annos)
Part I. The Agencies Generally
Chapter 7. Judicial Review (Refs & Annos)

5 U.S.C.A. § 706

§ 706. Scope of review

Currentness

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall--

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

Notes of Decisions (5750)

5 U.S.C.A. § 706, 5 USCA § 706
Current through P.L. 118-158. Some statute sections may be more current, see credits for details.

End of Document

65 FR 82462-01, 2000 WL 1875566(F.R.)
RULES and REGULATIONS
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
45 CFR Parts 160 and 164
RIN 0991-AB08

Standards for Privacy of Individually Identiifiable Health Information

Thursday, December 28, 2000

***82462** AGENCY: Office of the Assistant Secretary for Planning and Evaluation, DHHS.

ACTION: Final rule.

SUMMARY: This rule includes standards to protect the privacy of individually identifiable health information. The rules below, which apply to health plans, health care clearinghouses, and certain health care providers, present standards with respect to the rights of individuals who are the subjects of this information, procedures for the exercise of those rights, and the authorized and required uses and disclosures of this information.

The use of these standards will improve the efficiency and effectiveness of public and private health programs and health care services by providing enhanced protections for individually identifiable health information. These protections will begin to address growing public concerns that advances in electronic technology and evolution in the health care industry are resulting, or may result, in a substantial erosion of the privacy surrounding individually identifiable health information maintained by health care providers, health plans and their administrative contractors. This rule implements the privacy requirements of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996.

DATES: The final rule is effective on February 26, 2001.

FOR FURTHER INFORMATION CONTACT: Kimberly Coleman, 1-866-OCR-PRIV (1-866-627-7748) or TTY 1-866-788-4989.

SUPPLEMENTARY INFORMATION: Availability of copies, and electronic access.
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Purpose of the Administrative Simplification Regulations

This regulation has three major purposes: (1) To protect and enhance the rights of consumers by providing them access to their health information and controlling the inappropriate use of that information; (2) to improve the quality of health care in the U.S. by restoring trust in the health care system among consumers, health care professionals, and the multitude of organizations and individuals committed to the delivery of care; and (3) to improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, and individual organizations and individuals.

This regulation is the second final regulation to be issued in the package of rules mandated under title II subtitle F section 261-264 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, titled "Administrative Simplification." Congress called for steps to improve "the efficiency and effectiveness of the health care system by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information." To achieve that end, Congress required the Department to promulgate a set of interlocking regulations establishing standards and protections for health information systems. The first regulation in this set, Standards for Electronic Transactions 65 FR 50312, was published on August 17, 2000 (the "Transactions Rule"). This regulation establishing Standards for Privacy of Individually Identifiable Health Information is the second final rule in the package. A rule establishing a unique identifier for employers to use in electronic health care transactions, a rule establishing a unique identifier for providers for such transactions, and a rule establishing standards for the security of electronic information systems have been proposed. See 63 FR 25272 and 25320 (May 7, 1998); 63 FR 32784 (June 16, 1998); 63 FR 43242 (August 12, 1998). Still to be proposed are rules establishing a unique identifier for health plans for electronic transactions, standards for claims attachments, and standards for transferring among health plans appropriate standard data elements needed for coordination of benefits. (See section C, below, for a more detailed explanation of the statutory mandate for these regulations.)

In enacting HIPAA, Congress recognized the fact that administrative simplification cannot succeed if we do not also protect the privacy and confidentiality of personal health information. The provision of high-quality health care requires the exchange of personal, often-sensitive information between an individual and a skilled practitioner. Vital to that interaction is the patient's ability to trust that the information shared will be protected and kept confidential. Yet many patients are concerned that their information is not protected. Among the factors adding to this concern are the growth of the number of organizations involved in the provision of care and the processing of claims, the growing use of electronic information technology, increased efforts to market health care and other products to consumers, and the increasing ability to collect highly sensitive information about a person's current and future health status as a result of advances in scientific research.

Rules requiring the protection of health privacy in the United States have been enacted primarily by the states. While virtually every state has enacted one or more laws to safeguard privacy, these laws vary significantly from state to state and typically apply to only part of the health care system. Many states have adopted laws that protect the health information relating to certain health conditions such as mental illness, communicable diseases, cancer, HIV/AIDS, and other stigmatized conditions. An examination of state health privacy laws and regulations, ***82464** however, found that "state laws, with a few notable exceptions, do not extend comprehensive protections to people's medical records." Many state rules fail to provide such basic protections as ensuring a patient's legal right to see a copy of his or her medical record. See Health Privacy Project, "The State of Health Privacy: An Uneven Terrain," Institute for Health Care Research and Policy, Georgetown University (July 1999) (http://www.healthprivacy.org) (the "Georgetown Study").

Until now, virtually no federal rules existed to protect the privacy of health information and guarantee patient access to such information. This final rule establishes, for the first time, a set of basic national privacy standards and fair information practices that provides all Americans with a basic level of protection and peace of mind that is essential to their full participation in their care. The rule sets a floor of ground rules for health care providers, health plans, and health care clearinghouses to follow, in order to protect patients and encourage them to seek needed care. The rule seeks to balance the needs of the individual with the needs of the society. It creates a framework of protection that can be strengthened by both the federal government and by states as health information systems continue to evolve.

Need for a National Health Privacy Framework

The Importance of Privacy

Privacy is a fundamental right. As such, it must be viewed differently than any ordinary economic good. The costs and benefits of a regulation must, of course, be considered as a means of identifying and weighing options. At the same time, it is important not to lose sight of the inherent meaning of privacy: it speaks to our individual and collective freedom.

A right to privacy in personal information has historically found expression in American law. All fifty states today recognize in tort law a common law or statutory right to privacy. Many states specifically provide a remedy for public revelation of private facts. Some states, such as California and Tennessee, have a right to privacy as a matter of state constitutional law. The multiple historical sources for legal rights to privacy are traced in many places, including Chapter 13 of Alan Westin's Privacy and Freedom and in Ellen Alderman & Caroline Kennedy, The Right to Privacy (1995).

Throughout our nation's history, we have placed the rights of the individual at the forefront of our democracy. In the Declaration of Independence, we asserted the “unalienable right” to “life, liberty and the pursuit of happiness.” Many of the most basic protections in the Constitution of the United States are imbued with an attempt to protect individual privacy while balancing it against the larger social purposes of the nation.

To take but one example, the Fourth Amendment to the United States Constitution guarantees that “the right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated.” By referring to the need for security of “persons” as well as “papers and effects” the Fourth Amendment suggests enduring values in American law that relate to privacy. The need for security of “persons” is consistent with obtaining patient consent before performing invasive medical procedures. The need for security in “papers and effects” underscores the importance of protecting information about the person, contained in sources such as personal diaries, medical records, or elsewhere. As is generally true for the right of privacy in information, the right is not absolute. The test instead is what constitutes an “unreasonable” search of the papers and effects.

The United States Supreme Court has upheld the constitutional protection of personal health information. In Whalen v. Roe, 429 U.S. 589 (1977), the Court analyzed a New York statute that created a database of persons who obtained drugs for which there was both a lawful and unlawful market. The Court, in upholding the statute, recognized at least two different kinds of interests within the constitutionally protected “zone of privacy.” “One is the individual interest in avoiding disclosure of personal matters,” such as this regulation principally addresses. This interest in avoiding disclosure, discussed in Whalen in the context of medical information, was found to be distinct from a different line of cases concerning “the interest in independence in making certain kinds of important decisions.”

Individuals' right to privacy in information about themselves is not absolute. It does not, for instance, prevent reporting of public health information on communicable diseases or stop law enforcement from getting information when due process has been observed. But many people believe that individuals should have some right to control personal and sensitive information about themselves. Among different sorts of personal information, health information is among the most sensitive. Many people believe that details about their physical self should not generally be put on display for neighbors, employers, and government officials to see. Informed consent laws place limits on the ability of other persons to intrude physically on a person's body. Similar concerns apply to intrusions on information about the person.

Moving beyond these facts of physical treatment, there is also significant intrusion when records reveal details about a person's mental state, such as during treatment for mental health. If, in Justice Brandeis' words, the “right to be let alone” means anything, then it likely applies to having outsiders have access to one's intimate thoughts, words, and emotions. In the recent case of Jaffee v. Redmond, 116 S.Ct. 1923 (1996), the Supreme Court held that statements made to a therapist during a counseling session were protected against civil discovery under the Federal Rules of Evidence. The Court noted that all fifty states have adopted some form of the psychotherapist-patient privilege. In upholding the federal privilege, the Supreme Court stated that it “serves the public interest by facilitating the appropriate treatment for individuals suffering the effects of a mental or emotional problem. The mental health of our citizenry, no less than its physical health, is a public good of transcendent importance.”

Many writers have urged a philosophical or common-sense right to privacy in one's personal information. Examples include Alan Westin, Privacy and Freedom (1967) and Janna Malamud Smith, Private Matters: In Defense of the Personal Life (1997). These writings emphasize the link between privacy and freedom and privacy and the “personal life,” or the ability to develop one's own personality and self-expression. Smith, for instance, states:

The bottom line is clear. If we continually, gratuitously, reveal other people's privacies, we harm them and ourselves, we undermine the richness of the personal life, and we fuel a social atmosphere of mutual exploitation. Let me put it another way: Little in life is as precious as the freedom to say and do things with people you love that you would not say or do if someone else were present. And few experiences are as fundamental to liberty and autonomy as maintaining control over when, how, to whom, and where you disclose personal material. Id. at 240-241.

In 1890, Louis D. Brandeis and Samuel D. Warren defined the right to privacy as "the right to be let alone." See L. Brandeis, S. Warren, "The Right ***82465** To Privacy," 4 Harv.L.Rev. 193. More than a century later, privacy continues to play an important role in Americans' lives. In their book, The Right to Privacy, (Alfred A. Knopf, New York, 1995) Ellen Alderman and Caroline Kennedy describe the importance of privacy in this way:

Privacy covers many things. It protects the solitude necessary for creative thought. It allows us the independence that is part of raising a family. It protects our right to be secure in our own homes and possessions, assured that the government cannot come barging in. Privacy also encompasses our right to self-determination and to define who we are. Although we live in a world of noisy self-confession, privacy allows us to keep certain facts to ourselves if we so choose. The right to privacy, it seems, is what makes us civilized.

Or, as Cavoukian and Tapscott observed the right of privacy is: "the claim of individuals, groups, or institutions to determine for themselves when, how, and to what extent information about them is communicated." See A. Cavoukian, D. Tapscott, "Who Knows: Safeguarding Your Privacy in a Networked World," Random House (1995).

Increasing Public Concern About Loss of Privacy

Today, it is virtually impossible for any person to be truly "let alone." The average American is inundated with requests for information from potential employers, retail shops, telephone marketing firms, electronic marketers, banks, insurance companies, hospitals, physicians, health plans, and others. In a 1998 national survey, 88 percent of consumers said they were "concerned" by the amount of information being requested, including 55 percent who said they were "very concerned." See Privacy and American Business, 1998 Privacy Concerns & Consumer Choice Survey (http://www.pandab.org). These worries are not just theoretical. Consumers who use the Internet to make purchases or request "free" information often are asked for personal and financial information. Companies making such requests routinely promise to protect the confidentiality of that information. Yet several firms have tried to sell this information to other companies even after promising not to do so.

Americans' concern about the privacy of their health information is part of a broader anxiety about their lack of privacy in an array of areas. A series of national public opinion polls conducted by Louis Harris & Associates documents a rising level of public concern about privacy, growing from 64 percent in 1978 to 82 percent in 1995. Over 80 percent of persons surveyed in 1999 agreed with the statement that they had "lost all control over their personal information." See Harris Equifax, Health Information Privacy Study (1993) (http:// www.epic.org/privacy/medical/polls.html). A Wall Street Journal/ABC poll on September 16, 1999 asked Americans what concerned them most in the coming century. "Loss of personal privacy" was the first or second concern of 29 percent of respondents. All other issues, such a terrorism, world war, and global warming had scores of 23 percent or less.

This growing concern stems from several trends, including the growing use of interconnected electronic media for business and personal activities, our increasing ability to know an individual's genetic make-up, and, in health care, the increasing complexity of the system. Each of these trends brings the potential for tremendous benefits to individuals and society generally. At the same time, each also brings new potential for invasions of our privacy.

Increasing Use of Interconnected Electronic Information Systems

Until recently, health information was recorded and maintained on paper and stored in the offices of community-based physicians, nurses, hospitals, and other health care professionals and institutions. In some ways, this imperfect system of record

keeping created a false sense of privacy among patients, providers, and others. Patients' health information has never remained completely confidential. Until recently, however, a breach of confidentiality involved a physical exchange of paper records or a verbal exchange of information. Today, however, more and more health care providers, plans, and others are utilizing electronic means of storing and transmitting health information. In 1996, the health care industry invested an estimated $10 billion to $15 billion on information technology. See National Research Council, Computer Science and Telecommunications Board, “For the Record: Protecting Electronic Health Information,” (1997). The electronic information revolution is transforming the recording of health information so that the disclosure of information may require only a push of a button. In a matter of seconds, a person's most profoundly private information can be shared with hundreds, thousands, even millions of individuals and organizations at a time. While the majority of medical records still are in paper form, information from those records is often copied and transmitted through electronic means.

This ease of information collection, organization, retention, and exchange made possible by the advances in computer and other electronic technology affords many benefits to individuals and to the health care industry. Use of electronic information has helped to speed the delivery of effective care and the processing of billions of dollars worth of health care claims. Greater use of electronic data has also increased our ability to identify and treat those who are at risk for disease, conduct vital research, detect fraud and abuse, and measure and improve the quality of care delivered in the U.S. The National Research Council recently reported that “the Internet has great potential to improve Americans” health by enhancing communications and improving access to information for care providers, patients, health plan administrators, public health officials, biomedical researchers, and other health professionals.” See “Networking Health: Prescriptions for the Internet,” National Academy of Sciences (2000).

At the same time, these advances have reduced or eliminated many of the financial and logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals. And they have made our information available to many more people. The shift from paper to electronic records, with the accompanying greater flows of sensitive health information, thus strengthens the arguments for giving legal protection to the right to privacy in health information. In an earlier period where it was far more expensive to access and use medical records, the risk of harm to individuals was relatively low. In the potential near future, when technology makes it almost free to send lifetime medical records over the Internet, the risks may grow rapidly. It may become cost-effective, for instance, for companies to offer services that allow purchasers to obtain details of a person's physical and mental treatments. In addition to legitimate possible uses for such services, malicious or inquisitive persons may download medical records for purposes ranging from identity theft to embarrassment to prurient interest in the life of a celebrity or neighbor. The comments to the proposed privacy rule indicate that many persons believe that they have a right to live in society without having these details of their lives laid open to unknown and possibly hostile eyes. These technological changes, in short, may provide a reason for institutionalizing ***82466** privacy protections in situations where the risk of harm did not previously justify writing such protections into law.

The growing level of trepidation about privacy in general, noted above, has tracked the rise in electronic information technology. Americans have embraced the use of the Internet and other forms of electronic information as a way to provide greater access to information, save time, and save money. For example, 60 percent of Americans surveyed in 1999 reported that they have a computer in their home; 82 percent reported that they have used a computer; 64 percent say they have used the Internet; and 58 percent have sent an e-mail. Among those who are under the age of 60, these percentages are even higher. See “National Survey of Adults on Technology,” Henry J. Kaiser Family Foundation (February, 2000). But 59 percent of Americans reported that they worry that an unauthorized person will gain access to their information. A recent survey suggests that 75 percent of consumers seeking health information on the Internet are concerned or very concerned about the health sites they visit sharing their personal health information with a third party without their permission. Ethics Survey of Consumer Attitudes about Health Web Sites, California Health Care Foundation, at 3 (January, 2000).

Unless public fears are allayed, we will be unable to obtain the full benefits of electronic technologies. The absence of national standards for the confidentiality of health information has made the health care industry and the population in general uncomfortable about this primarily financially-driven expansion in the use of electronic data. Many plans, providers, and clearinghouses have taken steps to safeguard the privacy of individually identifiable health information. Yet they must currently

rely on a patchwork of State laws and regulations that are incomplete and, at times, inconsistent. States have, to varying degrees, attempted to enhance confidentiality by establishing laws governing at least some aspects of medical record privacy. This approach, though a step in the right direction, is inadequate. These laws fail to provide a consistent or comprehensive legal foundation of health information privacy. For example, there is considerable variation among the states in the type of information protected and the scope of the protections provided. See Georgetown Study, at Executive Summary; Lawrence O. Gostin, Zita Lazzarrini, Kathleen M. Flaherty, Legislative Survey of State Confidentiality Laws, with Specific Emphasis on HIV and Immunization, Report to Centers for Disease Control, Council of State and Territorial Epidemiologists, and Task Force for Child Survival and Development, Carter Presidential Center (1996) (Gostin Study).

Moreover, electronic health data is becoming increasingly "national"; as more information becomes available in electronic form, it can have value far beyond the immediate community where the patient resides. Neither private action nor state laws provide a sufficiently comprehensive and rigorous legal structure to allay public concerns, protect the right to privacy, and correct the market failures caused by the absence of privacy protections (see discussion below of market failure under section V.C). Hence, a national policy with consistent rules is necessary to encourage the increased and proper use of electronic information while also protecting the very real needs of patients to safeguard their privacy.

Advances in Genetic Sciences

Recently, scientists completed nearly a decade of work unlocking the mysteries of the human genome, creating tremendous new opportunities to identify and prevent many of the leading causes of death and disability in this country and around the world. Yet the absence of privacy protections for health information endanger these efforts by creating a barrier of distrust and suspicion among consumers. A 1995 national poll found that more than 85 percent of those surveyed were either "very concerned" or "somewhat concerned" that insurers and employers might gain access to and use genetic information. See Harris Poll, 1995 #34. Sixty-three percent of the 1,000 participants in a 1997 national survey said they would not take genetic tests if insurers and employers could gain access to the results. See "Genetic Information and the Workplace," Department of Labor, Department of Health and Human Services, Equal Employment Opportunity Commission, January 20, 1998. "In genetic testing studies at the National Institutes of Health, thirty-two percent of eligible people who were offered a test for breast cancer risk declined to take it, citing concerns about loss of privacy and the potential for discrimination in health insurance." Sen. Leahy's comments for March 10, 1999 Introduction of the Medical Information Privacy and Security Act.

The Changing Health Care System

The number of entities who are maintaining and transmitting individually identifiable health information has increased significantly over the last 10 years. In addition, the rapid growth of integrated health care delivery systems requires greater use of integrated health information systems. The health care industry has been transformed from one that relied primarily on one-on-one interactions between patients and clinicians to a system of integrated health care delivery networks and managed care providers. Such a system requires the processing and collection of information about patients and plan enrollees (for example, in claims files or enrollment records), resulting in the creation of databases that can be easily transmitted. This dramatic change in the practice of medicine brings with it important prospects for the improvement of the quality of care and reducing the cost of that care. It also, however, means that increasing numbers of people have access to health information. And, as health plan functions are increasingly outsourced, a growing number of organizations not affiliated with our physicians or health plans also have access to health information.

According to the American Health Information Management Association (AHIMA), an average of 150 people "from nursing staff to x-ray technicians, to billing clerks" have access to a patient's medical records during the course of a typical hospitalization. While many of these individuals have a legitimate need to see all or part of a patient's records, no laws govern who those people are, what information they are able to see, and what they are and are not allowed to do with that information once they have access to it. According to the National Research Council, individually identifiable health information frequently is shared with:

- Consulting physicians;

- Managed care organizations;

- Health insurance companies

- Life insurance companies;

- Self-insured employers;

- Pharmacies;

- Pharmacy benefit managers;

- Clinical laboratories;

- Accrediting organizations;

- State and Federal statistical agencies; and

- Medical information bureaus.

Much of this sharing of information is done without the knowledge of the patient involved. While many of these functions are important for smooth functioning of the health care system, there are no rules governing how that ***82467** information is used by secondary and tertiary users. For example, a pharmacy benefit manager could receive information to determine whether an insurance plan or HMO should cover a prescription, but then use the information to market other products to the same patient. Similarly, many of us obtain health insurance coverage though our employer and, in some instances, the employer itself acts as the insurer. In these cases, the employer will obtain identifiable health information about its employees as part of the legitimate health insurance functions such as claims processing, quality improvement, and fraud detection activities. At the same time, there is no comprehensive protection prohibiting the employer from using that information to make decisions about promotions or job retention.
Public concerns reflect these developments. A 1993 Lou Harris poll found that 75 percent of those surveyed worry that medical information from a computerized national health information system will be used for many non-health reasons, and 38 percent are very concerned. This poll, taken during the health reform efforts of 1993, showed that 85 percent of respondents believed that protecting the confidentiality of medical records is “absolutely essential” or “very essential” in health care reform. An ACLU Poll in 1994 also found that 75 percent of those surveyed are concerned a “great deal” or a “fair amount’" about insurance companies putting medical information about them into a computer information bank to which others have access. Harris Equifax, Health Information Privacy Study 2,33 (1993) http:// www.epic.org/privacy/medical/poll.html. Another survey found that 35 percent of Fortune 500 companies look at people's medical records before making hiring and promotion decisions. Starr, Paul. “Health and the Right to Privacy,” American Journal of Law and Medicine, 1999. Vol 25, pp. 193-201.

Concerns about the lack of attention to information privacy in the health care industry are not merely theoretical. In the absence of a national legal framework of health privacy protections, consumers are increasingly vulnerable to the exposure of their personal health information. Disclosure of individually identifiable information can occur deliberately or accidentally and can occur within an organization or be the result of an external breach of security. Examples of recent privacy breaches include:

- A Michigan-based health system accidentally posted the medical records of thousands of patients on the Internet (The Ann Arbor News, February 10, 1999).

- A Utah-based pharmaceutical benefits management firm used patient data to solicit business for its owner, a drug store (Kiplingers, February 2000).

- An employee of the Tampa, Florida, health department took a computer disk containing the names of 4,000 people who had tested positive for HIV, the virus that causes AIDS (USA Today, October 10, 1996).

- The health insurance claims forms of thousands of patients blew out of a truck on its way to a recycling center in East Hartford, Connecticut (The Hartford Courant, May 14, 1999).

- A patient in a Boston-area hospital discovered that her medical record had been read by more than 200 of the hospital's employees (The Boston Globe, August 1, 2000).

- A Nevada woman who purchased a used computer discovered that the computer still contained the prescription records of the customers of the pharmacy that had previously owned the computer. The pharmacy data base included names, addresses, social security numbers, and a list of all the medicines the customers had purchased. (The New York Times, April 4, 1997 and April 12, 1997).

- A speculator bid $4000 for the patient records of a family practice in South Carolina. Among the businessman's uses of the purchased records was selling them back to the former patients. (New York Times, August 14, 1991).

- In 1993, the Boston Globe reported that Johnson and Johnson marketed a list of 5 million names and addresses of elderly incontinent women. (ACLU Legislative Update, April 1998).

- A few weeks after an Orlando woman had her doctor perform some routine tests, she received a letter from a drug company promoting a treatment for her high cholesterol. (Orlando Sentinel, November 30, 1997).

No matter how or why a disclosure of personal information is made, the harm to the individual is the same. In the face of industry evolution, the potential benefits of our changing health care system, and the real risks and occurrences of harm, protection of privacy must be built into the routine operations of our health care system.

Privacy Is Necessary To Secure Effective, High Quality Health Care

While privacy is one of the key values on which our society is built, it is more than an end in itself. It is also necessary for the effective delivery of health care, both to individuals and to populations. The market failures caused by the lack of effective privacy protections for health information are discussed below (see section V.C below). Here, we discuss how privacy is a necessary foundation for delivery of high quality health care. In short, the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers.

The need for privacy of health information, in particular, has long been recognized as critical to the delivery of needed medical care. More than anything else, the relationship between a patient and a clinician is based on trust. The clinician must trust the patient to give full and truthful information about their health, symptoms, and medical history. The patient must trust the clinician to use that information to improve his or her health and to respect the need to keep such information private. In order to receive accurate and reliable diagnosis and treatment, patients must provide health care professionals with accurate, detailed information about their personal health, behavior, and other aspects of their lives. The provision of health information assists in the diagnosis of an illness or condition, in the development of a treatment plan, and in the evaluation of the effectiveness of that treatment. In the absence of full and accurate information, there is a serious risk that the treatment plan will be inappropriate to the patient's situation.

Patients also benefit from the disclosure of such information to the health plans that pay for and can help them gain access to needed care. Health plans and health care clearinghouses rely on the provision of such information to accurately and promptly

process claims for payment and for other administrative functions that directly affect a patient's ability to receive needed care, the quality of that care, and the efficiency with which it is delivered.

Accurate medical records assist communities in identifying troubling public health trends and in evaluating the effectiveness of various public health efforts. Accurate information helps public and private payers make correct payments for care received and lower costs by identifying fraud. Accurate information provides scientists with data they need to conduct research. We cannot improve the quality of health care without information about which treatments work, and which do not.

Individuals cannot be expected to share the most intimate details of their lives unless they have confidence that such information will not be used or ***82468** shared inappropriately. Privacy violations reduce consumers' trust in the health care system and institutions that serve them. Such a loss of faith can impede the quality of the health care they receive, and can harm the financial health of health care institutions.

Patients who are worried about the possible misuse of their information often take steps to protect their privacy. Recent studies show that a person who does not believe his privacy will be protected is much less likely to participate fully in the diagnosis and treatment of his medical condition. A national survey conducted in January 1999 found that one in five Americans believe their health information is being used inappropriately. See California HealthCare Foundation, “National Survey: Confidentiality of Medical Records” (January, 1999) (http://www.chcf.org). More troubling is the fact that one in six Americans reported that they have taken some sort of evasive action to avoid the inappropriate use of their information by providing inaccurate information to a health care provider, changing physicians, or avoiding care altogether. Similarly, in its comments on our proposed rule, the Association of American Physicians and Surgeons reported 78 percent of its members reported withholding information from a patient's record due to privacy concerns and another 87 percent reported having had a patient request to withhold information from their records. For an example of this phenomenon in a particular demographic group, see Drs. Bearman, Ford, and Moody, “Foregone Health Care among Adolescents,” JAMA, vol. 282, no. 23 (999); Cheng, T.L., et al., “Confidentiality in Health Care: A Survey of Knowledge, Perceptions, and Attitudes among High School Students,” JAMA, vol. 269, no. 11 (1993), at 1404-1407.

The absence of strong national standards for medical privacy has widespread consequences. Health care professionals who lose the trust of their patients cannot deliver high-quality care. In 1999, a coalition of organizations representing various stakeholders including health plans, physicians, nurses, employers, disability and mental health advocates, accreditation organizations as well as experts in public health, medical ethics, information systems, and health policy adopted a set of “best principles” for health care privacy that are consistent with the standards we lay out here. (See the Health Privacy Working Group, “Best Principles for Health Privacy” (July, 1999) (Best Principles Study). The Best Principles Study states that—

To protect their privacy and avoid embarrassment, stigma, and discrimination, some people withhold information from their health care providers, provide inaccurate information, doctor-hop to avoid a consolidated medical record, pay out-of-pocket for care that is covered by insurance, and—in some cases—avoid care altogether.

Best Principles Study, at 9. In their comments on our proposed rule, numerous organizations representing health plans, health providers, employers, and others acknowledged the value of a set of national privacy standards to the efficient operation of their practices and businesses.

Breaches of Health Privacy Harm More Than Our Health Status

A breach of a person's health privacy can have significant implications well beyond the physical health of that person, including the loss of a job, alienation of family and friends, the loss of health insurance, and public humiliation. For example:

- A banker who also sat on a county health board gained access to patients' records and identified several people with cancer and called in their mortgages. See the National Law Journal, May 30, 1994.

- A physician was diagnosed with AIDS at the hospital in which he practiced medicine. His surgical privileges were suspended. See Estate of Behringer v. Medical Center at Princeton, 249 N.J. Super. 597.

- A candidate for Congress nearly saw her campaign derailed when newspapers published the fact that she had sought psychiatric treatment after a suicide attempt. See New York Times, October 10, 1992, Section 1, page 25.

- A 30-year FBI veteran was put on administrative leave when, without his permission, his pharmacy released information about his treatment for depression. (Los Angeles Times, September 1, 1998) Consumer Reports found that 40 percent of insurers disclose personal health information to lenders, employers, or marketers without customer permission. "Who's reading your Medical Records," Consumer Reports, October 1994, at 628, paraphrasing Sweeny, Latanya, "Weaving Technology and Policy Together to Maintain Confidentiality," The Journal Of Law Medicine and Ethics (Summer & Fall 1997) Vol. 25, Numbers 2,3.

The answer to these concerns is not for consumers to withdraw from society and the health care system, but for society to establish a clear national legal framework for privacy. By spelling out what is and what is not an allowable use of a person's identifiable health information, such standards can help to restore and preserve trust in the health care system and the individuals and institutions that comprise that system. As medical historian Paul Starr wrote: "Patients have a strong interest in preserving the privacy of their personal health information but they also have an interest in medical research and other efforts by health care organizations to improve the medical care they receive. As members of the wider community, they have an interest in public health measures that require the collection of personal data." (P. Starr, "Health and the Right to Privacy," American Journal of Law & Medicine, 25, nos. 2&3 (1999) 193-201). The task of society and its government is to create a balance in which the individual's needs and rights are balanced against the needs and rights of society as a whole.

National standards for medical privacy must recognize the sometimes competing goals of improving individual and public health, advancing scientific knowledge, enforcing the laws of the land, and processing and paying claims for health care services. This need for balance has been recognized by many of the experts in this field. Cavoukian and Tapscott described it this way: "An individual's right to privacy may conflict with the collective rights of the public * * *. We do not suggest that privacy is an absolute right that reigns supreme over all other rights. It does not. However, the case for privacy will depend on a number of factors that can influence the balance—the level of harm to the individual involved versus the needs of the public."

The Federal Response

There have been numerous federal initiatives aimed at protecting the privacy of especially sensitive personal information over the past several years—and several decades. While the rules below are likely the largest single federal initiative to protect privacy, they are by no means alone in the field. Rather, the rules arrive in the context of recent legislative activity to grapple with advances in technology, in addition to an already established body of law granting federal protections for personal privacy.

In 1965, the House of Representatives created a Special Subcommittee on Invasion of Privacy. In 1973, this Department's predecessor agency, the Department of Health, Education and Welfare issued The Code of Fair Information Practice Principles establishing an important baseline for ***82469** information privacy in the U.S. These principles formed the basis for the federal Privacy Act of 1974, which regulates the government's use of personal information by limiting the disclosure of personally-identifiable information, allows consumers access to information about them, requires federal agencies to specify the purposes for collecting personal information, and provides civil and criminal penalties for misuse of information.

In the last several years, with the rapid expansion in electronic technology—and accompanying concerns about individual privacy—laws, regulations, and legislative proposals have been developed in areas ranging from financial privacy to genetic privacy to the safeguarding of children on-line. For example, the Children's Online Privacy Protection Act was enacted in 1998, providing protection for children when interacting at web-sites. In February, 2000, President Clinton signed Executive Order 13145, banning the use of genetic information in federal hiring and promotion decisions. The landmark financial modernization bill, signed by the President in November, 1999, likewise contained financial privacy protections for consumers. There also

has been recent legislative activity on establishing legal safeguards for the privacy of individuals' Social Security numbers, and calls for regulation of on-line privacy in general.

These most recent laws, regulations, and legislative proposals come against the backdrop of decades of privacy-enhancing statutes passed at the federal level to enact safeguards in fields ranging from government data files to video rental records. In the 1970s, individual privacy was paramount in the passage of the Fair Credit Reporting Act (1970), the Privacy Act (1974), the Family Educational Rights and Privacy Act (1974), and the Right to Financial Privacy Act (1978). These key laws were followed in the next decade by another series of statutes, including the Privacy Protection Act (1980), the Electronic Communications Privacy Act (1986), the Video Privacy Protection Act (1988), and the Employee Polygraph Protection Act (1988). In the last ten years, Congress and the President have passed additional legal privacy protection through, among others, the Telephone Consumer Protection Act (1991), the Driver's Privacy Protection Act (1994), the Telecommunications Act (1996), the Children's Online Privacy Protection Act (1998), the Identity Theft and Assumption Deterrence Act (1998), and Title V of the Gramm-Leach-Bliley Act (1999) governing financial privacy.

In 1997, a Presidential advisory commission, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, recognized the need for patient privacy protection in its recommendations for a Consumer Bill of Rights and Responsibilities (November 1997). In 1997, Congress enacted the Balanced Budget Act (Public Law 105-34), which added language to the Social Security Act (18 U.S.C. 1852) to require Medicare+Choice organizations to establish safeguards for the privacy of individually identifiable patient information. Similarly, the Veterans Benefits section of the U.S. Code provides for confidentiality of medical records in cases involving drug abuse, alcoholism or alcohol abuse, HIV infection, or sickle cell anemia (38 U.S.C. 7332).

As described in more detail in the next section, Congress recognized the importance of protecting the privacy of health information by enacting the Health Insurance Portability and Accountability Act of 1996. The Act called on Congress to enact a medical privacy statute and asked the Secretary of Health and Human Services to provide Congress with recommendations for protecting the confidentiality of health care information. The Congress further recognized the importance of such standards by providing the Secretary with authority to promulgate regulations on health care privacy in the event that lawmakers were unable to act within the allotted three years.

Finally, it also is important for the U.S. to join the rest of the developed world in establishing basic medical privacy protections. In 1995, the European Union (EU) adopted a Data Privacy Directive requiring its 15 member states to adopt consistent privacy laws by October 1998. The EU urged all other nations to do the same or face the potential loss of access to information from EU countries.

Statutory Background

History of the Privacy Component of the Administrative Simplification Provisions

The Congress addressed the opportunities and challenges presented by the rapid evolution of health information systems in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, which was enacted on August 21, 1996. Sections 261 through 264 of HIPAA are known as the Administrative Simplification provisions. The major part of these Administrative Simplification provisions are found at section 262 of HIPAA, which enacted a new part C of title XI of the Social Security Act (hereinafter we refer to the Social Security Act as the “Act” and we refer to all other laws cited in this document by their names).

In section 262, Congress primarily sought to facilitate the efficiencies and cost savings for the health care industry that the increasing use of electronic technology affords. Thus, section 262 directs HHS to issue standards to facilitate the electronic exchange of information with respect to financial and administrative transactions carried out by health plans, health care clearinghouses, and health care providers who transmit information electronically in connection with such transactions.

At the same time, Congress recognized the challenges to the confidentiality of health information presented by the increasing complexity of the health care industry, and by advances in health information systems technology and communications. Section 262 thus also directs HHS to develop standards to protect the security, including the confidentiality and integrity, of health information.

Congress has long recognized the need for protection of health information privacy generally, as well as the privacy implications of electronic data interchange and the increased ease of transmitting and sharing individually identifiable health information. Congress has been working on broad health privacy legislation for many years and, as evidenced by the self-imposed three year deadline included in the HIPAA, discussed below, believes it can and should enact such legislation. A significant portion of the first Administrative Simplification section debated on the floor of the Senate in 1994 (as part of the Health Security Act) consisted of privacy provisions. In the version of the HIPAA passed by the House of Representatives in 1996, the requirement for the issuance of privacy standards was located in the same section of the bill (section 1173) as the requirements for issuance of the other HIPAA Administrative Simplification standards. In conference, the requirement for privacy standards was moved to a separate section in the same part of HIPAA, section 264, so that Congress could link the Privacy standards to Congressional action.

Section 264(b) requires the Secretary of HHS to develop and submit to the Congress recommendations for:

- The rights that an individual who is a subject of individually identifiable health information should have. ***82470**

- The procedures that should be established for the exercise of such rights.

- The uses and disclosures of such information that should be authorized or required.

The Secretary's Recommendations were submitted to the Congress on September 11, 1997. Section 264(c)(1) provides that:
If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by [August 21, 1999], the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than [February 21, 2000]. Such regulations shall address at least the subjects described in subsection (b).

As the Congress did not enact legislation regarding the privacy of individually identifiable health information prior to August 21, 1999, HHS published proposed rules setting forth such standards on November 3, 1999, 64 FR 59918, and is now publishing the mandated final regulation.
These privacy standards have been, and continue to be, an integral part of the suite of Administrative Simplification standards intended to simplify and improve the efficiency of the administration of our health care system.

The Administrative Simplification Provisions, and Regulatory Actions to Date
Part C of title XI consists of sections 1171 through 1179 of the Act. These sections define various terms and impose several requirements on HHS, health plans, health care clearinghouses, and health care providers who conduct the identified transactions electronically.

The first section, section 1171 of the Act, establishes definitions for purposes of part C of title XI for the following terms: code set, health care clearinghouse, health care provider, health information, health plan, individually identifiable health information, standard, and standard setting organization.

Section 1172 of the Act makes the standard adopted under part C applicable to: (1) Health plans, (2) health care clearinghouses, and (3) health care providers who transmit health information in electronic form in connection with transactions referred

to in section 1173(a)(1) of the Act (hereinafter referred to as the "covered entities"). Section 1172 also contains procedural requirements concerning the adoption of standards, including the role of standard setting organizations and required consultations, summarized in subsection F and section VI, below.

Section 1173 of the Act requires the Secretary to adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically. Section 1173(a)(1) describes the transactions to be promulgated, which include the nine transactions listed in section 1173(a)(2) and other transactions determined appropriate by the Secretary. The remainder of section 1173 sets out requirements for the specific standards the Secretary is to adopt: Unique health identifiers, code sets, security standards, electronic signatures, and transfer of information among health plans. Of particular relevance to this proposed rule is section 1173(d), the security standard provision. The security standard authority applies to both the transmission and the maintenance of health information, and requires the entities described in section 1172(a) to maintain reasonable and appropriate safeguards to ensure the integrity and confidentiality of the information, protect against reasonably anticipated threats or hazards to the security or integrity of the information or unauthorized uses or disclosures of the information, and to ensure compliance with part C by the entity's officers and employees.

In section 1174 of the Act, the Secretary is required to establish standards for all of the above transactions, except claims attachments, by February 21, 1998. The statutory deadline for the claims attachment standard is February 21, 1999.

As noted above, a proposed rule for most of the transactions was published on May 7, 1998, and the final Transactions Rule was promulgated on August 17, 2000. The delay was caused by the deliberate consensus building process, working with industry, and the large number of comments received (about 17,000). In addition, in a series of Notices of Proposed Rulemakings, HHS published other proposed standards, as described above. Each of these steps was taken in concert with the affected professions and industries, to ensure rapid adoption and compliance.

Generally, after a standard is established, it may not be changed during the first year after adoption except for changes that are necessary to permit compliance with the standard. Modifications to any of these standards may be made after the first year, but not more frequently than once every 12 months. The Secretary also must ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets and that there are crosswalks from prior versions.

Section 1175 of the Act prohibits health plans from refusing to process, or from delaying processing of, a transaction that is presented in standard format. It also establishes a timetable for compliance: each person to whom a standard or implementation specification applies is required to comply with the standard within 24 months (or 36 months for small health plans) of its adoption. A health plan or other entity may, of course, comply voluntarily before the effective date. The section also provides that compliance with modifications to standards or implementation specifications must be accomplished by a date designated by the Secretary, which date may not be earlier than 180 days from the notice of change.

Section 1176 of the Act establishes civil monetary penalties for violation of the provisions in part C of title XI of the Act, subject to several limitations. Penalties may not be more than $100 per person per violation and not more than $25,000 per person for violations of a single standard for a calendar year. The procedural provisions of section 1128A of the Act apply to actions taken to obtain civil monetary penalties under this section.

Section 1177 establishes penalties for any person that knowingly uses a unique health identifier, or obtains or discloses individually identifiable health information in violation of the part. The penalties include: (1) A fine of not more than $50,000 and/or imprisonment of not more than 1 year; (2) if the offense is "under false pretenses," a fine of not more than $100,000 and/or imprisonment of not more than 5 years; and (3) if the offense is with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, a fine of not more than $250,000 and/or imprisonment of not more than 10 years.

Under section 1178 of the Act, the requirements of part C, as well as any standards or implementation specifications adopted thereunder, preempt contrary state law. There are three exceptions to this general rule of preemption: State laws that the Secretary determines are necessary for certain purposes set forth in the statute; state laws that the Secretary determines address controlled substances; and state laws relating to the privacy of ***82471** individually identifiable health information that are contrary to and more stringent than the federal requirements. There also are certain areas of state law (generally relating to public health and oversight of health plans) that are explicitly carved out of the general rule of preemption and addressed separately.

Section 1179 of the Act makes the above provisions inapplicable to financial institutions (as defined by section 1101 of the Right to Financial Privacy Act of 1978) or anyone acting on behalf of a financial institution when "authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments for a financial institution."

Finally, as explained above, section 264 requires the Secretary to issue standards with respect to the privacy of individually identifiable health information. Section 264 also contains a preemption provision that provides that contrary provisions of state laws that are more stringent than the federal standards, requirements, or implementation specifications will not be preempted.

Our Approach to This Regulation

Balance

A number of facts informed our approach to this regulation. Determining the best approach to protecting privacy depends on where we start, both with respect to existing legal expectations and also with respect to the expectations of individuals, health care providers, payers and other stakeholders. From the comments we received on the proposed rule, and from the extensive fact finding in which we engaged, a confused picture developed. We learned that stakeholders in the system have very different ideas about the extent and nature of the privacy protections that exist today, and very different ideas about appropriate uses of health information. This leads us to seek to balance the views of the different stakeholders, weighing the varying interests on each particular issue with a view to creating balance in the regulation as a whole.

For example, we received hundreds of comments explaining the legitimacy of various uses and disclosure of health information. We agree that many uses and disclosures of health information are "legitimate," but that is not the end of the inquiry. Neither privacy, nor the important social goals described by the commenters, are absolutes. In this regulation, we are asking health providers and institutions to add privacy into the balance, and we are asking individuals to add social goals into the balance.

The vast difference among regulated entities also informed our approach in significant ways. This regulation applies to solo practitioners, and multi-national health plans. It applies to pharmacies and information clearinghouses. These entities differ not only in the nature and scope of their businesses, but also in the degree of sophistication of their information systems and information needs. We therefore designed the core requirements of this regulation to be flexible and "scalable." This is reflected throughout the rule, particularly in the implementation specifications for making the minimum necessary uses and disclosures, and in the administrative policies and procedures requirements.

We also are informed by the rapid evolution in industry organization and practice. Our goal is to enhance privacy protections in ways that do not impede this evolution. For example, we received many comments asking us to assign a status under this regulation based on a label or title. For example, many commenters asked whether "disease management" is a "health care operation," or whether a "pharmacy benefits manager" is a covered entity. From the comments and our fact-finding, however, we learned that these terms do not have consistent meanings today; rather, they encompass diverse activities and information practices. Further, the statutory definitions of key terms such as health care provider and health care clearinghouse describe functions, not specific types of persons or entities. To respect both the Congressional approach and industry evolution, we design the rule to follow activities and functions, not titles and labels.

Similarly, many comments asked whether a particular person would be a "business associate" under the rule, based on the nature of the person's business. Whether a business associate arrangement must exist under the rule, however, depends on the relationship between the entities and the services being performed, not on the type of persons or companies involved.

Our approach is also significantly informed by the limited jurisdiction conferred by HIPAA. In large part, we have the authority to regulate those who create and disclose health information, but not many key stakeholders who receive that health information from a covered entity. Again, this led us to look to the balance between the burden on covered entities and need to protect privacy in determining our approach to such disclosures. In some instances, we approach this dilemma by requiring covered entities to obtain a representation or documentation of purpose from the person requesting information. While there would be advantages to legislation regulating such third persons directly, we cannot justify abandoning any effort to enhance privacy.

It also became clear from the comments and our fact-finding that we have expectations as a society that conflict with individuals' views about the privacy of health information. We expect the health care industry to develop treatment protocols for the delivery of high quality health care. We expect insurers and the government to reduce fraud in the health care system. We expect to be protected from epidemics, and we expect medical research to produce miracles. We expect the police to apprehend suspects, and we expect to pay for our care by credit card. All of these activities involve disclosure of health information to someone other than our physician.

While most commenters support the concept of health privacy in general, many go on to describe activities that depend on the disclosure of health information and urge us to protect those information flows. Section III, in which we respond to the comments, describes our approach to balancing these conflicting expectations.

Finally, we note that many commenters were concerned that this regulation would lessen current privacy protections. It is important to understand this regulation as a new federal floor of privacy protections that does not disturb more protective rules or practices. Nor do we intend this regulation to describe a set of a "best practices." Rather, this regulation describes a set of basic consumer protections and a series of regulatory permissions for use and disclosure of health information. The protections are a mandatory floor, which other governments and any covered entity may exceed. The permissions are just that, permissive —the only disclosures of health information required under this rule are to the individual who is the subject of the information or to the Secretary for enforcement of this rule. We expect covered entities to rely on their professional ethics and use their own best judgements in deciding which of these permissions they will use.

Combining Workability With New Protections

This rule establishes national minimum standards to protect the privacy of individually identifiable health information in prescribed ***82472** settings. The standards address the many varied uses and disclosures of individually identifiable health information by health plans, certain health care providers and health care clearinghouses. The complexity of the standards reflects the complexity of the health care marketplace to which they apply and the variety of subjects that must be addressed. The rule applies not only to the core health care functions relating to treating patients and reimbursing health care providers, but also to activities that range from when individually identifiable health information should be available for research without authorization to whether a health care provider may release protected health information about a patient for law enforcement purposes. The number of discrete provisions, and the number of commenters requesting that the rule recognize particular activities, is evidence of the significant role that individually identifiable health information plays in many vital public and private concerns.

At the same time, the large number of comments from individuals and groups representing individuals demonstrate the deep public concern about the need to protect the privacy of individually identifiable health information. The discussion above is rich with evidence about the importance of protecting privacy and the potential adverse consequences to individuals and their health if such protections are not extended.

The need to balance these competing interests—the necessity of protecting privacy and the public interest in using identifiable health information for vital public and private purposes—in a way that is also workable for the varied stakeholders causes much of the complexity in the rule. Achieving workability without sacrificing protection means some level of complexity, because the rule must track current practices and current practices are complex. We believe that the complexity entailed in reflecting those practices is better public policy than a perhaps simpler rule that disturbed important information flows.

Although the rule taken as a whole is complicated, we believe that the standards are much less complex as they apply to particular actors. What a health plan or covered health care provider must do to comply with the rule is clear, and the two-year delayed implementation provides a substantial period for trade and professional associations, working with their members, to assess the effects of the standards and develop policies and procedures to come into compliance with them. For individuals, the system may look substantially more complicated because, for the first time, we are ensuring that individuals will receive detailed information about how their individually identifiable health information may be used and disclosed. We also provide individuals with additional tools to exercise some control over those uses and disclosures. The additional complexity for individuals is the price of expanding their understanding and their rights.

The Department will work actively with members of the health care industry, representatives of individuals and others during the implementation of this rule. As stated elsewhere, our focus is to develop broader understanding of how the standards work and to facilitate compliance. We intend to provide guidance and check lists as appropriate, particularly to small businesses affected by the rule. We also will work with trade and professional associations to develop guidance and provide technical assistance so that they can help their members understand and comply with these new standards. If this effort is to succeed, the various public and private participants inside and outside of the health care system will need to work together to assure that the competing interests described above remain in balance and that an ethic that recognizes their importance is established.

Enforcement

The Secretary has decided to delegate her responsibility under this regulation to the Department's Office for Civil Rights (OCR). OCR will be responsible for enforcement of this regulation. Enforcement activities will include working with covered entities to secure voluntary compliance through the provision of technical assistance and other means; responding to questions regarding the regulation and providing interpretations and guidance; responding to state requests for exception determinations; investigating complaints and conducting compliance reviews; and, where voluntary compliance cannot be achieved, seeking civil monetary penalties and making referrals for criminal prosecution.

Consent

Current Law and Practice

The issue that drew the most comments overall is the question of when individuals' permission should be obtained prior to use or disclosure of their health information. We learned that individuals' views and the legal view of “consent” for use and disclosure of health information are different and in many ways incompatible. Comments from individuals revealed a common belief that, today, people must be asked permission for each and every release of their health information. Many believe that they “own” the health records about them. However, current law and practice do not support this view.

Current privacy protection practices are determined in part by the standards and practices that the professional associations have adopted for their members. Professional codes of conduct for ethical behavior generally can be found as opinions and guidelines developed by organizations such as the American Medical Association, American Nurses' Association, the American Hospital Association, the American Psychiatric Association, and the American Dental Association. These are generally issued though an organization's governing body. The codes do not have the force of law, but providers often recognize them as binding rules.

Our review of professional codes of ethics revealed partial, but loose, support for individuals' expectations of privacy. For example, the American Medical Association's Code of Ethics recognizes both the right to privacy and the need to balance it

against societal needs. It reads in part: "conflicts between a patient's right to privacy and a third party's need to know should be resolved in favor of the patient, except where that would result in serious health hazard or harm to the patient or others." AMA Policy No 140.989. See also, Mass. Med. Society, Patient Privacy and Confidentiality (1996), at 14:

Patients enter treatment with the expectation that the information they share will be used exclusively for their clinical care. Protection of our patients' confidences is an integral part of our ethical training.

These codes, however, do not apply to many who obtain information from providers. For example, the National Association of Insurance Commissioners model code, "Health Information Privacy Model Act" (1998), applies to insurers but has not been widely adopted. Codes of ethics are also often written in general terms that do not provide guidance to providers and plans confronted with specific questions about protecting health information.

State laws are a crucial means of protecting health information, and today state laws vary dramatically. Some states defer to the professional codes of conduct, others provide general guidelines for privacy protection, and ***82473** others provide detailed requirements relating to the protection of information relating to specific diseases or to entire classes of information. Cf., D.C. Code Ann. § 2-3305.14(16) and Haw. Rev. Stat. 323C, et seq. In general, state statutes and case law addressing consent to use of health information do not support the public's strong expectations regarding consent for use and disclosure of health information. Only about half of the states have a general law that prohibits disclosure of health information without patient authorization and some of these are limited to hospital medical records.

Even when a state has a law limiting disclosure of health information, the law typically exempts many types of disclosure from the authorization requirement. Georgetown Study, Key Findings; Lisa Dahm, "50-State Survey on Patient Health Care Record Confidentiality," American Health Lawyers Association (1999). One of the most common exemptions from a consent requirement is disclosure of health information for treatment and related purposes. See, e.g., Wis.Stat. § 164.82; Cal. Civ. Code 56:10; National Conference of Commissioners on Uniform State Laws, Uniform Health-Care Information Act, Minneapolis, MN, August 9, 1985. Some states include utilization review and similar activities in the exemption. See, e.g., Ariz. Rev. Stat. § 12-2294. Another common exemption from consent is disclosure of health information for purposes of obtaining payment. See, e.g., Fla. Stat. Ann. § 455.667; Tex. Rev. Civ. Stat. Art. 4495, § 5.08(h); 410 Ill. Comp. Stat. 50/3(d). Other common exemptions include disclosures for emergency care, and for disclosures to government authorities (such as a department of public health). See Gostin Study, at 1-2; 48-51. Some states also exempt disclosure to law enforcement officials (e.g., Massachusetts, Ch. 254 of the Acts of 2000), coroners (Wis. Stat. § 146.82), and for such purposes as business operations, oversight, research, and for directory information. Under these exceptions, providers can disclose health information without any consent or authorization from the patient. When states require specific, written authorization for disclosure of health information, the authorizations are usually only required for certain types of disclosures or certain types of information, and one authorization can suffice for multiple disclosures over time.

The states that do not have laws prohibiting disclosure of health information impose no specific requirements for consent or authorization prior to release of health information. There may, however, be other controls on release of health information. For instance, most health care professional licensure laws include general prohibitions against "breaches of confidentiality." In some states, patients can hold providers accountable for some unauthorized disclosures of health information about them under various tort theories, such as invasion of privacy and breach of a confidential relationship. While these controls may affect certain disclosure practices, they do not amount to a requirement that a provider obtain authorization for each and every disclosure of health information.

Further, patients are typically not given a choice; they must sign the "consent" in order to receive care. As the Georgetown Study points out, "In effect, the authorization may function more as a waiver of consent—the patient may not have an opportunity to object to any disclosures." Georgetown Study, Key Findings.

In the many cases where neither state law nor professional ethical standards exist, the only privacy protection individuals have is limited to the policies and procedures that the health care entity adopts. Corporate privacy policies are often proprietary. While several professional associations attached their privacy principles to their comments, health care entities did not. One study we found indicates that these policies are not adequate to provide appropriate privacy protections and alleviate public concern. The Committee on Maintaining Privacy and Security in Health Care Applications of the National Information Infrastructure made multiple findings highlighting the need for heightened privacy and security, including:

Finding 5: The greatest concerns regarding the privacy of health information derives from widespread sharing of patient information throughout the health care industry and the inadequate federal and state regulatory framework for systematic protection of health information.

For the Record: Protecting Electronic Health Information, National Academy Press, Washington DC, 1997.

Consent Under This Rule

In the NPRM, we expressed concern about the coercive nature of consents currently obtained by providers and plans relating to the use and disclosure of health information. We also expressed concern about the lack of information available to the patient during the process, and the fact that patients often were not even presented with a copy of the consent that they have signed. These and other concerns led us to propose that covered entities be permitted to use and disclose protected health information for treatment, payment and health care operations without the express consent of the subject individual.

In the final rule, we alter our proposed approach and require, in most instances, that health care providers who have a direct treatment relationship with their patients obtain the consent of their patients to use and disclose protected health information for treatment, payment and health care operations. While our concern about the coerced nature of these consents remains, many comments that we received from individuals, health care professionals, and organizations that represent them indicated that both patients and practitioners believe that patient consent is an important part of the current health care system and should be retained.

Providing and obtaining consent clearly has meaning for patients and practitioners. Patient advocates argued that the act of signing focuses the patient's attention on the substance of the transaction and provides an opportunity for the patient to ask questions about or seek modifications in the provider's practices. Many health care practitioners and their representatives argued that seeking a patient's consent to disclose confidential information is an ethical requirement that strengthens the physician-patient relationship. Both practitioners and patients argued that the approach proposed in the NPRM actually reduced patient protections by eliminating the opportunity for patients to agree to how their confidential information would be used and disclosed.

While we believe that the provisions in the NPRM that provided for detailed notice to the patient and the right to request restrictions would have provided an opportunity for patients and providers to discuss and negotiate over information practices, it is clear from the comments that many practitioners and patients believe the approach proposed in the NPRM is not an acceptable replacement for the patient providing consent.

To encourage a more informed interaction between the patient and the provider during the consent process, the final rule requires that the consent form that is presented to the patient be accompanied by a notice that contains a detailed discussion of the provider's health information practices. The consent form must reference the notice and also must inform the patient that he ***82474** or she has the right to ask the health care provider to request certain restrictions as to how the information of the patient will be used or disclosed. Our goal is to provide an opportunity for and to encourage more informed discussions between patients and providers about how protected health information will be used and disclosed within the health care system.

We considered and rejected other approaches to consent, including those that involved individuals providing a global consent to uses and disclosures when they sign up for insurance. While such approaches do require the patient to provide consent,

it is not really an informed one or a voluntary one. It is also unclear how a consent obtained at the enrollment stage would be meaningfully communicated to the many providers who create the health information in the first instance. The ability to negotiate restrictions or otherwise have a meaningful discussion with the front-line provider would be independent of, and potentially in conflict with, the consent obtained at the enrollment stage. In addition, employers today are moving toward simplified enrollment forms, using check-off boxes and similar devices. The opportunity for any meaningful consideration or interaction at that point is slight. For these and other reasons, we decided that, to the extent a consent can accomplish the goal sought by individuals and providers, it must be focused on the direct interaction between an individual and provider.

The comments and fact-finding indicate that our approach will not significantly change the administrative aspect of consent as it exists today. Most direct treatment providers today obtain some type of consent for some uses and disclosures of health information. Our regulation will ensure that those consents cover the routine uses and disclosures of health information, and provide an opportunity for individuals to obtain further information and have further discussion, should they so desire.

Administrative Costs

Section 1172(b) of the Act provides that "[a]ny standard adopted under this part [part C of title XI of the Act] shall be consistent with the objective of reducing the administrative costs of providing and paying for health care." The privacy and security standards are the platform on which the remaining standards rest; indeed, the design of part C of title XI makes clear that the various standards are intended to function together. Thus, the costs of privacy and security are properly attributable to the suite of administrative simplification regulations as a whole, and the cost savings realized should likewise be calculated on an aggregated basis, as is done below. Because the privacy standards are an integral and necessary part of the suite of Administrative Simplification standards, and because that suite of standards will result in substantial administrative cost savings, the privacy standards are "consistent with the objective of reducing the administrative costs of providing and paying for health care."

As more fully discussed in the Regulatory Impact and Regulatory Flexibility analyses below, we recognize that these privacy standards will entail substantial initial and ongoing administrative costs for entities subject to the rules. It is also the case that the privacy standards, like the security standards authorized by section 1173(d) of the Act, are necessitated by the technological advances in information exchange that the remaining Administrative Simplification standards facilitate for the health care industry. The same technological advances that make possible enormous administrative cost savings for the industry as a whole have also made it possible to breach the security and privacy of health information on a scale that was previously inconceivable. The Congress recognized that adequate protection of the security and privacy of health information is a sine qua non of the increased efficiency of information exchange brought about by the electronic revolution, by enacting the security and privacy provisions of the law. Thus, as a matter of policy as well as law, the administrative standards should be viewed as a whole in determining whether they are "consistent with" the objective of reducing administrative costs.

Consultations

The Congress required the Secretary to consult with specified groups in developing the standards under sections 262 and 264. Section 264(d) of HIPAA specifically requires the Secretary to consult with the National Committee on Vital and Health Statistics (NCVHS) and the Attorney General in carrying out her responsibilities under the section. Section 1172(b)(3) of the Act, which was enacted by section 262, requires that, in developing a standard under section 1172 for which no standard setting organization has already developed a standard, the Secretary must, before adopting the standard, consult with the National Uniform Billing Committee (NUBC), the National Uniform Claim Committee (NUCC), the Workgroup for Electronic Data Interchange (WEDI), and the American Dental Association (ADA). Section 1172(f) also requires the Secretary to rely on the recommendations of the NCVHS and consult with other appropriate federal and state agencies and private organizations.

We engaged in the required consultations including the Attorney General, NUBC, NUCC, WEDI and the ADA. We consulted with the NCVHS in developing the Recommendations, upon which this proposed rule is based. We continued to consult with this committee by requesting the committee to review the proposed rule and provide comments prior to its publication, and by reviewing transcripts of its public meeting on privacy and related topics. We consulted with representatives of the

National Congress of American Indians, the National Indian Health Board, and the self governance tribes. We also met with representatives of the National Governors' Association, the National Conference of State Legislatures, the National Association of Public Health Statistics and Information Systems, and a number of other state organizations to discuss the framework for the proposed rule, issues of special interests to the states, and the process for providing comments on the proposed rule.

Many of these groups submitted comments to the proposed rule, and those were taken into account in developing the final regulation.

In addition to the required consultations, we met with numerous individuals, entities, and agencies regarding the regulation, with the goal of making these standards as compatible as possible with current business practices, while still enhancing privacy protection. During the open comment period, we met with dozens of groups.

Relevant federal agencies participated in the interagency working groups that developed the NPRM and the final regulation, with additional representatives from all operating divisions and many staff offices of HHS. The following federal agencies and offices were represented on the interagency working groups: the Department of Justice, the Department of Commerce, the Social Security Administration, the Department of Defense, the Department of Veterans Affairs, the Department of Labor, the Office of Personnel Management, and the Office of Management and Budget. ***82475**

II. Section-by-Section Description of Rule Provisions

Part 160—Subpart A—General Provisions

Part 160 applies to all the administrative simplification regulations. We include the entire regulation text in this rule, not just those provisions relevant to this Privacy regulation. For example, the term "trading partner" is defined here, for use in the Health Insurance Reform: Standards for Electronic Transactions regulation, published at 65 FR 50312, August 17, 2000 (the "Transactions Rule"). It does not appear in the remainder of this Privacy rule.

Sections 160.101 and 160.104 of Subpart A of part 160 were promulgated in the Transactions Rule, and we do not change them here. We do, however, make changes and additions to § 160.103, the definitions section of Subpart A. The definitions that were promulgated in the Transactions Rule and that remain unchanged here are: Act, ANSI, covered entity, compliance date, group health plan, HCFA, HHS, health care provider, health information, health insurance issuer, health maintenance organization, modify or modification, Secretary, small health plan, standard setting organization, and trading partner agreement. Of these terms, we discuss further in this preamble only covered entity and health care provider.

Section 160.102—Applicability

The proposed rule stated that the subchapter (Parts 160, 162, and 164) applies to the entities set out at section 1172(a) of the Act: Health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction covered by the subchapter. The final rule adds a provision (§ 160.102(b)) clarifying that to the extent required under section 201(a)(5) of HIPAA, nothing in the subchapter is to be construed to diminish the authority of any Inspector General. This was done in response to comment, to clarify that the administrative simplification rules, including the rules below, do not conflict with the cited provision of HIPAA.

Section 160.103—Definitions

Business Associate

We proposed to define the term "business partner" to mean, with respect to a covered entity, a person to whom the covered entity discloses protected health information so that the person can carry out, assist with the performance of, or perform on behalf of, a function or activity for the covered entity. "Business partner" would have included contractors or other persons who receive protected health information from the covered entity (or from another business partner of the covered entity) for

the purposes described in the previous sentence, including lawyers, auditors, consultants, third-party administrators, health care clearinghouses, data processing firms, billing firms, and other covered entities. “Business partner” would have excluded persons who are within the covered entity's workforce, as defined in this section.

This rule reflects the change in the name from “business partner” to “business associate,” included in the Transactions Rule.

In the final rule, we change the definition of “business associate” to clarify the circumstances in which a person is acting as a business associate of a covered entity. The changes clarify that the business association occurs when the right to use or disclose the protected health information belongs to the covered entity, and another person is using or disclosing the protected health information (or creating, obtaining and using the protected health information) to perform a function or activity on behalf of the covered entity. We also clarify that providing specified services to a covered entity creates a business associate relationship if the provision of the service involves the disclosure of protected health information to the service provider. In the proposed rule, we had included a list of persons that were considered to be business partners of the covered entity. However, it is not always clear whether the provision of certain services to a covered entity is “for” the covered entity or whether the service provider is acting “on behalf of” the covered entity. For example, a person providing management consulting services may need protected health information to perform those services, but may not be acting “on behalf of” the covered entity. This we believe led to some general confusion among the commenters as to whether certain arrangements fell within the definition of a business partner under the proposed rule. The construction of the final rule clarifies that the provision of the specified services gives rise to a business associate relationship if the performance of the service involves disclosure of protected health information by the covered entity to the business associate. The specified services are legal, actuarial, accounting, consulting, management, administrative accreditation, data aggregation, and financial services. The list is intended to include the types of services commonly provided to covered entities where the disclosure of protected health information is routine to the performance of the service, but when the person providing the service may not always be acting “on behalf of” the covered entity.

In the final rule, we reorganize the list of examples of the functions or activities that may be conducted by business associates. We place a part of the proposed list in the portion of the definition that addresses when a person is providing functions or activities for or on behalf of a covered entity. We place other parts of the list in the portion of the definition that specifies the services that give rise to a business associate relationship, as discussed above. We also have expanded the examples to provide additional guidance and in response to questions from commenters.

We have added data aggregation to the list of services that give rise to a business associate relationship. Data aggregation, as discussed below, is where a business associate in its capacity as the business associate of one covered entity combines the protected health information of such covered entity with protected health information received by the business associate in its capacity as a business associate of another covered entity in order to permit the creation of data for analyses that relate to the health care operations of the respective covered entities. Adding this service to the business associate definition clarifies the ability of covered entities to contract with business associates to undertake quality assurance and comparative analyses that involve the protected health information of more than one contracting covered entity. For example, a state hospital association could act as a business associate of its member hospitals and could combine data provided to it to assist the hospitals in evaluating their relative performance in areas such as quality, efficiency and other patient care issues. As discussed below, however, the business associate contracts of each of the hospitals would have to permit the activity, and the protected health information of one hospital could not be disclosed to another hospital unless the disclosure is otherwise permitted by the rule.

The definition also states that a business associate may be a covered entity, and that business associate excludes a person who is part of the covered entity's workforce.

We also clarify in the final rule that a business association arises with ***82476** respect to a covered entity when a person performs functions or activities on behalf of, or provides the specified services to or for, an organized health care health care arrangement in which the covered entity participates. This change recognizes that where covered entities participate in certain joint arrangements for the financing or delivery of health care, they often contract with persons to perform functions or to provide

services for the joint arrangement. This change is consistent with changes made in the final rule to the definition of health care operations, which permits covered entities to use or disclose protected health information not only for their own health care operations, but also for the operations of an organized health care arrangement in which the covered entity participates. By making these changes, we avoid the confusion that could arise in trying to determine whether a function or activity is being provided on behalf of (or if a specified service is being provided to or for) a covered entity or on behalf of or for a joint enterprise involving the covered entity. The change clarifies that in either instance the person performing the function or activity (or providing the specified service) is a business associate.

We also add language to the final rule that clarifies that the mere fact that two covered entities participate in an organized health care arrangement does not make either of the covered entities a business associate of the other covered entity. The fact that the entities participate in joint health care operations or other joint activities, or pursue common goals through a joint activity, does not mean that one party is performing a function or activity on behalf of the other party (or is providing a specified services to or for the other party).

In general under this provision, actions relating to the protected health information of an individual undertaken by a business associate are considered, for the purposes of this rule, to be actions of the covered entity, although the covered entity is subject to sanctions under this rule only if it has knowledge of the wrongful activity and fails to take the required actions to address the wrongdoing. For example, if a business associate maintains the medical records or manages the claims system of a covered entity, the covered entity is considered to have protected health information and the covered entity must ensure that individuals who are the subject of the information can have access to it pursuant to § 164.524.

The business associate relationship does not describe all relationships between covered entities and other persons or organizations. While we permit uses or disclosures of protected health information for a variety of purposes, business associate contracts or other arrangements are only required for those cases in which the covered entity is disclosing information to someone or some organization that will use the information on behalf of the covered entity, when the other person will be creating or obtaining protected health information on behalf of the covered entity, or when the business associate is providing the specified services to the covered entity and the provision of those services involves the disclosure of protected health information by the covered entity to the business associate. For example, when a health care provider discloses protected health information to health plans for payment purposes, no business associate relationship is established. While the covered provider may have an agreement to accept discounted fees as reimbursement for services provided to health plan members, neither entity is acting on behalf of or providing a service to the other.

Similarly, where a physician or other provider has staff privileges at an institution, neither party to the relationship is a business associate based solely on the staff privileges because neither party is providing functions or activities on behalf of the other. However, if a party provides services to or for the other, such as where a hospital provides billing services for physicians with staff privileges, a business associate relationship may arise with respect to those services. Likewise, where a group health plan purchases insurance or coverage from a health insurance issuer or HMO, the provision of insurance by the health insurance issuer or HMO to the group health plan does not make the issuer a business associate. In such case, the activities of the health insurance issuer or HMO are on their own behalf and not on the behalf of the group health plan. We note that where a group health plan contracts with a health insurance issuer or HMO to perform functions or activities or to provide services that are in addition to or not directly related to the provision of insurance, the health insurance issuer or HMO may be a business associate with respect to those additional functions, activities or services. We also note that covered entities are permitted to disclose protected health information to oversight agencies that act to provide oversight of federal programs and the health care system. These oversight agencies are not performing services for or on behalf of the covered entities and so are not business associates of the covered entities. Therefore HCFA, the federal agency that administers Medicare, is not required to enter into a business associate contract in order to disclose protected health information to the Department's Office of Inspector General.

We do not require a covered entity to enter into a business associate contract with a person or organization that acts merely as a conduit for protected health information (e.g., the US Postal Service, certain private couriers and their electronic equivalents).

A conduit transports information but does not access it other than on a random or infrequent basis as may be necessary for the performance of the transportation service, or as required by law. Since no disclosure is intended by the covered entity and the probability of exposure of any particular protected health information to a conduit is very small, we do not consider a conduit to be a business associate of the covered entity.

We do not consider a financial institution to be acting on behalf of a covered entity, and therefore no business associate contract is required, when it processes consumer-conducted financial transactions by debit, credit or other payment card, clears checks, initiates or processes electronic funds transfers, or conducts any other activity that directly facilitates or effects the transfer of funds for compensation for health care. A typical consumer-conducted payment transaction is when a consumer pays for health care or health insurance premiums using a check or credit card. In these cases the identity of the consumer is always included and some health information (e.g., diagnosis or procedure) may be implied through the name of the health care provider or health plan being paid. Covered entities that initiate such payment activities must meet the minimum necessary disclosure requirements described in the preamble to § 164.514.

Covered Entity

We provided this definition in the NPRM for convenience of reference and proposed it to mean the entities to which part C of title XI of the Act applies. These are the entities described in section 1172(a)(1): Health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction referred ***82477** to in section 1173(a)(1) of the Act (a "standard transaction").

We note that health care providers who do not submit HIPAA transactions in standard form become covered by this rule when other entities, such as a billing service or a hospital, transmit standard electronic transactions on their behalf. A provider could not circumvent these requirements by assigning the task to its business associate since the business associate would be considered to be acting on behalf of the provider. See the definition of "business associate."

Where a public agency is required or authorized by law to administer a health plan jointly with another entity, we consider each agency to be a covered entity with respect to the health plan functions it performs. Unlike private sector health plans, public plans are often required by or expressly authorized by law to jointly administer health programs that meet the definition of "health plan" under this regulation. In some instances the public entity is required or authorized to administer the program with another public agency. In other instances, the public entity is required or authorized to administer the program with a private entity. In either circumstance, we note that joint administration does not meet the definition of "business associate" in § 164.501. Examples of joint administration include state and federal administration of the Medicaid and SCHIP program, or joint administration of a Medicare+Choice plan by the Health Care Financing Administration and the issuer offering the plan.

Health Care

We proposed to define "health care" to mean the provision of care, services, or supplies to a patient and to include any: (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counseling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body; (2) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or (3) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients.

The final rule revises both the NPRM definition and the definition as provided in the Transactions Rule, to now mean "care, services, or supplies related to the health of an individual. Health care includes the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

We delete the term "providing" from the definition to delineate more clearly the relationship between "treatment," as the term is defined in § 164.501, and "health care." Other key revisions include adding the term "assessment" in subparagraph (1) and deleting proposed subparagraph (3) from the rule. Therefore the procurement or banking of organs, blood (including autologous blood), sperm, eyes or any other tissue or human product is not considered to be health care under this rule and the organizations that perform such activities would not be considered health care providers when conducting these functions. As described in § 164.512(h), covered entities are permitted to disclose protected health information without individual authorization, consent, or agreement (see below for explanation of authorizations, consents, and agreements) as necessary to facilitate cadaveric donation.

Health Care Clearinghouse

In the NPRM, we defined "health care clearinghouse" as a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements. The entity receives health care transactions from health care providers or other entities, translates the data from a given format into one acceptable to the intended payor or payors, and forwards the processed transaction to appropriate payors and clearinghouses. Billing services, repricing companies, community health management information systems, community health information systems, and "value-added" networks and switches would have been considered to be health care clearinghouses for purposes of this part, if they perform the functions of health care clearinghouses as described in the preceding sentences.

In the final regulation, we modify the definition of health care clearinghouse to reflect changes in the definition published in the Transactions Rule. The definition in the final rule is:

Health care clearinghouse means a public or private entity, including billing services, repricing companies, community health management information systems or community health information systems, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

We note here that the term health care clearinghouse may have other meanings and connotations in other contexts, but the regulation defines it specifically, and an entity is considered a health care clearinghouse only to the extent that it meets the criteria in this definition. Telecommunications entities that provide connectivity or mechanisms to convey information, such as telephone companies and Internet Service Providers, are not health care clearinghouses as defined in the rule unless they actually carry out the functions outlined in our definition. Value added networks and switches are not health care clearinghouses unless they carry out the functions outlined in the definition. The examples of entities in our proposed definition we continue to consider to be health care clearinghouses, as well as any other entities that meet that definition, to the extent that they perform the functions in the definition.

In order to fall within this definition of clearinghouse, the covered entity must perform the clearinghouse function on health information received from some other entity. A department or component of a health plan or health care provider that transforms nonstandard information into standard data elements or standard transactions (or vice versa) is not a clearinghouse for purposes of this rule, unless it also performs these functions for another entity. As described in more detail in § 164.504(d), we allow affiliates to perform clearinghouse functions for each other without triggering the definition of "clearinghouse" if the conditions in § 164.504(d) are met.

Health Care Provider

We proposed to define health care provider to mean a provider of services as defined in section 1861(u) of the Act, a provider of medical or health services as defined in section 1861(s) of the Act, and any other person or organization who furnishes, bills, or is paid for health care services or supplies in the normal course of business. ***82478**

In the final rule, we delete the term "services and supplies," in order to eliminate redundancy within the definition. The definition also reflects the addition of the applicable U.S.C. citations (42 U.S.C. 1395x(u) and 42 U.S.C. 1395x(s), respectively) for the referenced provisions of the Act that were promulgated in the Transactions Rule.

To assist the reader, we also provide here excerpts from the relevant sections of the Act. (Refer to the U.S.C. sections cited above for complete definitions in sections 1861(u) and 1861(s).) Section 1861(u) of the Act defines a "provider of services," to include, for example,

a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1814(g) (42 U.S.C. 1395f(g)) and section 1835(e) (42 U.S.C. 1395n(e)), a fund." Section 1861(s) of the Act defines the term, "medical and other health services," and includes a list of covered items or services, as illustrated by the following excerpt:

(s) Medical and other health services. The term "medical and other health services" means any of the following items or services:

(1) Physicians' services;

(2) (A) services and supplies * * * furnished as an incident to a physician's professional service, or kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services * * * incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services and outpatient occupational therapy services;

(E) rural health clinic services and federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies;

(G) antigens * * * prepared by a physician * * * for a particular patient, including antigens so prepared which are forwarded to another qualified person * * * for administration to such patient, * * * by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1876 (42 U.S.C. 1395mm) to a member of an eligible organization by a physician assistant or by a nurse practitioner * * * and such services and supplies furnished as an incident to his service to such a member * * * and

(ii) services furnished pursuant to a risk-sharing contract under section 1876(g) (42 U.S.C. 1395mm(g)) to a member of an eligible organization by a clinical psychologist * * * or by a clinical social worker * * * (and) furnished as an incident to such clinical psychologist's services or clinical social worker's services * * *;

(I) blood clotting factors, for hemophilia patients * * *;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this title (42 U.S.C. 1395 et seq.), but only in the case of (certain) drugs furnished * * *

(K)(i) services which would be physicians' services if furnished by a physician * * * and which are performed by a physician assistant * * *; and

(ii) services which would be physicians' services if furnished by a physician * * * and which are performed by a nurse * * *;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services * * *;

(O) erythropoietin for dialysis patients * * *;

(P) prostate cancer screening tests * * *;

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anti-cancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients) * * *;

(R) colorectal cancer screening tests * * *;

(S) diabetes outpatient self-management training services * * *; and

(T) an oral drug (which is approved by the federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen * * *

(3) diagnostic X-ray tests * * * furnished in a place of residence used as the patient's home * * * ;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition * * * ;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), * * * and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery * * * [;]

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required * * * ;

(10) (A) pneumococcal vaccine and its administration * * *; and

(B) hepatitis B vaccine and its administration * * *, and

(11) services of a certified registered nurse anesthetist * * *;

(12) * * * extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if * * *;

(13) screening mammography * * *;

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement * * *. (etc.)

Health Plan

We proposed to define "health plan" essentially as section 1171(5) of the Act defines it. Section 1171 of the Act refers to several definitions in section 2791 of the Public Health Service Act, 42 U.S.C. 300gg-91, as added by Public Law 104-191.

As defined in section 1171(5), a "health plan" is an individual plan or group health plan that provides, or pays the cost of, medical care. We proposed that this definition include, but not be limited to the 15 types of plans (e.g., group health plan, health insurance issuer, health maintenance organization) listed in the statute, as well as any combination of them. Such term would have included, when applied to public benefit programs, the component of the government agency that administers the program. Church plans and government plans would have been included to the extent that they fall into one or more of the listed categories.

In the proposed rule, "health plan" included the following, singly or in combination:

(1) A group health plan, defined as an employee welfare benefit plan (as currently defined in section 3(1) of the Employee Retirement Income and Security Act of 1974, 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance or otherwise, that:

(i) Has 50 or more participants; or

(ii) Is administered by an entity other than the employer that established and maintains the plan.

(2) A health insurance issuer, defined as an insurance company, insurance service, or insurance organization that is licensed to engage in the business of insurance in a state and is subject to state or other law that regulates insurance.

(3) A health maintenance organization, defined as a federally qualified health maintenance organization, an organization recognized as a health maintenance organization under state law, or a similar organization regulated for solvency under state law in the same manner and to the same extent as such a health maintenance organization.

(4) Part A or Part B of the Medicare program under title XVIII of the Act.

(5) The Medicaid program under title XIX of the Act. ***82479**

(6) A Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss).

(7) A long-term care policy, including a nursing home fixed-indemnity policy.

(8) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(9) The health care program for active military personnel under title 10 of the United States Code.

(10) The veterans health care program under 38 U.S.C. chapter 17.

(11) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in 10 U.S.C. 1072(4).

(12) The Indian Health Service program under the Indian Health Care Improvement Act (25 U.S.C. 1601, et seq.).

(13) The Federal Employees Health Benefits Program under 5 U.S.C. chapter 89.

(14) An approved state child health plan for child health assistance that meets the requirements of section 2103 of the Act.

(15) A Medicare Plus Choice organization as defined in 42 CFR 422.2, with a contract under 42 CFR part 422, subpart K.

In addition to the 15 specific categories, we proposed that the list include any other individual plan or group health plan, or combination thereof, that provides or pays for the cost of medical care. The Secretary would determine which plans that meet these criteria would to be considered health plans for the purposes of this rule.

Consistent with the other titles of HIPAA, our proposed definition did not include certain types of insurance entities, such as workers' compensation and automobile insurance carriers, other property and casualty insurers, and certain forms of limited benefits coverage, even when such arrangements provide coverage for health care services.

In the final rule, we add two provisions to clarify the types of policies or programs that we do not consider to be a health plan. First, the rule excepts any policy, plan or program to the extent that it provides, or pays for the cost of, excepted benefits, as defined in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1). We note that, while coverage for on-site medical clinics is excluded from definition of “health plans,” such clinics may meet the definition of “health care provider” and persons who work in the clinic may also meet the definition of health care provider.” Second, many commenters were confused by the statutory inclusion as a health plan of any “other individual or group plan that provides or pays the cost of medical care;” they questioned how the provision applied to many government programs. We therefore clarify that while many government programs (other than the programs specified in the statute) provide or pay the cost of medical care, we do not consider them to be individual or group plans and therefore, do not consider them to be health plans. Government funded programs that do not have as their principal purpose the provision of, or payment for, the cost of health care but which do incidentally provide such services are not health plans (for example, programs such as the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and the Food Stamp Program, which provide or pay for nutritional services, are not considered to be health plans). Government funded programs that have as their principal purpose the provision of health care, either directly or by grant, are also not considered to be health plans. Examples include the Ryan White Comprehensive AIDS Resources Emergency Act, government funded health centers and immunization programs. We note that some of these may meet the rule's definition of health care provider.

We note that in certain instances eligibility for or enrollment in a health plan that is a government program providing public benefits, such as Medicaid or SCHIP, is determined by an agency other than the agency that administers the program, or individually identifiable health information used to determine enrollment or eligibility in such a health plan is collected by an agency other than the agency that administers the health plan. In these cases, we do not consider an agency that is not otherwise

a covered entity, such as a local welfare agency, to be a covered entity because it determines eligibility or enrollment or collects enrollment information as authorized by law. We also do not consider the agency to be a business associate when conducting these functions, as we describe further in the business associate discussion above.

The definition in the final rule also reflects the following changes promulgated in the Transactions Rule:

(1) Exclusion of nursing home fixed-indemnity policies;

(2) Addition of the word "issuer" to Medicare supplemental policy, and long-term care policy;

(3) Addition or revision of the relevant statutory cites where appropriate;

(4) Deletion of the term "or assisted" when referring to government programs;

(5) Replacement of the word "organization" with "program" when referring to Medicare + Choice;

(6) Deletion of the term "health" when referring to a group plan in subparagraph (xvi);

(7) Extraction of the definitions of "group health plan," "health insurance issuer," and "health maintenance organization" into Part 160 as distinct definitions;

(8) In the definition of "group health plan," deletion of the term "currently" from the reference to the statutory cite of ERISA, addition of the relevant statutory cite for the term "participant," and addition of the term "reimbursement;"

(9) In the definition of "health insurance issuer," addition of the relevant statutory cite, deletion of the term "or other law" after "state law," addition of health maintenance organizations for consistency with the statute, and clarification that the term does not include a group health plan; and

(10) In the definition of "health maintenance organization," addition of the relevant statutory cite.

Finally, we add to this definition a high risk pool that is a mechanism established under state law to provide health insurance coverage or comparable coverage to eligible individuals. High risk pools are designed mainly to provide health insurance coverage for individuals who, due to health status or pre-existing conditions, cannot obtain insurance through the individual market or who can do so only at very high premiums. Some states use their high risk pool as an alternative mechanism under section 2744 of HIPAA. We do not reference the definition of "qualified high risk pool" in HIPAA because that definition includes the requirements for a state to use its risk pool as its alternative mechanism under HIPAA. Some states may have high risk pools, but do not use them as their alternative mechanism and therefore may not meet the definition in HIPAA. We want to make clear that state high risk pools are covered entities under this rule whether or not they meet the definition of a qualified high risk pool under section 2744. High risk pools, as described in this rule, do not include any program established under state law solely to provide excepted benefits. For example, a state program established to provide workers' compensation coverage is not ***82480** considered to be a high risk pool under the rule.

Implementation Specification

This definition was adopted in the Transactions Rule and is minimally revised here. We add the words "requirements or" before the word "instructions." The word "instructions" is appropriate in the context of the implementation specifications adopted in the Transactions Rule, which are generally a series of instructions as to how to use particular electronic forms. However, that word is not apropos in the context of the rules below. In the rules below, the implementation specifications are specific requirements for how to comply with a given standard. The change to this definition thus ties in to this regulatory framework.

Standard

This definition was adopted in the Transactions Rule and we have modified it to make it clearer. We also add language reflecting section 264 of the statute, to clarify that the standards adopted by this rule meet this definition.

State

We modify the definition of state as adopted in the Transactions Rule to clarify that this term refers to any of the several states.

Transaction

We change the term "exchange" to the term "transmission" in the definition of Transaction to clarify that these transactions may be one-way communications.

Workforce

We proposed in the NPRM to define workforce to mean employees, volunteers, trainees, and other persons under the direct control of a covered entity, including persons providing labor on an unpaid basis.

The definition in the final rule reflects one revision established in the Transactions Rule, which replaces the term "including persons providing labor on an unpaid basis" with the term "whether or not they are paid by the covered entity." In addition, we clarify that if the assigned work station of persons under contract is on the covered entity's premises and such persons perform a substantial proportion of their activities at that location, the covered entity may choose to treat them either as business associates or as part of the workforce, as explained in the discussion of the definition of business associate. If there is no business associate contract, we assume the person is a member of the covered entity's workforce. We note that independent contractors may or may not be workforce members. However, for compliance purposes we will assume that such personnel are members of the workforce if no business associate contract exists.

Part 160—Subpart B—Preemption of State Laws

Statutory Background

Section 1178 of the Act establishes a "general rule" that state law provisions that are contrary to the provisions or requirements of part C of title XI or the standards or implementation specifications adopted or established thereunder are preempted by the federal requirements. The statute provides three exceptions to this general rule: (1) In section 1178(a)(2)(A)(i), for state laws that the Secretary determines are necessary to prevent fraud and abuse, ensure appropriate state regulation of insurance and health plans, for state reporting on health care delivery, and other purposes; (2) in section 1178(a)(2)(A)(ii), for state laws that address controlled substances; and (3) in section 1178(a)(2)(B), for state laws relating to the privacy of individually identifiable health information that as provided for by the related provision of section 264(c)(2) of HIPAA, are contrary to and more stringent than the federal requirements. Section 1178 also carves out, in sections 1178(b) and 1178(c), certain areas of state authority that are not limited or invalidated by the provisions of part C of title XI: these areas relate to public health and state regulation of health plans.

The NPRM proposed a new Subpart B of the proposed part 160. The new Subpart B, which would apply to all standards, implementation specifications, and requirements adopted under HIPAA, would consist of four sections. Proposed § 160.201 provided that the provisions of Subpart B applied to exception determinations and advisory opinions issued by the Secretary under section 1178. Proposed § 160.202 set out proposed definitions for four terms: (1) "Contrary," (2) "more stringent," (3) "relates to the privacy of individually identifiable health information," and (4) "state law." The definition of "contrary" was drawn from case law concerning preemption. A seven-part set of specific criteria, drawn from fair information principles, was proposed for the definition of "more stringent." The definition of "relates to the privacy of individually identifiable health information" was also based on case law. The definition of "state law" was drawn from the statutory definition of this term

elsewhere in HIPAA. We note that state action having the force and effect of law may include common law. We eliminate the term "decision" from the proposed rule because it is redundant.

Proposed § 160.203 proposed a general rule reflecting the statutory general rule and exceptions that generally mirrored the statutory language of the exceptions. The one substantive addition to the statutory exception language was with respect to the statutory exception, "for other purposes." The following language was added: "for other purposes related to improving the Medicare program, the Medicaid program, or the efficiency and effectiveness of the health care system."

Proposed § 160.204 proposed two processes, one for the making of exception determinations, relating to determinations under section 1178(a)(2)(A) of the Act, the other for the rendering of advisory opinions, with respect to section 1178(a)(2)(B) of the Act. The processes proposed were similar in the following respects: (1) Only the state could request an exception determination or advisory opinion, as applicable; (2) both required the request to contain the same information, except that a request for an exception determination also had to set out the length of time the requested exception would be in effect, if less than three years; (3) both sets of requirements provided that requests had to be submitted to the Secretary as required by the Secretary, and until the Secretary's determination was made, the federal standard, requirement or implementation specification remained in effect; (4) both sets of requirements provided that the Secretary's decision would be effective intrastate only; (5) both sets of requirements provided that any change to either the federal or state basis for the Secretary's decision would require a new request, and the federal standard, implementation specification, or requirement would remain in effect until the Secretary acted favorably on the new request; (6) both sets of requirements provided that the Secretary could seek changes to the federal rules or urge states or other organizations to seek changes; and (7) both sets of requirements provided for annual publication of Secretarial decisions. In addition, the process for exception determinations provided for a maximum effective period of three years for such determinations.

The following changes have been made to subpart B in the final rules. First, § 160.201 now expressly ***82481** implements section 1178. Second, the definition of "more stringent" has been changed by eliminating the criterion relating to penalties and by framing the criterion under paragraph (1) more generally. Also, we have clarified that the term "individual" means the person who is the subject of the individually identifiable health information, since the term "individual" is defined this way only in subpart E of part 164, not in part 160. Third, the definition of "state law" has been changed by substituting the words "statute, constitutional provision" for the word "law," the words "common law" for the word "decision," and adding the words "force and" before the word "effect" in the proposed definition. Fourth, in § 160.203, several criteria relating to the statutory grounds for exception determinations have been further spelled out: (1) The words " related to the provision of or payment for health care" have been added to the exception for fraud and abuse; (2) the words "to the extent expressly authorized by statute or regulation" have been added to the exception for state regulation of health plans; (3) the words "of serving a compelling need related to public health, safety, or welfare, and, where a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, where the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served" have been added to the general exception "for other purposes"; and (4) the statutory provision regarding controlled substances has been elaborated on as follows: "Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substance, as defined at 21 U.S.C. 802, or which is deemed a controlled substance by state law."

The most extensive changes have been made to proposed § 160.204. The provision for advisory opinions has been eliminated. Section 160.204 now sets out only a process for requesting exception determinations. In most respects, this process is the same as proposed. However, the proposed restriction of the effect of exception determinations to wholly intrastate transactions has been eliminated. Section 160.204(a) has been modified to allow any person, not just a state, to submit a request for an exception determination, and clarifies that requests from states may be made by the state's chief elected official or his or her designee. Proposed § 160.204(a)(3) stated that if it is determined that the federal standard, requirement, or implementation specification in question meets the exception criteria as well as or better than the state law for which the exception is requested, the request will be denied; this language has been deleted. Thus, the criterion for granting or denying an exception request is whether the applicable exception criterion or criteria are met.

A new § 160.205 is also adopted, replacing part of what was proposed at proposed § 160.204. The new § 160.205 sets out the rules relating to the effectiveness of exception determinations. Exception determinations are effective until either the underlying federal or state laws change or the exception is revoked, by the Secretary, based on a determination that the grounds supporting the exception no longer exist. The proposed maximum of three years has been eliminated.

Relationship to Other Federal Laws

Covered entities subject to these rules are also subject to other federal statutes and regulations. For example, federal programs must comply with the statutes and regulations that govern them. Pursuant to their contracts, Medicare providers must comply with the requirements of the Privacy Act of 1974. Substance abuse treatment facilities are subject to the Substance Abuse Confidentiality provisions of the Public Health Service Act, section 543 and its regulations. And, health care providers in schools, colleges, and universities may come within the purview of the Family Educational Rights and Privacy Act. Thus, covered entities will need to determine how the privacy regulation will affect their ability to comply with these other federal laws.

Many commenters raised questions about how different federal statutes and regulations intersect with the privacy regulation. While we address specific concerns in the response to comments later in the preamble, in this section, we explore some of the general interaction issues. These summaries do not identify all possible conflicts or overlaps of the privacy regulation and other federal laws, but should provide general guidance for complying with both the privacy regulation and other federal laws. The summaries also provide examples of how covered entities can analyze other federal laws when specific questions arise. HHS may consult with other agencies concerning the interpretation of other federal laws as necessary.

Implied Repeal Analysis

When faced with the need to determine how different federal laws interact with one another, we turn to the judiciary's approach. Courts apply the implied repeal analysis to resolve tensions that appear to exist between two or more statutes. While the implication of a regulation-on-regulation conflict is unclear, courts agree that administrative rules and regulations that do not conflict with express statutory provisions have the force and effect of law. Thus, we believe courts would apply the standard rules of interpretation that apply to statutes to address questions of interpretation with regard to regulatory conflicts.

When faced with two potentially conflicting statutes, courts attempt to construe them so that both are given effect. If this construction is not possible, courts will look for express language in the later statute, or an intent in its legislative history, indicating that Congress intended the later statute to repeal the earlier one. If there is no expressed intent to repeal the earlier statute, courts will characterize the statutes as either general or specific. Ordinarily, later, general statutes will not repeal the special provisions of an earlier, specific statute. In some cases, when a later, general statute creates an irreconcilable conflict or is manifestly inconsistent with the earlier, specific statute in a manner that indicates a clear and manifest Congressional intent to repeal the earlier statute, courts will find that the later statute repeals the earlier statute by implication. In these cases, the latest legislative action may prevail and repeal the prior law, but only to the extent of the conflict.

There should be few instances in which conflicts exist between a statute or regulation and the rules below. For example, if a statute permits a covered entity to disclose protected health information and the rules below permit such a disclosure, no conflict arises; the covered entity could comply with both and choose whether or not to disclose the information. In instances in which a potential conflict appears, we would attempt to resolve it so that both laws applied. For example, if a statute or regulation permits dissemination of protected health information, but the rules below prohibit the use or disclosure without an authorization, we believe a covered entity would be able to comply with both because it could obtain an authorization under § 164.508 before disseminating the information under the other law.

Many apparent conflicts will not be true conflicts. For example, if a conflict ***82482** appears to exist because a previous statute or regulation requires a specific use or disclosure of protected health information that the rules below appear to prohibit, the

use or disclosure pursuant to that statute or regulation would not be a violation of the privacy regulation because § 164.512(a) permits covered entities to use or disclose protected health information as required by law.

If a statute or regulation prohibits dissemination of protected health information, but the privacy regulation requires that an individual have access to that information, the earlier, more specific statute would apply. The interaction between the Clinical Laboratory Improvement Amendments regulation is an example of this type of conflict. From our review of several federal laws, it appears that Congress did not intend for the privacy regulation to overrule existing statutory requirements in these instances.

Examples of Interaction

We have summarized how certain federal laws interact with the privacy regulation to provide specific guidance in areas deserving special attention and to serve as examples of the analysis involved. In the Response to Comment section, we have provided our responses to specific questions raised during the comment period.

The Privacy Act

The Privacy Act of 1974, 5 U.S.C. 552a, prohibits disclosures of records contained in a system of records maintained by a federal agency (or its contractors) without the written request or consent of the individual to whom the record pertains. This general rule is subject to various statutory exceptions. In addition to the disclosures explicitly permitted in the statute, the Privacy Act permits agencies to disclose information for other purposes compatible with the purpose for which the information was collected by identifying the disclosure as a "routine use" and publishing notice of it in the Federal Register. The Act applies to all federal agencies and certain federal contractors who operate Privacy Act systems of records on behalf of federal agencies.

Some federal agencies and contractors of federal agencies that are covered entities under the privacy rules are subject to the Privacy Act. These entities must comply with all applicable federal statutes and regulations. For example, if the privacy regulation permits a disclosure, but the disclosure is not permitted under the Privacy Act, the federal agency may not make the disclosure. If, however, the Privacy Act allows a federal agency the discretion to make a routine use disclosure, but the privacy regulation prohibits the disclosure, the federal agency will have to apply its discretion in a way that complies with the regulation. This means not making the particular disclosure.

The Freedom of Information Act

FOIA, 5 U.S.C. 552, provides for public disclosure, upon the request of any person, of many types of information in the possession of the federal government, subject to nine exemptions and three exclusions. For example, Exemption 6 permits federal agencies to withhold "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. 552(b)(6).

Uses and disclosures required by FOIA come within § 164.512(a) of the privacy regulation that permits uses or disclosures required by law if the uses or disclosures meet the relevant requirements of the law. Thus, a federal agency must determine whether it may apply an exemption or exclusion to redact the protected health information when responding to a FOIA request. When a FOIA request asks for documents that include protected health information, we believe the agency, when appropriate, must apply Exemption 6 to preclude the release of medical files or otherwise redact identifying details before disclosing the remaining information.

We offer the following analysis for federal agencies and federal contractors who operate Privacy Act systems of records on behalf of federal agencies and must comply with FOIA and the privacy regulation. If presented with a FOIA request that would result in the disclosure of protected health information, a federal agency must first determine if FOIA requires the disclosure or if an exemption or exclusion would be appropriate. We believe that generally a disclosure of protected health information, when requested under FOIA, would come within FOIA Exemption 6. We recognize, however, that the application of this exemption to information about deceased individuals requires a different analysis than that applicable to living individuals because, as a

general rule, under the Privacy Act, privacy rights are extinguished at death. However, under FOIA, it is entirely appropriate to consider the privacy interests of a decedent's survivors under Exemption 6. See Department of Justice FOIA Guide 2000, Exemption 6: Privacy Considerations. Covered entities subject to FOIA must evaluate each disclosure on a case-by-case basis, as they do now under current FOIA procedures.

Federal Substance Abuse Confidentiality Requirements

The federal confidentiality of substance abuse patient records statute, section 543 of the Public Health Service Act, 42 U.S.C. 290dd-2, and its implementing regulation, 42 CFR part 2, establish confidentiality requirements for patient records that are maintained in connection with the performance of any federally-assisted specialized alcohol or drug abuse program. Substance abuse programs are generally programs or personnel that provide alcohol or drug abuse treatment, diagnosis, or referral for treatment. The term "federally-assisted" is broadly defined and includes federally conducted or funded programs, federally licensed or certified programs, and programs that are tax exempt. Certain exceptions apply to information held by the Veterans Administration and the Armed Forces.

There are a number of health care providers that are subject to both these rules and the substance abuse statute and regulations. In most cases, a conflict will not exist between these rules. These privacy rules permit a health care provider to disclose information in a number of situations that are not permitted under the substance abuse regulation. For example, disclosures allowed, without patient authorization, under the privacy rule for law enforcement, judicial and administrative proceedings, public health, health oversight, directory assistance, and as required by other laws would generally be prohibited under the substance abuse statute and regulation. However, because these disclosures are permissive and not mandatory, there is no conflict. An entity would not be in violation of the privacy rules for failing to make these disclosures.

Similarly, provisions in the substance abuse regulation provide for permissive disclosures in case of medical emergencies, to the FDA, for research activities, for audit and evaluation activities, and in response to certain court orders. Because these are permissive disclosures, programs subject to both the privacy rules and the substance abuse rule are able to comply with both rules even if the privacy rules restrict these types of disclosures. In addition, the privacy rules generally require that an individual be given access to his or her own health information. Under the substance abuse ***82483** regulation, programs may provide such access, so there is no conflict.

The substance abuse regulation requires notice to patients of the substance abuse confidentiality requirements and provides for written consent for disclosure. While the privacy rules have requirements that are somewhat different, the program may use notice and authorization forms that include all the elements required by both regulations. The substance abuse rule provides a sample notice and a sample authorization form and states that the use of these forms would be sufficient. While these forms do not satisfy all of the requirements of the privacy regulation, there is no conflict because the substance abuse regulation does not mandate the use of these forms.

Employee Retirement Income Security Act of 1974

ERISA was enacted in 1974 to regulate pension and welfare employee benefit plans established by private sector employers, unions, or both, to provide benefits to their workers and dependents. Under ERISA, plans that provide "through the purchase of insurance or otherwise * * * medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, [or] death" are defined as employee welfare benefit plans. 29 U.S.C. 1002(1). In 1996, HIPAA amended ERISA to require portability, nondiscrimination, and renewability of health benefits provided by group health plans and group health insurance issuers. Numerous, although not all, ERISA plans are covered under the rules proposed below as "health plans."

Section 514(a) of ERISA, 29 U.S.C. 1144(a), preempts all state laws that "relate to" any employee benefit plan. However, section 514(b) of ERISA, 29 U.S.C. 1144(b)(2)(A), expressly saves from preemption state laws that regulate insurance. Section 514(b)(2)(B) of ERISA, 29 U.S.C. 1144(b)(2)(B), provides that an ERISA plan is deemed not to be an insurer for the purpose of regulating the plan under the state insurance laws. Thus, under the deemer clause, states may not treat ERISA plans as insurers

subject to direct regulation by state law. Finally, section 514(d) of ERISA, 29 U.S.C. 1144(d), provides that ERISA does not "alter, amend, modify, invalidate, impair, or supersede any law of the United States."

We considered whether the preemption provision of section 264(c)(2) of HIPAA would give effect to state laws that would otherwise be preempted by section 514(a) of ERISA. As discussed above, our reading of the statutes together is that the effect of section 264(c)(2) is only to leave in place state privacy protections that would otherwise apply and that are more stringent than the federal privacy protections.

Many health plans covered by the privacy regulation are also subject to ERISA requirements. Our discussions and consultations have not uncovered any particular ERISA requirements that would conflict with the rules.

The Family Educational Rights and Privacy Act

FERPA, as amended, 20 U.S.C. 1232g, provides parents of students and eligible students (students who are 18 or older) with privacy protections and rights for the records of students maintained by federally funded educational agencies or institutions or persons acting for these agencies or institutions. We have excluded education records covered by FERPA, including those education records designated as education records under Parts B, C, and D of the Individuals with Disabilities Education Act Amendments of 1997, from the definition of protected health information. For example, individually identifiable health information of students under the age of 18 created by a nurse in a primary or secondary school that receives federal funds and that is subject to FERPA is an education record, but not protected health information. Therefore, the privacy regulation does not apply. We followed this course because Congress specifically addressed how information in education records should be protected in FERPA.

We have also excluded certain records, those described at 20 U.S.C. 1232g(a)(4)(B)(iv), from the definition of protected health information because FERPA also provided a specific structure for the maintenance of these records. These are records (1) of students who are 18 years or older or are attending post-secondary educational institutions, (2) maintained by a physician, psychiatrist, psychologist, or recognized professional or paraprofessional acting or assisting in that capacity, (3) that are made, maintained, or used only in connection with the provision of treatment to the student, and (4) that are not available to anyone, except a physician or appropriate professional reviewing the record as designated by the student. Because FERPA excludes these records from its protections only to the extent they are not available to anyone other than persons providing treatment to students, any use or disclosure of the record for other purposes, including providing access to the individual student who is the subject of the information, would turn the record into an education record. As education records, they would be subject to the protections of FERPA.

These exclusions are not applicable to all schools, however. If a school does not receive federal funds, it is not an educational agency or institution as defined by FERPA. Therefore, its records that contain individually identifiable health information are not education records. These records may be protected health information. The educational institution or agency that employs a school nurse is subject to our regulation as a health care provider if the school nurse or the school engages in a HIPAA transaction.

While we strongly believe every individual should have the same level of privacy protection for his/her individually identifiable health information, Congress did not provide us with authority to disturb the scheme it had devised for records maintained by educational institutions and agencies under FERPA. We do not believe Congress intended to amend or preempt FERPA when it enacted HIPAA.

With regard to the records described at 20 U.S.C. 1232g(a)(4)(b)(iv), we considered requiring health care providers engaged in HIPAA transactions to comply with the privacy regulation up to the point these records were used or disclosed for purposes other than treatment. At that point, the records would be converted from protected health information into education records. This conversion would occur any time a student sought to exercise his/her access rights. The provider, then, would need to treat the record in accordance with FERPA's requirements and be relieved from its obligations under the privacy regulation. We chose not to adopt this approach because it would be unduly burdensome to require providers to comply with two different,

yet similar, sets of regulations and inconsistent with the policy in FERPA that these records be exempt from regulation to the extent the records were used only to treat the student.

Gramm-Leach-Bliley

In 1999, Congress passed Gramm-Leach-Bliley (GLB), Pub. L. 106-102, which included provisions, section 501 et seq., that limit the ability of financial institutions to disclose "nonpublic personal information" about consumers to non-affiliated third parties and require financial institutions to provide customers with their privacy policies and practices with respect to nonpublic ***82484** personal information. In addition, Congress required seven agencies with jurisdiction over financial institutions to promulgate regulations as necessary to implement these provisions. GLB and its accompanying regulations define "financial institutions" as including institutions engaged in the financial activities of bank holding companies, which may include the business of insuring. See 15 U.S.C. 6809(3); 12 U.S.C. 1843(k). However, Congress did not provide the designated federal agencies with the authority to regulate health insurers. Instead, it provided states with an incentive to adopt and have their state insurance authorities enforce these rules. See 15 U.S.C. 6805. If a state were to adopt laws consistent with GLB, health insurers would have to determine how to comply with both sets of rules.

Thus, GLB has caused concern and confusion among health plans that are subject to our privacy regulation. Although Congress remained silent as to its understanding of the interaction of GLB and HIPAA's privacy provisions, the Federal Trade Commission and other agencies implementing the GLB privacy provisions noted in the preamble to their GLB regulations that they "would consult with HHS to avoid the imposition of duplicative or inconsistent requirements." 65 Fed. Reg. 33646, 33648 (2000). Additionally, the FTC also noted that "persons engaged in providing insurance" would be within the enforcement jurisdiction of state insurance authorities and not within the jurisdiction of the FTC. Id.

Because the FTC has clearly stated that it will not enforce the GLB privacy provisions against persons engaged in providing insurance, health plans will not be subject to dual federal agency jurisdiction for information that is both nonpublic personal information and protected health information. If states choose to adopt GLB-like laws or regulations, which may or may not track the federal rules completely, health plans would need to evaluate these laws under the preemption analysis described in subpart B of Part 160.

Federally Funded Health Programs

These rules will affect various federal programs, some of which may have requirements that are, or appear to be, inconsistent with the requirements of these regulations. These programs include those operated directly by the federal government (such as health programs for military personnel and veterans) as well as programs in which health services or benefits are provided by the private sector or by state or local governments, but which are governed by various federal laws (such as Medicare, Medicaid, and ERISA).

Congress explicitly included some of these programs in HIPAA, subjecting them directly to the privacy regulation. Section 1171 of the Act defines the term "health plan" to include the following federally conducted, regulated, or funded programs: Group plans under ERISA that either have 50 or more participants or are administered by an entity other than the employer who established and maintains the plan; federally qualified health maintenance organizations; Medicare; Medicaid; Medicare supplemental policies; the health care program for active military personnel; the health care program for veterans; the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); the Indian health service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.; and the Federal Employees Health Benefits Program. There also are many other federally conducted, regulated, or funded programs in which individually identifiable health information is created or maintained, but which do not come within the statutory definition of "health plan." While these latter types of federally conducted, regulated, or assisted programs are not explicitly covered by part C of title XI in the same way that the programs listed in the statutory definition of "health plan" are covered, the statute may nonetheless apply to transactions and other activities conducted under such programs. This is likely to be the case when the federal entity or federally regulated or funded entity

provides health services; the requirements of part C may apply to such an entity as a "health care provider." Thus, the issue of how different federal requirements apply is likely to arise in numerous contexts.

There are a number of authorities under the Public Health Service Act and other legislation that contain explicit confidentiality requirements, either in the enabling legislation or in the implementing regulations. Many of these are so general that there would appear to be no problem of inconsistency, in that nothing in those laws or regulations would appear to restrict the provider's ability to comply with the privacy regulation's requirements.

There may, however, be authorities under which either the requirements of the enabling legislation or of the program regulations would impose requirements that differ from these rules.

For example, regulations applicable to the substance abuse block grant program funded under section 1943(b) of the Public Health Service Act require compliance with 42 CFR part 2, and, thus, raise the issues identified above in the substance abuse confidentiality regulations discussion. There are a number of federal programs which, either by statute or by regulation, restrict the disclosure of patient information to, with minor exceptions, disclosures "required by law." See, for example, the program of projects for prevention and control of sexually transmitted diseases funded under section 318(e)(5) of the Public Health Service Act (42 CFR 51b.404); the regulations implementing the community health center program funded under section 330 of the Public Health Service Act (42 CFR 51c.110); the regulations implementing the program of grants for family planning services under title X of the Public Health Service Act (42 CFR 59.15); the regulations implementing the program of grants for black lung clinics funded under 30 U.S.C. 437(a) (42 CFR 55a.104); the regulations implementing the program of maternal and child health projects funded under section 501 of the Act (42 CFR 51a.6); the regulations implementing the program of medical examinations of coal miners (42 CFR 37.80(a)). These legal requirements would restrict the grantees or other entities providing services under the programs involved from making many of the disclosures that §§ 164.510 or 164.512 would permit. In some cases, permissive disclosures for treatment, payment, or health care operations would also be limited. Because §§ 164.510 and 164.512 are merely permissive, there would not be a conflict between the program requirements, because it would be possible to comply with both. However, entities subject to both sets of requirements would not have the total range of discretion that they would have if they were subject only to this regulation.

Food, Drug, and Cosmetic Act

The Food, Drug, and Cosmetic Act, 21 U.S.C. 301, et seq., and its accompanying regulations outline the responsibilities of the Food and Drug Administration with regard to monitoring the safety and effectiveness of drugs and devices. Part of the agency's responsibility is to obtain reports about adverse events, track medical devices, and engage in other types of post marketing surveillance. Because many of these reports contain protected health information, the information within them may come within the purview of the privacy rules. ***82485** Although some of these reports are required by the Food, Drug, and Cosmetic Act or its accompanying regulations, other types of reporting are voluntary. We believe that these reports, while not mandated, play a critical role in ensuring that individuals receive safe and effective drugs and devices. Therefore, in § 164.512(b)(1)(iii), we have provided that covered entities may disclose protected health information to a person subject to the jurisdiction of the Food and Drug Administration for specified purposes, such as reporting adverse events, tracking medical devices, or engaging in other post marketing surveillance. We describe the scope and conditions of such disclosures in more detail in § 164.512(b).

Clinical Laboratory Improvement Amendments

CLIA, 42 U.S.C. 263a, and the accompanying regulations, 42 CFR part 493, require clinical laboratories to comply with standards regarding the testing of human specimens. This law requires clinical laboratories to disclose test results or reports only to authorized persons, as defined by state law. If a state does not define the term, the federal law defines it as the person who orders the test.

We realize that the person ordering the test is most likely a health care provider and not the individual who is the subject of the protected health information included within the result or report. Under this requirement, therefore, a clinical laboratory may be prohibited by law from providing the individual who is the subject of the test result or report with access to this information.

Although we believe individuals should be able to have access to their individually identifiable health information, we recognize that in the specific area of clinical laboratory testing and reporting, the Health Care Financing Administration, through regulation, has provided that access may be more limited. To accommodate this requirement, we have provided at § 164.524(1)(iii) that covered entities maintaining protected health information that is subject to the CLIA requirements do not have to provide individuals with a right of access to or a right to inspect and obtain a copy of this information if the disclosure of the information to the individual would be prohibited by CLIA.

Not all clinical laboratories, however, will be exempted from providing individuals with these rights. If a clinical laboratory operates in a state in which the term "authorized person" is defined to include the individual, the clinical laboratory would have to provide the individual with these rights. Similarly, if the individual was the person who ordered the test and an authorized person included such a person, the laboratory would be required to provide the individual with these rights.

Additionally, CLIA regulations exempt the components or functions of "research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients" from the CLIA regulatory scheme. 42 CFR 493.3(a)(2). If subject to the access requirements of this regulation, such entities would be forced to meet the requirements of CLIA from which they are currently exempt. To eliminate this additional regulatory burden, we have also excluded covered entities that are exempt from CLIA under that rule from the access requirement of this regulation.

Although we are concerned about the lack of immediate access by the individual, we believe that, in most cases, individuals who receive clinical tests will be able to receive their test results or reports through the health care provider who ordered the test for them. The provider will receive the information from the clinical laboratory. Assuming that the provider is a covered entity, the individual will have the right of access and right to inspect and copy this protected health information through his or her provider.

Other Mandatory Federal or State Laws

Many federal laws require covered entities to provide specific information to specific entities in specific circumstances. If a federal law requires a covered entity to disclose a specific type of information, the covered entity would not need an authorization under § 164.508 to make the disclosure because the final rule permits covered entities to make disclosures that are required by law under § 164.512(a). Other laws, such as the Social Security Act (including its Medicare and Medicaid provisions), the Family and Medical Leave Act, the Public Health Service Act, Department of Transportation regulations, the Environmental Protection Act and its accompanying regulations, the National Labor Relations Act, the Federal Aviation Administration, and the Federal Highway Administration rules, may also contain provisions that require covered entities or others to use or disclose protected health information for specific purposes.

When a covered entity is faced with a question as to whether the privacy regulation would prohibit the disclosure of protected health information that it seeks to disclose pursuant to a federal law, the covered entity should determine if the disclosure is required by that law. In other words, it must determine if the disclosure is mandatory rather than merely permissible. If it is mandatory, a covered entity may disclose the protected health information pursuant to § 164.512(a), which permits covered entities to disclose protected health information without an authorization when the disclosure is required by law. If the disclosure is not required (but only permitted) by the federal law, the covered entity must determine if the disclosure comes within one of the other permissible disclosures. If the disclosure does not come within one of the provisions for permissible disclosures, the covered entity must obtain an authorization from the individual who is the subject of the information or de-identify the information before disclosing it.

If another federal law prohibits a covered entity from using or disclosing information that is also protected health information, but the privacy regulation permits the use or disclosure, a covered entity will need to comply with the other federal law and not use or disclose the information.

Federal Disability Nondiscrimination Laws

The federal laws barring discrimination on the basis of disability protect the confidentiality of certain medical information. The information protected by these laws falls within the larger definition of "health information" under this privacy regulation. The two primary disability nondiscrimination laws are the Americans with Disabilities Act (ADA), 42 U.S.C. 12101 et seq., and the Rehabilitation Act of 1973, as amended, 29 U.S.C. 701 et seq., although other laws barring discrimination on the basis of disability (such as the nondiscrimination provisions of the Workforce Investment Act of 1988, 29 U.S.C. 2938) may also apply. Federal disability nondiscrimination laws cover two general categories of entities relevant to this discussion: employers and entities that receive federal financial assistance.

Employers are not covered entities under the privacy regulation. Many employers, however, are subject to the federal disability nondiscrimination laws and, therefore, must protect the ***82486** confidentiality of all medical information concerning their applicants and employees.

The employment provisions of the ADA, 42 U.S.C. 12111 et seq., expressly cover employers of 15 or more employees, employment agencies, labor organizations, and joint labor-management committees. Since 1992, employment discrimination complaints arising under sections 501, 503, and 504 of the Rehabilitation Act also have been subject to the ADA's employment nondiscrimination standards. See "Rehabilitation Act Amendments," Pub. L. No. 102-569, 106 Stat. 4344. Employers subject to ADA nondiscrimination standards have confidentiality obligations regarding applicant and employee medical information. Employers must treat such medical information, including medical information from voluntary health or wellness programs and any medical information that is voluntarily disclosed as a confidential medical record, subject to limited exceptions.

Transmission of health information by an employer to a covered entity, such as a group health plan, is governed by the ADA confidentiality restrictions. The ADA, however, has been interpreted to permit an employer to use medical information for insurance purposes. See 29 CFR part 1630 App. at § 1630.14(b) (describing such use with reference to 29 CFR 1630.16(f), which in turn explains that the ADA regulation "is not intended to disrupt the current regulatory structure for self-insured employers * * * or current industry practices in sales, underwriting, pricing, administrative and other services, claims and similar insurance related activities based on classification of risks as regulated by the states"). See also, "Enforcement Guidance on Disability-Related Inquiries and Medical Examinations of Employees under the Americans with Disabilities Act," 4, n.10 (July 26, 2000), __ FEP Manual (BNA) __ ("Enforcement Guidance on Employees"). See generally, "ADA Enforcement Guidance on Preemployment Disability-Related Questions and Medical Examinations" (October 10, 1995), 8 FEP Manual (BNA) 405:7191 (1995) (also available at http://www.eeoc.gov). Thus, use of medical information for insurance purposes may include transmission of health information to a covered entity.

If an employer-sponsored group health plan is closely linked to an employer, the group health plan may be subject to ADA confidentiality restrictions, as well as this privacy regulation. See Carparts Distribution Center, Inc. v. Automotive Wholesaler's Association of New England, Inc., 37 F.3d 12 (1st Cir. 1994)(setting forth three bases for ADA Title I jurisdiction over an employer-provided medical reimbursement plan, in a discrimination challenge to the plan's HIV/AIDS cap). Transmission of applicant or employee health information by the employer's management to the group health plan may be permitted under the ADA standards as the use of medical information for insurance purposes. Similarly, disclosure of such medical information by the group health plan, under the limited circumstances permitted by this privacy regulation, may involve use of the information for insurance purposes as broadly described in the ADA discussion above.

Entities that receive federal financial assistance, which may also be covered entities under the privacy regulation, are subject to section 504 of the Rehabilitation Act (29 U.S.C. 794) and its implementing regulations. Each federal agency has promulgated such regulations that apply to entities that receive financial assistance from that agency ("recipients"). These regulations may

limit the disclosure of medical information about persons who apply to or participate in a federal financially assisted program or activity. For example, the Department of Labor's section 504 regulation (found at 29 CFR part 32), consistent with the ADA standards, requires recipients that conduct employment-related programs, including employment training programs, to maintain confidentiality regarding any information about the medical condition or history of applicants to or participants in the program or activity. Such information must be kept separate from other information about the applicant or participant and may be provided to certain specified individuals and entities, but only under certain limited circumstances described in the regulation. See 29 CFR 32.15(d). Apart from those circumstances, the information must be afforded the same confidential treatment as medical records, id. Also, recipients of federal financial assistance from the Department of Health and Human Services, such as hospitals, are subject to the ADA's employment nondiscrimination standards. They must, accordingly, maintain confidentiality regarding the medical condition or history of applicants for employment and employees.

The statutes and implementing regulations under which the federal financial assistance is provided may contain additional provisions regulating collection and disclosure of medical, health, and disability-related information. See, e.g., section 188 of the Workforce Investment Act of 1988 (29 U.S.C. 2938) and 29 CFR 37.3(b). Thus, covered entities that are subject to this privacy regulation, may also be subject to the restrictions in these laws as well.

U.S. Safe Harbor Privacy Principles (European Union Directive on Data Protection)

The E.U. Directive became effective in October 1998 and prohibits European Union Countries from permitting the transfer of personal data to another country without ensuring that an "adequate level of protection," as determined by the European Commission, exists in the other country or pursuant to one of the Directive's derogations of this rule, such as pursuant to unambiguous consent or to fulfill a contract with the individual. In July 2000, the European Commission concluded that the U.S. Safe Harbor Privacy Principles[FN1] constituted "adequate protection." Adherence to the Principles is voluntary. Organizations wishing to engage in the exchange of personal data with E.U. countries may assert compliance with the Principles as one means of obtaining data from E.U. countries.

The Department of Commerce, which negotiated these Principles with the European Commission, has provided guidance for U.S. organizations seeking to adhere to the guidelines and comply with U.S. law. We believe this guidance addresses the concerns covered entities seeking to transfer personal data from E.U. countries may have. When "U.S. law imposes a conflicting obligation, U.S. organizations whether in the safe harbor or not must comply with the law." An organization does not need to comply with the Principles if a conflicting U.S. law "explicitly authorizes" the particular conduct. The organization's non-compliance is "limited to the extent necessary to meet the overriding legitimate interests further[ed] by such authorization." However, if only a difference exists such that an "option is allowable under the Principles and/or U.S. law, organizations are expected to opt for the higher protection where possible." Questions regarding compliance and interpretation will be decided based on U.S. law. See Department of Commerce, Memorandum on Damages for Breaches ***82487** of Privacy, Legal Authorizations and Mergers and Takeovers in U.S. Law 5 (July 17, 2000); Department of Commerce, Safe Harbor Privacy Principles Issued by the U.S. Department of Commerce on July 21, 2000, 65 FR 45666 (2000). The Principles and our privacy regulation are based on common principles of fair information practices. We believe they are essentially consistent and that an organization complying with our privacy regulation can fairly and correctly self-certify that it complies with the Principles. If a true conflict arises between the privacy regulation and the Principles, the Department of Commerce's guidance provides that an entity must comply with the U.S. law.

Part 160—Subpart C—Compliance and Enforcement

Proposed § 164.522 included five paragraphs addressing activities related to the Secretary's enforcement of the rule. These provisions were based on procedures and requirements in various civil rights regulations. Proposed § 164.522(a) provided that the Secretary would, to the extent practicable, seek the cooperation of covered entities in obtaining compliance, and could provide technical assistance to covered entities to help them comply voluntarily. Proposed § 164.522(b) provided that individuals could file complaints with the Secretary. However, where the complaint related to the alleged failure of a covered entity to amend or correct protected health information as proposed in the rule, the Secretary would not make certain determinations such as

whether protected health information was accurate or complete. This paragraph also listed the requirements for filing complaints and indicated that the Secretary may investigate such complaints and what might be reviewed as part of such investigation.

Under proposed § 164.522(c), the Secretary would be able to conduct compliance reviews. Proposed § 164.522(d) described the responsibilities that covered entities keep records and reports as prescribed by the Secretary, cooperate with compliance reviews, permit the Secretary to have access to their facilities, books, records, and other sources of information during normal business hours, and seek records held by other persons. This paragraph also stated that the Secretary would maintain the confidentiality of protected health information she collected and prohibit covered entities from taking retaliatory action against individuals for filing complaints or for other activities. Proposed § 164.522(e) provided that the Secretary would inform the covered entity and the individual complainant if an investigation or review indicated a failure to comply and would seek to resolve the matter informally if possible. If the matter could not be resolved informally, the Secretary would be able to issue written findings, be required to inform the covered entity and the complainant, and be able to pursue civil enforcement action or make a criminal referral. The Secretary would also be required to inform the covered entity and the individual complainant if no violation was found.

We make the following changes and additions to proposed § 164.522 in the final rule. First, we have moved this section to part 160, as a new subpart C, “Compliance and Enforcement.” Second, we add new sections that explain the applicability of these provisions and incorporate certain definitions. Accordingly, we change the proposed references to violations to “this subpart” to violations of “the applicable requirements of part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.” Third, the final rule at § 160.306(a) provides that any person, not just an “individual” (the person who is the subject of the individually identifiable health information) may file a complaint with the Secretary. Other references in this subpart to an individual have been changed accordingly. Fourth, we delete the proposed § 164.522(a) language that indicated that the Secretary would not determine whether information was accurate or complete, or whether errors or omissions might have an adverse effect on the individual. While the policy is not changed in that the Secretary will not make such determinations, we believe the language is unnecessary and may suggest that we would make all other types of determinations, such as all determinations in which the regulation defers to the professional judgment of the covered entity. Fifth, § 160.306(b)(3) requires that complaints be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown. Sixth, § 160.310(b) requires cooperation with investigations as well as compliance reviews. Seventh, § 160.310 (c)(1) provides that the Secretary must be provided access to a covered entity's facilities, books, records, accounts, and other sources of information, including protected health information, at any time and without notice where exigent circumstances exist, such as where documents might be hidden or destroyed. Eighth, the provision proposed at § 164.522(d) that would prohibit covered entities from taking retaliatory action against individuals for filing a complaint with the Secretary or for certain other actions has been changed and moved to § 164.530. Ninth, § 160. 312(a)(2) deletes the reference in the proposed rule to using violation findings as a basis for initiating action to secure penalties. This deletion is not a substantive change. This language was removed because penalties will be addressed in the enforcement regulation. As in the NPRM, the Secretary may promulgate alternative procedures for complaints relating to national security. For example, to protect classified information, we may promulgate rules that would allow an intelligence community agency to create a separate body within that agency to receive complaints.

The Department plans to issue an Enforcement Rule that applies to all of the regulations that the Department issues under the Administrative Simplification provisions of HIPAA. This regulation will address the imposition of civil monetary penalties and the referral of criminal cases where there has been a violation of this rule. Penalties are provided for under section 262 of HIPAA. The Enforcement Rule would also address the topics covered by Subpart C below. It is expected that this Enforcement Rule would replace Subpart C.

Part 164—Subpart A—General Provisions

Section 164.102—Statutory Basis

In the NPRM, we provided that the provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation standards under part C of title XI of the Act and section 264 of Public Law 104-191. The final rule adopts this language.

Section 164.104—Applicability

In the NPRM, we provided that except as otherwise provided, the provisions of this part apply to covered entities: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with any transaction referred to in section 1173(a)(1) of the Act. The final rule adopts this language. ***82488**

Section 164.106—Relationship to Other Parts

The final rule adds a new provision stating that in complying with the requirements of this part, covered entities are required to comply with the applicable provisions of parts 160 and 162 of this subchapter. This language references Subchapter C in this regulation, Administrative Data Standards and Related Requirements; Part 160, General Administrative Requirements; and Part 162, Administrative Requirements. Part 160 includes requirements such as keeping records and submitting compliance reports to the Secretary and cooperating with the Secretary's complaint investigations and compliance reviews. Part 162 includes requirements such as requiring a covered entity that conducts an electronic transaction, adopted under this part, with another covered entity to conduct the transaction as a standard transaction as adopted by the Secretary.

Part 164—Subpart B-D—Reserved

Part 164—Subpart E—Privacy

Section 164.500—Applicability

The discussion below describes the entities and the information that are subject to the final regulation.

Many of the provisions of the regulation are presented as “standards.” Generally, the standards indicate what must be accomplished under the regulation and implementation specifications describe how the standards must be achieved.

Covered Entities

We proposed in the NPRM to apply the standards in the regulation to health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions referred to in section 1173(a)(1) of the Act. The proposal referred to these entities as “covered entities.”

We have revised § 164.500 to clarify the applicability of the rule to health care clearinghouses. As we stated in the preamble to the NPRM, we believe that in most instances health care clearinghouses will receive protected health information as a business associate to another covered entity. This understanding was confirmed by the comments and by our fact finding. Clearinghouses rarely have direct contact with individuals, and usually will not be in a position to create protected health information or to receive it directly from them. Unlike health plans and providers, clearinghouses usually convey and repackage information and do not add materially to the substance of protected health information of an individual.

The revised language provides that clearinghouses are not subject to certain requirements in the rule when acting as business associates of other covered entities. As revised, a clearinghouse acting as a business associate is subject only to the provisions of this section, to the definitions, to the general rules for uses and disclosures of protected health information (subject to limitations), to the provision relating to health care components, to the provisions relating to uses and disclosures for which consent, individual authorization or an opportunity to agree or object is not required (subject to limitations), to the transition requirements and to the compliance date. With respect to the uses and disclosures authorized under § 164.502 or § 164.512, a clearinghouse acting as a business associate is not authorized by the rule to make any use or disclosure not permitted by its

business associate contract. Clearinghouses acting as business associates are not subject to the other requirements of this rule, which include the provisions relating to procedural requirements, requirements for obtaining consent, individual authorization or agreement, provision of a notice, individual rights to request privacy protection, access and amend information and receive an accounting of disclosures and the administrative requirements.

We note that, even as business associates, clearinghouses remain covered entities. Clearinghouses, like other covered entities, are responsible under this regulation for abiding by the terms of business associate contracts. For example, while the provisions regarding individuals' access to and right to request corrections to protected health information about them apply only to health plans and covered health care providers, clearinghouses may have some responsibility for providing such access under their business associate contracts. A clearinghouse (or any other covered entity) that violates the terms of a business associate contract also is in direct violation of this rule and, as a covered entity, is subject to compliance and enforcement action.

We clarify that a covered entity is only subject to these rules to the extent that they possess protected health information. Moreover, these rules only apply with regard to protected health information. For example, if a covered entity does not disclose or receive from its business associate any protected health information and no protected health information is created or received by its business associate on behalf of the covered entity, then the business associate requirements of this rule do not apply.

We clarify that the Department of Defense or any other federal agency and any non-governmental organization acting on its behalf, is not subject to this rule when it provides health care in another country to foreign national beneficiaries. The Secretary believes that this exemption is warranted because application of the rule could have the unintended effect of impeding or frustrating the conduct of such activities, such as interfering with the ability of military command authorities to obtain protected health information on prisoners of war, refugees, or detainees for whom they are responsible under international law. See the preamble to the definition of “individual” for further discussion.

Covered Information

We proposed in the NPRM to apply the requirements of the rule to individually identifiable health information that is or has been electronically transmitted or maintained by a covered entity. The provisions would have applied to the information itself, referred to as protected health information in the rule, and not to the particular records in which the information is contained. We proposed that once information was maintained or transmitted electronically by a covered entity, the protections would follow the information in whatever form, including paper records, in which it exists while held by a covered entity. The proposal would not have applied to information that was never electronically maintained or transmitted by a covered entity.

In the final rule, we extend the scope of protections to all individually identifiable health information in any form, electronic or non-electronic, that is held or transmitted by a covered entity. This includes individually identifiable health information in paper records that never has been electronically stored or transmitted. (See § 164.501, definition of “protected health information,” for further discussion.)

Section 164.501—Definitions

Correctional Institution

The proposed rule did not define the term correctional institution. The final rule defines correctional institution as any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, ***82489** a state, a territory, a political subdivision of a state or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. Other persons held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial. This language was necessary to explain the privacy rights and protections of inmates in this regulation.

Covered Functions

We add a new term, "covered functions," as a shorthand way of expressing and referring to the functions that the entities covered by section 1172(a) of the Act perform. Section 1171 defines the terms "health plan", "health care provider", and "health care clearinghouse" in functional terms. Thus, a "health plan" is an individual or group plan "that provides, or pays the cost of, medical care * * *", a "health care provider" "furnish[es] health care services or supplies," and a "health care clearinghouse" is an entity "that processes or facilitates the processing of * * * data elements of health information * * *". Covered functions, therefore, are the activities that any such entity engages in that are directly related to operating as a health plan, health care provider, or health care clearinghouse; that is, they are the functions that make it a health plan, health care provider, or health care clearinghouse.

The term "covered functions" is not intended to include various support functions, such as computer support, payroll and other office support, and similar support functions, although we recognize that these support functions must occur in order for the entity to carry out its health care functions. Because such support functions are often also performed for parts of an organization that are not doing functions directly related to the health care functions and may involve access to and/or use of protected health information, the rules below describe requirements for ensuring that workforce members who perform these support functions do not impermissibly use or disclose protected health information. See § 164.504.

Data Aggregation

The NPRM did not include a definition of data aggregation. In the final rule, data aggregation is defined, with respect to protected health information received by a business associate in its capacity as the business associate of a covered entity, as the combining of such protected health information by the business associate with protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit the creation of data for analyses that relate to the health care operations of the respective covered entities. The definition is included in the final rule to help describe how business associates can assist covered entities to perform health care operations that involve comparative analysis of protected health information from otherwise unaffiliated covered entities. Data aggregation is a service that gives rise to a business associate relationship if the performance of the service involves disclosure of protected health information by the covered entity to the business associate.

Designated Record Set

In the proposed rule, we defined designated record set as "a group of records under the control of a covered entity from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual and which is used by the covered entity to make decisions about the individual." We defined a "record" as "any item, collection, or grouping of protected health information maintained, collected, used, or disseminated by a covered entity."

In the final rule, we modify the definition of designated record set to specify certain records maintained by or for a covered entity that are always part of a covered entity's designated record sets and to include other records that are used to make decisions about individuals. We do not use the means of retrieval of a record as a defining criteria.

For health plans, designated record sets include, at a minimum, the enrollment, payment, claims adjudication, and case or medical management record systems of the plan. For covered health care providers, designated record sets include, at a minimum, the medical record and billing record about individuals maintained by or for the provider. In addition to these records, designated record sets include any other group of records that are used, in whole or in part, by or for a covered entity to make decisions about individuals. We note that records that otherwise meet the definition of designated record set and which are held by a business associate of the covered entity are part of the covered entity's designated record sets. Although we do not specify particular types of records that are always included in the designated record sets of clearinghouses when they are not acting

as business associates, this definition includes a group of records that such a clearinghouse uses, in whole or in part, to make decisions about individuals.

For the most part we retain, with slight modifications, the definition of "record," defining it as any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated.

Direct Treatment Relationship

This term was not included in the proposed rule. Direct treatment relationship means a relationship between a health care provider and an individual that is not an indirect treatment relationship (see definition of indirect treatment relationship, below). For example, outpatient pharmacists and Web-based providers generally have direct treatment relationships with patients. Outpatient pharmacists fill prescriptions written by other providers, but they furnish the prescription and advice about the prescription directly to the patient, not through another treating provider. Web-based providers generally deliver health care independently, without the orders of another provider.

A provider may have direct treatment relationships with some patients and indirect treatment relationships with others. In some provisions of the final rule, providers with indirect treatment relationships are excepted from requirements that apply to other providers. See § 164.506 regarding consent for uses and disclosures of protected health information for treatment, payment, and health care operations, and § 164.520 regarding notice of information practices. These exceptions apply only with respect to the individuals with whom the provider has an indirect treatment relationship.

Disclosure

We proposed to define "disclosure" to mean the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information. The final rule is unchanged. We note that the transfer of protected health information from a covered entity to a business associate is a disclosure for purposes of this regulation.

Health Care Operations

The preamble to the proposed rule explained that in order for treatment and payment to occur, protected health ***82490** information must be used within entities and shared with business partners. In the proposed rule we provided a definition for "health care operations" to clarify the activities we considered to be "compatible with and directly related to" treatment and payment and for which protected health information could be used or disclosed without individual authorization. These activities included conducting quality assessment and improvement activities, reviewing the competence or qualifications and accrediting/licensing of health care professionals and plans, evaluating health care professional and health plan performance, training future health care professionals, insurance activities relating to the renewal of a contract for insurance, conducting or arranging for medical review and auditing services, and compiling and analyzing information in anticipation of or for use in a civil or criminal legal proceeding. Recognizing the dynamic nature of the health care industry, we acknowledged that the specified categories may need to be modified as the industry evolves.

The preamble discussion of the proposed general rules listed certain activities that would not be considered health care operations because they were sufficiently unrelated to treatment and payment to warrant requiring an individual to authorize such use or disclosure. Those activities included: marketing of health and non-health items and services; disclosure of protected health information for sale, rent or barter; use of protected health information by a non-health related division of an entity; disclosure of protected health information for eligibility, enrollment, underwriting, or risk rating determinations prior to an individuals' enrollment in a health plan; disclosure to an employer for employment determinations; and fundraising.

In the final rule, we do not change the general approach of defining health care operations: health care operations are the listed activities undertaken by the covered entity that maintains the protected health information (i.e., one covered entity may not disclose protected health information for the operations of a second covered entity); a covered entity may use any protected

health information it maintains for its operations (e.g., a plan may use protected health information about former enrollees as well as current enrollees); we expand the proposed list to reflect many changes requested by commenters.

We modify the proposal that health care operations represent activities "in support of" treatment and payment functions. Instead, in the final rule, health care operations are the enumerated activities to the extent that the activities are related to the covered entity's functions as a health care provider, health plan or health care clearinghouse, i.e., the entity's "covered functions." We make this change to clarify that health care operations includes general administrative and business functions necessary for the covered entity to remain a viable business. While it is possible to draw a connection between all the enumerated activities and "treatment and payment," for some general business activities (e.g., audits for financial disclosure statements) that connection may be tenuous. The proposed concept also did not include the operations of those health care clearinghouses that may be covered by this rule outside their status as business associate to a covered entity. We expand the definition to include disclosures for the enumerated activities of organized health care arrangements in which the covered entity participates. See also the definition of organized health care arrangements, below.

In addition, we make the following changes and additions to the enumerated subparagraphs:

(1) We add language to clarify that the primary purpose of the studies encompassed by "quality assessment and improvement activities" must not be to obtain generalizable knowledge. A study with such a purpose would meet the rule's definition of research, and use or disclosure of protected health information would have to meet the requirements of §§ 164.508 or 164.512(i). Thus, studies may be conducted as a health care operation if development of generalizable knowledge is not the primary goal. However, if the study changes and the covered entity intends the results to be generalizable, the change should be documented by the covered entity as proof that, when initiated, the primary purpose was health care operations.

We add population-based activities related to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives, and related functions that do not entail direct patient care. Many commenters recommended adding the term "disease management" to health care operations. We were unable, however, to find a generally accepted definition of the term. Rather than rely on this label, we include many of the functions often included in discussions of disease management in this definition or in the definition of treatment. This topic is discussed further in the comment responses below.

(2) We have deleted "undergraduate and graduate" as a qualifier for "students," to make the term more general and inclusive. We add the term "practitioners." We expand the purposes encompassed to include situations in which health care providers are working to improve their skills. The rule also adds the training of non-health care professionals.

(3) The rule expands the range of insurance related activities to include those related to the creation, renewal or replacement of a contract for health insurance or health benefits, as well as ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss and excess of loss insurance). For these activities, we also eliminate the proposed requirement that these uses and disclosures apply only to protected health information about individuals already enrolled in a health plan. Under this provision, a group health plan that wants to replace its insurance carrier may disclose certain protected health information to insurance issuers in order to obtain bids on new coverage, and an insurance carrier interested in bidding on new business may use protected health information obtained from the potential new client to develop the product and pricing it will offer. For circumstances in which no new contract is issued, we add a provision in § 164.514(g) restricting the recipient health plan from using or disclosing protected health information obtained for this purpose, other than as required by law. Uses and disclosures in these cases come within the definition of "health care operations," provided that the requirements of § 164.514(g) are met, if applicable. See § 164.504(f) for requirements for such disclosures by group health plans, as well as specific restrictions on the information that may be disclosed to plan sponsors for such purposes. We note that a covered health care provider must obtain an authorization under § 164.508 in order to disclose protected health information about an individual for purposes of pre-enrollment underwriting; the underwriting is not an "operation" of the provider and that disclosure is not otherwise permitted by a provision of this rule.

(4) We delete reference to the "compiling and analyzing information in anticipation of or for use in a civil or criminal legal proceeding" and replace it with a broader reference to ***82491** conducting or arranging for "legal services."

We add two new categories of activities:

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies.

(6) Business management activities and general administrative functions, such as management activities relating to implementation of and compliance with the requirements of this subchapter, fundraising for the benefit of the covered entity to the extent permitted without authorization under § 164.514(f), and marketing of certain services to individuals served by the covered entity, to the extent permitted without authorization under § 164.514(e) (see discussion in the preamble to that section, below). For example, under this category we permit uses or disclosures of protected health information to determine from whom an authorization should be obtained, for example to generate a mailing list of individuals who would receive an authorization request.

We add to the definition of health care operations disclosure of protected health information for due diligence to a covered entity that is a potential successor in interest. This provision includes disclosures pursuant to the sale of a covered entity's business as a going concern, mergers, acquisitions, consolidations, and other similar types of corporate restructuring between covered entities, including a division of a covered entity, and to an entity that is not a covered entity but will become a covered entity if the transfer or sale is completed. Other types of sales of assets, or disclosures to organizations that are not and would not become covered entities, are not included in the definition of health care operations and could only occur if the covered entity obtained valid authorization for such disclosure in accordance with § 164.508, or if the disclosure is otherwise permitted under this rule.

We also add to health care operations disclosure of protected health information for resolution of internal grievances. These uses and disclosures include disclosure to an employee and/or employee representative, for example when the employee needs protected health information to demonstrate that the employer's allegations of improper conduct are untrue. We note that such employees and employee representatives are not providing services to or for the covered entity, and, therefore, no business associate contract is required. Also included are resolution of disputes from patients or enrollees regarding the quality of care and similar matters.

We also add use for customer service, including the provision of data and statistical analyses for policyholders, plan sponsors, or other customers, as long as the protected health information is not disclosed to such persons. We recognize that part of the general management of a covered entity is customer service. We clarify that customer service may include the use of protected health information to provide data and statistical analyses. For example, a plan sponsor may want to understand why its costs are rising faster than average, or why utilization in one plant location is different than in another location. An association that sponsors an insurance plan for its members may want information on the relative costs of its plan in different areas. Some plan sponsors may want more detailed analyses that attempt to identify health problems in a work site. We note that when a plan sponsor has several different group health plans, or when such plans provide insurance or coverage through more than one health insurance issuer or HMO, the covered entities may jointly engage in this type of analysis as a health care operation of the organized health care arrangement.

This activity qualifies as a health care operation only if it does not result in the disclosure of protected health information to the customer. The results of the analyses must be presented in a way that does not disclose protected health information. A disclosure of protected health information to the customer as a health care operation under this provision violates this rule. This provision is not intended to permit covered entities to circumvent other provisions in this rule, including requirements relating to disclosures of protected health information to plan sponsors or the requirements relating to research. See § 164.504(f) and § 164.512(i).

We use the term customer to provide flexibility to covered entities. We do not intend the term to apply to persons with whom the covered entity has no other business; this provision is intended to permit covered entities to provide service to their existing customer base.

We note that this definition, either alone or in conjunction with the definition of "organized health care arrangement," allows an entity such as an integrated staff model HMO, whether legally integrated or whether a group of associated entities, that hold themselves out as an organized arrangement to share protected health information under § 164.506. In these cases, the sharing of protected health information will be either for the operations of the disclosing entity or for the organized health care arrangement in which the entity is participating.

Whether a disclosure is allowable for health care operations under this provision is determined separately from whether a business associate contract is required. These provisions of the rule operate independently. Disclosures for health care operations may be made to an entity that is neither a covered entity nor a business associate of the covered entity. For example, a covered academic medical center may disclose certain protected health information to community health care providers who participate in one of its continuing medical education programs, whether or not such providers are covered health care providers under this rule. A provider attending a continuing education program is not thereby performing services for the covered entity sponsoring the program and, thus, is not a business associate for that purpose. Similarly, health plans may disclose for due diligence purposes to another entity that may or may not be a covered entity or a business associate.

Health Oversight Agency

The proposed rule would have defined "health oversight agency" as "an agency, person, or entity, including the employees or agents thereof, (1) That is: (i) A public agency; or (ii) A person or entity acting under grant of authority from or contract with a public agency; and (2) Which performs or oversees the performance of any audit; investigation; inspection; licensure or discipline; civil, criminal, or administrative proceeding or action; or other activity necessary for appropriate oversight of the health care system, of government benefit programs for which health information is relevant to beneficiary eligibility, or of government regulatory programs for which health information is necessary for determining compliance with program standards." The proposed rule also described the functions of health oversight agencies in the proposed health oversight section (§ 164.510(c)) by repeating much of this definition.

In the final rule, we modify the definition of health oversight agency by eliminating from the definition the language in proposed § 164.510(c) (now § 164.512(d)). In addition, the final rule clarifies this definition by specifying that a "health oversight agency" is an agency or authority of the United States, ***82492** a state, a territory, a political subdivision of a state or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or grantees, that is authorized by law to oversee the health care system or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

The preamble to the proposed rule listed the following as examples of health oversight agencies that conduct oversight activities relating to the health care system: state insurance commissions, state health professional licensure agencies, Offices of Inspectors General of federal agencies, the Department of Justice, state Medicaid fraud control units, Defense Criminal Investigative Services, the Pension and Welfare Benefit Administration, the HHS Office for Civil Rights, and the FDA. The proposed rule listed the Social Security Administration and the Department of Education as examples of health oversight agencies that conduct oversight of government benefit programs for which health information is relevant to beneficiary eligibility. The proposed rule listed the Occupational Health and Safety Administration and the Environmental Protection Agency as examples of oversight agencies that conduct oversight of government regulatory programs for which health information is necessary for determining compliance with program standards.

In the final rule, we include the following as additional examples of health oversight activities: (1) The U.S. Department of Justice's civil rights enforcement activities, and in particular, enforcement of the Civil Rights of Institutionalized Persons Act (42 U.S.C. 1997-1997j) and the Americans with Disabilities Act (42 U.S.C. 12101 et seq.), as well as the EEOC's civil rights enforcement activities under titles I and V of the ADA; (2) the FDA's oversight of food, drugs, biologics, devices, and other products pursuant to the Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.); and (3) data analysis — performed by a public agency or by a person or entity acting under grant of authority from or under contract with a public agency —to detect health care fraud.

"Overseeing the health care system," which is included in the definition of health oversight, encompasses activities such as: oversight of health care plans; oversight of health benefit plans; oversight of health care providers; oversight of health care and health care delivery; oversight activities that involve resolution of consumer complaints; oversight of pharmaceuticals, medical products and devices, and dietary supplements; and a health oversight agency's analysis of trends in health care costs, quality, health care delivery, access to care, and health insurance coverage for health oversight purposes.

We recognize that health oversight agencies, such as the U.S. Department of Labor's Pension and Welfare Benefits Administration, may perform more than one type of health oversight. For example, agencies may sometimes perform audits and investigations and at other times conduct general oversight of health benefit plans. Such entities are considered health oversight agencies under the rule for any and all of the health oversight functions that they perform.

The definition of health oversight agency does not include private organizations, such as private-sector accrediting groups. Accreditation organizations are performing health care operations functions on behalf of health plans and covered health care providers. Accordingly, in order to obtain protected health information without individuals' authorizations, accrediting groups must enter into business associate agreements with health plans and covered health care providers for these purposes. Similarly, private entities, such as coding committees, that help government agencies that are health plans make coding and payment decisions are performing health care payment functions on behalf the government agencies and, therefore, must enter into business associate agreements in order to receive protected health information from the covered entity (absent individuals' authorization for such disclosure).

Indirect Treatment Relationship

This term was not included in the proposed rule. An "indirect treatment relationship" is a relationship between a health care provider and an individual in which the provider delivers health care to the individual based on the orders of another health care provider and the health care services, products, diagnoses, or results are typically furnished to the patient through another provider, rather than directly. For example, radiologists and pathologists generally have indirect treatment relationships with patients because they deliver diagnostic services based on the orders of other providers and the results of those services are furnished to the patient through the direct treating provider. This definition is necessary to clarify the relationships between providers and individuals in the regulation. For example, see the consent discussion at § 164.506.

Individual

We proposed to define "individual" to mean the person who is the subject of the protected health information. We proposed that the term include, with respect to the signing of authorizations and other rights (such as access, copying, and correction), the following types of legal representatives:

(1) With respect to adults and emancipated minors, legal representatives (such as court-appointed guardians or persons with a power of attorney), to the extent to which applicable law permits such legal representatives to exercise the person's rights in such contexts.

(2) With respect to unemancipated minors, a parent, guardian, or person acting in loco parentis, provided that when a minor lawfully obtains a health care service without the consent of or notification to a parent, guardian, or other person acting in loco

parentis, the minor shall have the exclusive right to exercise the rights of an individual with respect to the protected health information relating to such care.

(3) With respect to deceased persons, an executor, administrator, or other person authorized under applicable law to act on behalf of the decedent's estate.

In addition, we proposed to exclude from the definition:

(1) Foreign military and diplomatic personnel and their dependents who receive health care provided by or paid for by the Department of Defense or other federal agency or by an entity acting on its behalf, pursuant to a country-to-country agreement or federal statute.

(2) Overseas foreign national beneficiaries of health care provided by the Department of Defense or other federal agency or by a non-governmental organization acting on its behalf.

In the final rule, we eliminate from the definition of "individual" the provisions designating a legal representative as the "individual" for purposes of exercising certain rights with regard to protected health information. Instead, we include in the final rule a separate standard for "personal representatives." A covered entity must treat a personal representative of an individual as the individual except under specified circumstances. See discussion in ***82493** § 164.502(g) regarding personal representatives.

In addition, we eliminate from the definition of "individual" the above exclusions for foreign military and diplomatic personnel and overseas foreign national beneficiaries. We address the special circumstances for use and disclosure of protected health information about individuals who are foreign military personnel in § 164.512(k). We address overseas foreign national beneficiaries in § 164.500, "Applicability." The protected health information of individuals who are foreign diplomatic personnel and their dependents are not subject to special treatment under the final rule.

Individually identifiable health information about one individual may exist in the health records of another individual; health information about one individual may include health information about a second person. For example, a patient's medical record may contain information about the medical conditions of the patient's parents, children, and spouse, as well as their names and contact information. For the purpose of this rule, if information about a second person is included within the protected health information of an individual, the second person is not the person who is the subject of the protected health information. The second person is not the "individual" with regard to that protected health information, and under this rule thus does not have the individual's rights (e.g., access and amendment) with regard to that information.

Individually Identifiable Health Information

We proposed to define "individually identifiable health information" to mean information that is a subset of health information, including demographic information collected from an individual, and that:

(1) Is created by or received from a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and

(i) Which identifies the individual, or

(ii) With respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

In the final rule, we change "created by or received from a health care provider * * *" to "created or received by a health care provider * * * "in order to conform to the statute. We otherwise retain the definition of "individually identifiable health information" without change in the final rule.

Inmate

The proposed rule did not define the term inmate. In the final rule, it is defined as a person incarcerated in or otherwise confined to a correctional institution. The addition of this definition is necessary to explain the privacy rights and protections of inmates in this regulation.

Law Enforcement Official

The proposed rule would have defined a "law enforcement official" as "an official of an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, or an Indian tribe, who is empowered by law to conduct: (1) An investigation or official proceeding inquiring into a violation of, or failure to comply with, any law; or (2) a criminal, civil, or administrative proceeding arising from a violation of, or failure to comply with, any law."

The final rule modifies this definition slightly. The definition in the final rule recognizes that law enforcement officials are empowered to prosecute cases as well as to conduct investigations and civil, criminal, or administrative proceedings. In addition, the definition in the final rule reflects the fact that when investigations begin, often it is not clear that law has been violated. Thus, the final rule describes law enforcement investigations and official proceedings as inquiring into a potential violation of law. In addition, it describes law enforcement-related civil, criminal, or administrative proceedings as arising from alleged violation of law.

Marketing

The proposed rule did not include a definition of "marketing." The proposed rule generally required that a covered entity would need an authorization from an individual to use or disclose protected health information for marketing.

In the final rule we define marketing as a communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service. The definition does not limit the type or means of communication that are considered marketing.

The definition of marketing contains three exceptions. If a covered entity receives direct or indirect remuneration from a third party for making a written communication otherwise described in an exception, then the communication is not excluded from the definition of marketing. The activities we except from the definition of marketing are encompassed by the definitions of treatment, payment, and health care operations. Covered entities may therefore use and disclose protected health information for these excepted activities without authorization under § 164.508 and pursuant to any applicable consent obtained under § 164.506.

The first exception applies to communications made by a covered entity for the purpose of describing the entities participating in a provider network or health plan network. It also applies to communications made by a covered entity for the purpose of describing if and the extent to which a product or service, or payment for a product or service, is provided by the covered entity or included in a benefit plan. This exception permits covered entities to use or disclose protected health information when discussing topics such as the benefits and services available under a health plan, the payment that may be made for a product or service, which providers offer a particular product or service, and whether a provider is part of a network or whether (and what amount of) payment will be provided with respect to the services of particular providers. This exception expresses our intent not to interfere with communications made to individuals about their health benefits.

The second exception applies to communications tailored to the circumstances of a particular individual, made by a health care provider to an individual as part of the treatment of the individual, and for the purpose of furthering the treatment of that individual. This exception leaves health care providers free to use or disclose protected health information as part of a discussion of its products and services, or the products and services of others, and to prescribe, recommend, or sell such products or services, as part of the treatment of an individual. This exception includes activities such as referrals, prescriptions, recommendations, and other communications that address how a product or service may relate to the individual's health. This exception expresses our intent not to interfere with communications made to individuals about their treatment.

The third exception applies to communications tailored to the ***82494** circumstances of a particular individual and made by a health care provider or health plan to an individual in the course of managing the treatment of that individual or for the purpose of directing or recommending to that individual alternative treatments, therapies, providers, or settings of care. As with the previous exception, this exception permits covered entities to discuss freely their products and services and the products and services of third parties, in the course of managing an individual's care or providing or discussing treatment alternatives with an individual, even when such activities involve the use or disclose protected health information.

Section 164.514 contains provisions governing use or disclosure of protected health information in marketing communications, including a description of certain marketing communications that may use or include protected health information but that may be made by a covered entity without individual authorization. The definition of health care operations includes those marketing communications that may be made without an authorization pursuant to § 164.514. Covered entities may therefore use and disclose protected health information for these activities pursuant to any applicable consent obtained under § 164.506, or, if they are not required to obtain a consent under § 164.506, without one.

Organized Health Care Arrangement

This term was not used in the proposed rule. We define the term in order to describe certain arrangements in which participants need to share protected health information about their patients to manage and benefit the common enterprise. To allow uses and disclosures of protected health information for these arrangements, we also add language to the definition of "health care operations." See discussion of that term above.

We include five arrangements within the definition of organized health care arrangement. The arrangements involve clinical or operational integration among legally separate covered entities in which it is often necessary to share protected health information for the joint management and operations of the arrangement. They may range in legal structure, but a key component of these arrangements is that individuals who obtain services from them have an expectation that these arrangements are integrated and that they jointly manage their operations. We include within the definition a clinically integrated care setting in which individuals typically receive health care from more than one health care provider. Perhaps the most common example of this type of organized health care arrangement is the hospital setting, where a hospital and a physician with staff privileges at the hospital together provide treatment to the individual. Participants in such clinically integrated settings need to be able to share health information freely not only for treatment purposes, but also to improve their joint operations. For example, any physician with staff privileges at a hospital must be able to participate in the hospital's morbidity and mortality reviews, even when the particular physician's patients are not being discussed. Nurses and other hospital personnel must also be able to participate. These activities benefit the common enterprise, even when the benefits to a particular participant are not evident. While protected health information may be freely shared among providers for treatment purposes under other provisions of this rule, some of these joint activities also support the health care operations of one or more participants in the joint arrangement. Thus, special rules are needed to ensure that this rule does not interfere with legitimate information sharing among the participants in these arrangements.

We also include within the definition an organized system of health care in which more than one covered entity participates, and in which the participating covered entities hold themselves out to the public as participating in a joint arrangement, and in which the joint activities of the participating covered entities include at least one of the following: utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party

on their behalf; quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or payment activities, if the financial risk for delivering health care is shared in whole or in part by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk. A common example of this type of organized health care arrangement is an independent practice association formed by a large number of physicians. They may advertise themselves as a common enterprise (e.g., Acme IPA), whether or not they are under common ownership or control, whether or not they practice together in an integrated clinical setting, and whether or not they share financial risk.

If such a group engages jointly in one or more of the listed activities, the participating covered entities will need to share protected health information to undertake such activities and to improve their joint operations. In this example, the physician participants in the IPA may share financial risk through common withhold pools with health plans or similar arrangements. The IPA participants who manage the financial arrangements need protected health information about all the participants' patients in order to manage the arrangement. (The participants may also hire a third party to manage their financial arrangements.) If the participants in the IPA engage in joint quality assurance or utilization review activities, they will need to share protected health information about their patients much as participants in an integrated clinical setting would. Many joint activities that require the sharing of protected health information benefit the common enterprise, even when the benefits to a particular participant are not evident.

We include three relationships related to group health plans as organized health care arrangements. First, we include a group health plan and an issuer or HMO with respect to the group health plan within the definition, but only with respect to the protected health information of the issuer or HMO that relates to individuals who are or have been participants or beneficiaries in the group health plan. We recognize that many group health plans are funded partially or fully through insurance, and that in some cases the group health plan and issuer or HMO need to coordinate operations to properly serve the enrollees. Second, we include a group health plan and one or more other group health plans each of which are maintained by the same plan sponsor. We recognize that in some instances plan sponsors provide health benefits through a combination of group health plans, and that they may need to coordinate the operations of such plans to better serve the participants and beneficiaries of the plans. Third, we include a combination of group health plans maintained by the same plan sponsor and the health insurance issuers and HMOs with respect to such plans, but again only with respect to the protected health information of such issuers and HMOs that relates to ***82495** individuals who are or have been enrolled in such group health plans. We recognize that is some instances a plan sponsor may provide benefits through more than one group health plan, and that such plans may fund the benefits through one or more issuers or HMOs. Again, coordinating health care operations among these entities may be necessary to serve the participants and beneficiaries in the group health plans. We note that the necessary coordination may necessarily involve the business associates of the covered entities and may involve the participation of the plan sponsor to the extent that it is providing plan administration functions and subject to the limits in § 164.504.

Payment

We proposed the term payment to mean:

(1) The activities undertaken by or on behalf of a covered entity that is:

(i) A health plan, or by a business partner on behalf of a health plan, to obtain premiums or to determine or fulfill its responsibility for coverage under the health plan and for provision of benefits under the health plan; or

(ii) A health care provider or health plan, or a business partner on behalf of such provider or plan, to obtain reimbursement for the provision of health care.

(2) Activities that constitute payment include:

(i) Determinations of coverage, adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, and medical data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges; and

(v) Utilization review activities, including precertification and preauthorization of services.

In the final rule, we maintain the general approach of defining of payment: payment activities are described generally in the first clause of the definition, and specific examples are given in the second clause. Payment activities relate to the covered entity that maintains the protected health information (i.e., one covered entity may not disclose protected health information for the payment activities of a second covered entity). A covered entity may use or disclose only the protected health information about the individual to whom care was rendered, for its payment activities (e.g., a provider may disclose protected health information only about the patient to whom care was rendered in order to obtain payment for that care, or only the protected health information about persons enrolled in the particular health plan that seeks to audit the provider's records). We expand the proposed list to reflect many changes requested by commenters.

We add eligibility determinations as an activity included in the definition of payment. We expand coverage determinations to include the coordination of benefits and the determination of a specific individual's cost sharing amounts. The rule deletes activities related to the improvement of methods of paying or coverage policies from this definition and instead includes them in the definition of health care operations. We add to the definition “collection activities.” We replace “medical data processing” activities with health care data processing related to billing, claims management, and collection activities. We add activities for the purpose of obtaining payment under a contract for reinsurance (including stop-loss and excess of loss insurance). Utilization review activities now include concurrent and retrospective review of services.

In addition, we modify this definition to clarify that the activities described in section 1179 of the Act are included in the definition of “payment.” We add new subclause (vi) allowing covered entities to disclose to consumer reporting agencies an individual's name, address, date of birth, social security number and payment history, account number, as well as the name and address of the individual's health care provider and/or health plan, as appropriate. Covered entities may make disclosure of this protected health information to consumer reporting agencies for purposes related to collection of premiums or reimbursement. This allows reporting not just of missed payments and overdue debt but also of subsequent positive payment experience (e.g., to expunge the debt). We consider such positive payment experience to be “related to” collection of premiums or reimbursement.

The remaining activities described in section 1179 are included in other language in this definition. For example, “authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care” are covered by paragraph (2)(iii) of the definition, which allows use and disclosure of protected health information for “billing, claims management, collection activities and related health care data processing.” “Claims management” also includes auditing payments, investigating and resolving payment disputes and responding to customer inquiries regarding payments. Disclosure of protected health information for compliance with civil or criminal subpoenas, or with other applicable laws, are covered under § 164.512 of this regulation. (See discussion above regarding the interaction between 1179 and this regulation.)

We modify the proposed regulation text to clarify that payment includes activities undertaken to reimburse health care providers for treatment provided to individuals.

Covered entities may disclose protected health information for payment purposes to any other entity, regardless of whether it is a covered entity. For example, a health care provider may disclose protected health information to a financial institution in order to cash a check or to a health care clearinghouse to initiate electronic transactions. However, if a covered entity engages another entity, such as a billing service or a financial institution, to conduct payment activities on its behalf, the other entity may meet the definition of "business associate" under this rule. For example, an entity is acting as a business associate when it is operating the accounts receivable system on behalf of a health care provider.

Similarly, payment includes disclosure of protected health information by a health care provider to an insurer that is not a "health plan" as defined in this rule, to obtain payment. For example, protected health information may be disclosed to obtain reimbursement from a disability insurance carrier. We do not interpret the definition of "payment" to include activities that involve the disclosure of protected health information by a covered entity, including a covered health care provider, to a plan sponsor for the purpose of obtaining payment under a group health plan maintained by such plan sponsor, or for the purpose of obtaining payment from a health insurance issuer or HMO with respect to a group health plan maintained by such plan sponsor, unless the plan sponsor is performing plan administration pursuant to § 164.504(f).

The Transactions Rule adopts standards for electronic health care transactions, including two for processing payments. We adopted the ASC X12N 835 transaction standard for "Health Care Payment and Remittance ***82496** Advice" transactions between health plans and health care providers, and the ASC X12N 820 standard for "Health Plan Premium Payments" transactions between entities that arrange for the provision of health care or provide health care coverage payments and health plans. Under these two transactions, information to effect funds transfer is transmitted in a part of the transaction separable from the part containing any individually identifiable health information.

We note that a covered entity may conduct the electronic funds transfer portion of the two payment standard transactions with a financial institution without restriction, because it contains no protected health information. The protected health information contained in the electronic remittance advice or the premium payment enrollee data portions of the transactions is not necessary either to conduct the funds transfer or to forward the transactions. Therefore, a covered entity may not disclose the protected health information to a financial institution for these purposes. A covered entity may transmit the portions of the transactions containing protected health information through a financial institution if the protected health information is encrypted so it can be read only by the intended recipient. In such cases no protected health information is disclosed and the financial institution is acting solely as a conduit for the individually identifiable data.

Plan Sponsor

In the final rule we add a definition of "plan sponsor." We define plan sponsor by referencing the definition of the term provided in (3)(16)(B) of the Employee Retirement Income Security Act (ERISA). The plan sponsor is the employer or employee organization, or both, that establishes and maintains an employee benefit plan. In the case of a plan established by two or more employers, it is the association, committee, joint board of trustees, or other similar group or representative of the parties that establish and maintain the employee benefit plan. This term includes church health plans and government health plans. Group health plans may disclose protected health information to plan sponsors who conduct payment and health care operations activities on behalf of the group health plan if the requirements for group health plans in § 164.504 are met.

The preamble to the Transactions Rule noted that plan sponsors of group health plans are not covered entities and, therefore, are not required to use the standards established in that regulation to perform electronic transactions, including enrollment and disenrollment transactions. We do not change that policy through this rule. Plan sponsors that perform enrollment functions are doing so on behalf of the participants and beneficiaries of the group health plan and not on behalf of the group health plan itself. For purposes of this rule, plan sponsors are not subject to the requirements of § 164.504 regarding group health plans when conducting enrollment activities.

Protected Health Information

We proposed to define "protected health information" to mean individually identifiable health information that is or has been electronically maintained or electronically transmitted by a covered entity, as well as such information when it takes any other form. For purposes of this definition, we proposed to define "electronically transmitted" as including information exchanged with a computer using electronic media, such as the movement of information from one location to another by magnetic or optical media, transmissions over the Internet, Extranet, leased lines, dial-up lines, private networks, telephone voice response, and "faxback" systems. We proposed that this definition not include "paper-to-paper" faxes, or person-to-person telephone calls, video teleconferencing, or messages left on voice-mail.

Further, "electronically maintained" was proposed to mean information stored by a computer or on any electronic medium from which the information may be retrieved by a computer, such as electronic memory chips, magnetic tape, magnetic disk, or compact disc optical media.

The proposal's definition explicitly excluded:

(1) Individually identifiable health information that is part of an "education record" governed by the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. 1232g.

(2) Individually identifiable health information of inmates of correctional facilities and detainees in detention facilities.

In this final rule we expand the definition of protected health information to encompass all individually identifiable health information transmitted or maintained by a covered entity, regardless of form. Specifically, we delete the conditions for individually identifiable health information to be "electronically maintained" or "electronically transmitted" and the corresponding definitions of those terms. Instead, the final rule defines protected health information to be individually identifiable health information that is:

(1) Transmitted by electronic media;

(2) Maintained in any medium described in the definition of electronic media at § 162.103 of this subchapter; or

(3) Transmitted or maintained in any other form or medium.

We refer to electronic media, as defined in § 162.103, which means the mode of electronic transmission. It includes the Internet (wide-open), Extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.

The definition of protected health information is set out in this form to emphasize the severability of this provision. As discussed below, we believe we have ample legal authority to cover all individually identifiable health information transmitted or maintained by covered entities. We have structured the definition this way so that, if a court were to disagree with our view of our authority in this area, the rule would still be operational, albeit with respect to a more limited universe of information.

Other provisions of the rules below may also be severable, depending on their scope and operation. For example, if the rule itself provides a fallback, as it does with respect to the various discretionary uses and disclosures permitted under § 164.512, the provisions would be severable under case law.

The definition in the final rule retains the exception relating to individually identifiable health information in "education records" governed by FERPA. We also exclude the records described in 20 U.S.C. 1232g(a)(4)(B)(iv). These are records of students held by post-secondary educational institutions or of students 18 years of age or older, used exclusively for health care treatment and

which have not been disclosed to anyone other than a health care provider at the student's request. (See discussion of FERPA above.)

We have removed the exception for individually identifiable health information of inmates of correctional facilities and detainees in detention facilities. Individually identifiable health information about inmates is protected health information under the final rule, and special rules for use and disclosure of the protected health ***82497** information about inmates and their ability to exercise the rights granted in this rule are described below.

Psychotherapy Notes

Section 164.508(a)(3)(iv)(A) of the proposed rule defined psychotherapy notes as notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session. The proposed definition excluded medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis and progress. Furthermore, we stated in the preamble of the proposed rule that psychotherapy notes would have to be maintained separately from the medical record.

In this final rule, we retain the definition of psychotherapy notes that we had proposed, but add to the regulation text the requirement that, to meet the definition of psychotherapy notes, the information must be separated from the rest of the individual's medical record.

Public Health Authority

The proposed rule would have defined "public health authority" as "an agency or authority of the United States, a state, a territory, or an Indian tribe that is responsible for public health matters as part of its official mandate."

The final rule changes this definition slightly to clarify that a "public health authority" also includes a person or entity acting under a grant of authority from or contract with a public health agency. Therefore, the final rule defines this term as an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Required By Law

In the preamble to the NPRM, we did not include a definition of "required by law." We discussed what it meant for an action to be considered to be "required" or "mandated" by law and included several examples of activities that would be considered as required by law for the purposes of the proposed rule, including a valid Inspector General subpoena, grand jury subpoena, civil investigative demand, or a statute or regulation requiring production of information justifying a claim would constitute a disclosure required by law.

In the final rule we include a new definition, move the preamble clarifications to the regulatory text and add several items to the illustrative list. For purposes of this regulation, "required by law" means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Among the examples listed in definition are Medicare conditions of participation with respect to health care providers participating in that program, court-ordered warrants, and subpoenas issued by a court. We note that disclosures "required by law" include disclosures of protected health information required by this regulation in § 164.502(a)(2). It does not include contracts between private parties or similar voluntary arrangements. This list is illustrative only and is not intended in any way to limit the scope of this paragraph or other paragraphs in § 164.512 that permit uses or disclosures to the extent required by other laws. We note that nothing in this

rule compels a covered entity to make a use or disclosure required by the legal demands or prescriptions listed in this clarification or by any other law or legal process, and a covered entity remains free to challenge the validity of such laws and processes.

Research

We proposed to define "research" as it is defined in the Federal Policy for the Protection of Human Subjects, at 45 CFR part 46, subpart A (referred to elsewhere in this rule as "Common Rule"), and in addition, elaborated on the meaning of the term "generalizable knowledge." In § 164.504 of the proposed rule we defined research as "* * * a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 'Generalizable knowledge' is knowledge related to health that can be applied to populations outside of the population served by the covered entity."

The final rule eliminates the further elaboration of "generalizable knowledge." Therefore, the rule defines "research" as the term is defined in the Common Rule: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research Information Unrelated to Treatment

We delete this definition and the associated requirements from the final rule. Refer to § 164.508(f) for new requirements regarding authorizations for research that includes treatment of the individual.

Treatment

The proposed rule defined "treatment" as the provision of health care by, or the coordination of health care (including health care management of the individual through risk assessment, case management, and disease management) among, health care providers; the referral of a patient from one provider to another; or the coordination of health care or other services among health care providers and third parties authorized by the health plan or the individual. The preamble noted that the definition was intended to relate only to services provided to an individual and not to an entire enrolled population.

In the final rule, we do not change the general approach to defining treatment: treatment means the listed activities undertaken by any health care provider, not just a covered health care provider. A plan can disclose protected health information to any health care provider to assist the provider's treatment activities; and a health care provider may use protected health information about an individual to treat another individual. A health care provider may use any protected health information it maintains for treatment purposes (e.g., a provider may use protected health information about former patients as well as current patients). We modify the proposed list of treatment activities to reflect changes requested by commenters.

Specifically, we modify the proposed definition of "treatment" to include the management of health care and related services. Under the definition, the provision, coordination, or management of health care or related services may be undertaken by one or more health care providers. "Treatment" includes coordination or management by a health care provider with a third party and consultation between health care providers. The term also includes referral by a health care provider of a patient to another health care provider.

Treatment refers to activities undertaken on behalf of a single patient, not a population. Activities are considered treatment only if delivered ***82498** by a health care provider or a health care provider working with another party. Activities of health plans are not considered to be treatment. Many services, such as a refill reminder communication or nursing assistance provided through a telephone service, are considered treatment activities if performed by or on behalf of a health care provider, such as a pharmacist, but are regarded as health care operations if done on behalf of a different type of entity, such as a health plan.

We delete specific reference to risk assessment, case management, and disease management. Activities often referred to as risk assessment, disease and case management are treatment activities only to the extent that they are services provided to a

particular patient by a health care provider; population based analyses or records review for the purposes of treatment protocol development or modification are health care operations, not treatment activities. If a covered entity is licensed as both a health plan and a health care provider, a single activity could be considered to be both treatment and health care operations; for compliance purposes we would consider the purpose of the activity. Given the integration of the health care system we believe that further classification of activities into either treatment or health care operations would not be helpful. See the definition of health care operations for additional discussion.

Use

We proposed to define "use" to mean the employment, application, utilization, examination, or analysis of information within an entity that holds the information. In the final rule, we clarify that use refers to the use of individually identifiable health information. We replace the term "holds" with the term "maintains." These changes are for clarity only, and are not intended to effect any substantive change.

Section 164.502—General Rules for Uses and Disclosures of Protected Health Information

Section 164.502(a)—Use and Disclosure for Treatment, Payment and Health Care Operations

As a general rule, we proposed in the NPRM to prohibit covered entities from using or disclosing protected health information except as authorized by the individual who is the subject of such information or as explicitly permitted by the rule. The proposed rule explicitly would have permitted covered entities to use or disclose an individual's protected health information without authorization for treatment, payment, and health care operations. The proposal would not have restricted to whom disclosures could be made for the purposes of treatment, payment, or operations. The proposal would have allowed disclosure of the protected health information of one individual for the treatment or payment of another, as appropriate. We also proposed to prohibit covered entities from seeking individual authorization for uses and disclosures for treatment, payment, and health care operations unless required by state or other applicable law.

We proposed two exceptions to this general rule which prohibited covered entities from using or disclosing research information unrelated to treatment or psychotherapy notes for treatment, payment, or health care operations purposes unless a specific authorization was obtained from the subject of the information. In addition, we proposed that a covered entity be prohibited from conditioning treatment, enrollment in a health plan or payment decisions on a requirement that the individual provide a specific authorization for the disclosure of these two types of information (see proposed § 164.508(a)(3)(iii)).

We also proposed to permit covered entities to use or disclose an individual's protected health information for specified public and public policy-related purposes, including public health, research, health oversight, law enforcement, and use by coroners. In addition, the proposal would have permitted covered entities to use and disclose protected health information when required to do so by other law or pursuant to an authorization from the individual allowing them to use or disclose the information for purposes other than treatment, payment or health care operations.

We proposed to require covered entities to disclose protected health information for only two purposes: to permit individuals to inspect and copy protected health information about themselves and for enforcement of the rule.

We proposed not to require covered entities to vary the level of protection accorded to protected health information based on the sensitivity of such information. In addition, we proposed to require that each affected entity assess its own needs and devise, implement, and maintain appropriate privacy policies, procedures, and documentation to address its business requirements.

In the final rule, the general standard remains that covered entities may use or disclose protected health information only as permitted or required by this rule. However, we make significant changes to the conditions under which uses and disclosures are permitted.

We revise the application of the general standard to require covered health care providers who have a direct treatment relationship with an individual to obtain a general "consent" from the individual in order to use or disclose protected health information about the individual for treatment, payment and health care operations (for details on who must obtain such consents and the requirements they must meet, see § 164.506). These consents are intended to accommodate both the covered provider's need to use or disclose protected health information for treatment, payment, and health care operations, and also the individual's interest in understanding and acquiescing to such uses and disclosures. In general, other covered entities are permitted to use and disclose protected health information to carry out treatment, payment, or health care operations (as defined in this rule) without obtaining such consent, as in the proposed rule. Covered entities must, as under the proposed rule, obtain the individual's "authorization" in order to use or disclose psychotherapy notes for most purposes: see § 164.508(a)(2) for exceptions to this rule. We delete the proposed special treatment of "research information unrelated to treatment."

We revise the application of the general standard to require all covered entities to obtain the individual's verbal "agreement" before using or disclosing protected health information for facility directories, to persons assisting in the individual's care, and for other purposes described in § 164.510. Unlike "consent" and "authorization," verbal agreement may be informal and implied from the circumstances (for details on who must obtain such agreements and the requirements they must meet, see § 164.510). Verbal agreements are intended to accommodate situations where it is neither appropriate to remove from the individual the ability to control the protected health information nor appropriate to require formal, written permission to share such information. For the most part, these provisions reflect current practices.

As under the proposed rule, we permit covered entities to use or disclose protected health information without the individual's consent, authorization or agreement for specified ***82499** public policy purposes, in compliance with the requirements in § 164.512.

We permit covered entities to disclose protected health information to the individual who is the subject of that information without any condition. We note that this may include disclosures to "personal representatives" of individuals as provided by § 164.502(g).

We permit a covered entity to use or disclose protected health information for other lawful purposes if the entity obtains a written "authorization" from the individual, consistent with the provisions of § 164.508. Unlike "consents," these "authorizations" are specific and detailed. (For details on who must obtain such authorizations and the requirements they must meet, see § 164.508.) They are intended to provide the individuals with concrete information about, and control over, the uses and disclosures of protected health information about themselves.

The final rule retains the provision that requires a covered entity to disclose protected health information only in two instances: When individuals request access to information about themselves, and when disclosures are compelled by the Secretary for compliance and enforcement purposes.

Finally, § 164.502(a)(1) also requires covered entities to use or disclose protected health information in compliance with the other provisions of § 164.502, for example, consistent with the minimum necessary standard, to create de-identified information, or to a personal representative of an individual. These provisions are described below.

We note that a covered entity may use or disclose protected health information as permitted by and in accordance with a provision of this rule, regardless of whether that use or disclosure fails to meet the requirements for use or disclosure under another provision of this rule.

Section 164.502(b)—Minimum Necessary Uses and Disclosures

The proposed rule required a covered entity to make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure (proposed § 164.506(b)). This final rule significantly modifies the proposed requirements for implementing the minimum necessary standard. In the

final rule, § 164.502(b) contains the basic standard and § 164.514 describes the requirements for implementing the standard. Therefore we discuss all aspects of the minimum necessary standard and specific requirements below in the discussion of § 164.514(d).

Section 164.502(c)—Uses and Disclosures Under a Restriction Agreement

The proposed rule would have required that covered health care providers permit individuals to request restrictions of uses and disclosures of protected health information and would have prohibited covered providers from using or disclosing protected health information in violation of any agreed-to restriction.

The final rule retains an individual's right to request restrictions on uses or disclosures for treatment, payment or health care operations and prohibits a covered entity from using or disclosing protected health information in a way that is inconsistent with an agreed upon restriction between the covered entity and the individual, but makes some changes to this right. Most significantly, under the final rule individuals have the right to request restrictions of all covered entities. This standard is set forth in § 164.522. Details about the changes to the standard are explained in the preamble discussion to § 164.522.

Section 164.502(d)—Creation of De-identified Information

In proposed § 164.506(d) of the NPRM, we proposed to permit use of protected health information for the purpose of creating de-identified information and we provided detailed mechanisms for doing so.

In § 164.502(d) of the final rule, we permit a covered entity to use protected health information to create de-identified information, whether or not the de-identified information is to be used by the covered entity. We clarify that de-identified information created in accordance with our procedures (which have been moved to § 164.514(a)) is not subject to the requirements of these privacy rules unless it is re-identified. Disclosure of a key or mechanism that could be used to re-identify such information is also defined to be disclosure of protected health information. See the preamble to § 164.514(a) for further discussion.

Section 164.502(e)—Business Associates

In the proposed rule, other than for purposes of consultation or referral for treatment, we would have allowed a covered entity to disclose protected health information to a business partner only pursuant to a written contract that would, among other specified provisions, limit the business partner's uses and disclosures of protected health information to those permitted by the contract, and would impose certain security, inspection and reporting requirements on the business partner. We proposed to define the term “business partner” to mean, with respect to a covered entity, a person to whom the covered entity discloses protected health information so that the person can carry out, assist with the performance of, or perform on behalf of, a function or activity for the covered entity.

In the final rule, we change the term “business partner” to “business associate” and in the definition clarify the full range of circumstances in which a person is acting as a business associate of a covered entity. (See definition of “business associate” in § 160.103.) These changes mean that § 164.502(e) requires a business associate contract (or other arrangement, as applicable) not only when the covered entity discloses protected health information to a business associate, but also when the business associate creates or receives protected health information on behalf of the covered entity.

In the final rule, we modify the proposed standard and implementation specifications for business associates in a number of significant ways. These modifications are explained in the preamble discussion of § 164.504(e).

Section 164.502(f)—Deceased Individuals

We proposed to extend privacy protections to the protected health information of a deceased individual for two years following the date of death. During the two-year time frame, we proposed in the definition of "individual" that the right to control the deceased individual's protected health information would be held by an executor or administrator, or other person (e.g., next of kin) authorized under applicable law to act on behalf of the decedent's estate. The only proposed exception to this standard allowed for uses and disclosures of a decedent's protected health information for research purposes without the authorization of a legal representative and without the Institutional Review Board (IRB) or privacy board approval required (in proposed § 164.510(j)) for most other uses and disclosures for research.

In the final rule (§ 164.502(f)), we modify the standard to extend protection of protected health information about deceased individuals for as long as the covered entity maintains the information. We retain the exception for uses and disclosures for research purposes, now part of § 164.512(i), but also require that the ***82500** covered entity take certain verification measures prior to release of the decedent's protected health information for such purposes (see §§ 164.514(h) and 164.512(i)(1)(iii)).

We remove from the definition of "individual" the provision related to deceased persons. Instead, we create a standard for "personal representatives" (§ 164.502(g), see discussion below) that requires a covered entity to treat a personal representative of an individual as the individual in certain circumstances, i.e., allows the representative to exercise the rights of the individual. With respect to deceased individuals, the final rule describes when a covered entity must allow a person who otherwise is permitted under applicable law to act with respect to the interest of the decedent or on behalf of the decedent's estate, to make decisions regarding the decedent's protected health information.

The final rule also adds a provision to § 164.512(g), that permits covered entities to disclose protected health information to a funeral director, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. Such disclosures are permitted both after death and in reasonable anticipation of death.

Section 164.502(g)—Personal Representatives

In the proposed rule we defined "individual" to include certain persons who were authorized to act on behalf of the person who is the subject of the protected health information. For adults and emancipated minors, the NPRM provided that "individual" includes a legal representative to the extent to which applicable law permits such legal representative to exercise the individual's rights in such contexts. With respect to unemancipated minors, we proposed that the definition of "individual" include a parent, guardian, or person acting in loco parentis, (hereinafter referred to as "parent") except when an unemancipated minor obtained health care services without the consent of, or notification to, a parent. Under the proposed rule, if a minor obtained health care services under these conditions, the minor would have had the exclusive rights of an individual with respect to the protected health information related to such health care services.

In the final rule, the definition of "individual" is limited to the subject of the protected health information, which includes unemancipated minors and other individuals who may lack capacity to act on their own behalf. We remove from the definition of "individual" the provisions regarding legal representatives. The circumstances in which a representative must be treated as an individual for purposes of this rule are addressed in a separate standard titled "personal representatives." (§ 164.502(g)). The standard regarding personal representatives incorporates some changes to the proposed provisions regarding legal representatives. In general, under the final regulation, the "personal representatives" provisions are directed at the more formal representatives, while § 164.510(b) addresses situations in which persons are informally acting on behalf of an individual.

With respect to adults or emancipated minors, we clarify that a covered entity must treat a person as a personal representative of an individual if such person is, under applicable law, authorized to act on behalf of the individual in making decisions related to health care. This includes a court-appointed guardian and a person with a power of attorney, as set forth in the NPRM, but may also include other persons. The authority of a personal representative under this rule is limited: the representative must be treated as the individual only to the extent that protected health information is relevant to the matters on which the personal representative is authorized to represent the individual. For example, if a person's authority to make health care decisions for an individual is limited to decisions regarding treatment for cancer, such person is a personal representative and must be treated as

the individual with respect to protected health information related to the cancer treatment of the individual. Such a person is not the personal representative of the individual with respect to all protected health information about the individual, and therefore, a covered entity may not disclose protected health information that is not relevant to the cancer treatment to the person, unless otherwise permitted under the rule. We intend this provision to apply to persons empowered under state or other law to make health related decisions for an individual, whether or not the instrument or law granting such authority specifically addresses health information.

In addition, we clarify that with respect to an unemancipated minor, if under applicable law a parent may act on behalf of an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this rule with respect to protected health information relevant to such personal representation, with three exceptions. Under the general rule, in most circumstances the minor would not have the capacity to act as the individual, and the parent would be able to exercise rights and authorities on behalf of the minor. Under the exceptions to the rule on personal representatives of unemancipated minors, the minor, and not the parent, would be treated as the individual and able to exercise the rights and authorities of an individual under the rule. These exceptions occur if: (1) The minor consents to a health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative; (2) the minor may lawfully obtain such health care service without the consent of a parent, and the minor, a court, or another person authorized by law consents to such health care service; or (3) a parent assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service. We note that the definition of health care includes services, but we use “health care service” in this provision to clarify that the scope of the rights of minors under this rule is limited to the protected health information related to a particular service.

Under this provision, we do not provide a minor with the authority to act under the rule unless the state has given them the ability to obtain health care without consent of a parent, or the parent has assented. In addition, we defer to state law where the state authorizes or prohibits disclosure of protected health information to a parent. See part 160, subpart B, Preemption of State Law. This rule does not affect parental notification laws that permit or require disclosure of protected health information to a parent. However, the rights of a minor under this rule are not otherwise affected by such notification.

In the final rule, the provision regarding personal representatives of deceased individuals has been changed to clarify the provision. The policy has not changed substantively from the NPRM.

Finally, we added a provision in the final rule to permit covered entities to elect not to treat a person as a personal representative in abusive situations. Under this provision, a covered entity need not treat a person as a personal representative of an individual if the covered entity, in the exercise of professional judgment, decides that it is ***82501** not in the best interest of the individual to treat the person as the individual's personal representative and the covered entity has a reasonable belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by such person, or that treating such person as the personal representative could endanger the individual.

Section 164.502(g) requires a covered entity to treat a person that meets the requirements of a personal representative as the individual (with the exceptions described above). We note that disclosure of protected health information to a personal representative is mandatory under this rule only if disclosure to the individual is mandatory. Disclosure to the individual is mandatory only under §§ 164.524 and 164.528. Further, as noted above, the personal representative's rights are limited by the scope of its authority under other law. Thus, this provision does not constitute a general grant of authority to personal representatives.

We make disclosure to personal representatives mandatory to ensure that an individual's rights under §§ 164.524 and 164.528 are preserved even when individuals are incapacitated or otherwise unable to act for themselves to the same degree as other individuals. If the covered entity were to have the discretion to recognize a personal representative as the individual, there could be situations in which no one could invoke an individual's rights under these sections.

We continue to allow covered entities to use their discretion to disclose certain protected health information to family members, relatives, close friends, and other persons assisting in the care of an individual, in accordance with § 164.510(b). We recognize that many health care decisions take place on an informal basis, and we permit disclosures in certain circumstance to permit this practice to continue. Health care providers may continue to use their discretion to address these informal situations.

Section 164.502(h)—Confidential Communications

In the NPRM, we did not directly address the issue of whether an individual could request that a covered entity restrict the manner in which it communicated with the individual. The NPRM did provide individuals with the right to request that health care providers restrict uses and disclosures of protected health information for treatment, payment and health operations, but providers were not required to agree to such a restriction.

In the final rule, we require covered providers to accommodate reasonable requests by patients about how the covered provider communicates with the individual. For example, an individual who does not want his or her family members to know about a certain treatment may request that the provider communicate with the individual at his or her place of employment, or to send communications to a designated address. Covered providers must accommodate the request unless it is unreasonable. Similarly, the final rule permits individuals to request that health plans communicate with them by alternative means, and the health plan must accommodate such a request if it is reasonable and the individual states that disclosure of the information could endanger the individual. The specific provisions relating to confidential communications are in § 164.522.

Section 164.502(i)—Uses and Disclosures Consistent with Notice

We proposed to prohibit covered entities from using or disclosing protected health information in a manner inconsistent with their notice of information practices. We retain this provision in the final rule. See § 164.520 regarding notice content and distribution requirements.

Section 164.502(j)—Disclosures by Whistleblowers and Workforce Member Crime Victims

Disclosures by Whistleblowers

In § 164.518(c)(4) of the NPRM we addressed the issue of whistleblowers by proposing that a covered entity not be held in violation of this rule because a member of its workforce or a person associated with a business associate of the covered entity used or disclosed protected health information that such person believed was evidence of a civil or criminal violation, and any disclosure was: (1) Made to relevant oversight agencies or law enforcement or (2) made to an attorney to allow the attorney to determine whether a violation of criminal or civil law had occurred or to assess the remedies or actions at law that may be available to the person disclosing the information.

We included an extensive discussion on how whistleblower actions can further the public interest, including reference to the need in some circumstances to utilize protected health information for this purpose as well as reference to the qui tam provisions of the Federal False Claims Act.

In the final rule we retitle the provision and include it in § 164.502 to reflect the fact that these disclosures are not made by the covered entity and therefore this material does not belong in the section on safeguarding information against disclosure.

We retain the basic concept in the NPRM of providing protection to a covered entity for the good faith whistleblower action of a member of its workforce or a business associate. We clarify that a whistleblower disclosure by an employee, subcontractor, or other person associated with a business associate is considered a whistleblower disclosure of the business associate under this provision. However, in the final rule, we modify the scope of circumstances under which a covered entity is protected in whistleblower situations. A covered entity is not in violation of the requirements of this rule when a member of its workforce

or a business associate of the covered entity discloses protected health information to: (i) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity; (ii) an appropriate health care accreditation organization; or (iii) an attorney, for the purpose of determining his or her legal options with respect to whistleblowing. We delete disclosures to a law enforcement official.

We expand the scope of this section to cover disclosures of protected health information to an oversight or accreditation organization for the purpose of reporting breaches of professional standards or problems with quality of care. The covered entity will not be in violation of this rule, provided that the disclosing individual believes in good faith that the covered entity has engaged in conduct which is unlawful or otherwise violates professional or clinical standards, or that the care, services or conditions provided by the covered entity potentially endanger one or more patients, workers or the public. Since these provisions only relate to whistleblower actions in relation to the covered entity, disclosure of protected health information to expose malfeasant conduct by another person, such as knowledge gained during the course of treatment about an individual's illicit drug use, would not be protected activity.

We clarify that this section only applies to protection of a covered entity, based on the whistleblower action of a member of its workforce or business associates. Since the HIPAA legislation only applies to covered entities, not their workforces, it is beyond the scope of this rule to directly regulate the ***82502** whistleblower actions of members of a covered entity's workforce.

In the NPRM, we had proposed to require covered entities to apply sanctions to members of its workforce who improperly disclose protected health information. In this final rule, we retain this requirement in § 164.530(e)(1) but modify the proposed provision on sanctions to clarify that the sanctions required under this rule do not apply to workforce members of a covered entity for whistleblower disclosures.

Disclosures by Workforce Members Who Are Crime Victims

The proposed rule did not address disclosures by workforce members who are victims of a crime. In the final rule, we clarify that a covered entity is not in violation of the rule when a workforce member of a covered entity who is the victim of a crime discloses protected health information to law enforcement officials about the suspected perpetrator of the crime. We limit the amount of protected health information that may be disclosed to the limited information for identification and location described in § 164.512(f)(2).

We note that this provision is similar to the provision in § 164.512(f)(5), which permits a covered entity to disclose protected health information to law enforcement that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity. This provision differs in that it permits the disclosure even if the crime occurred somewhere other than on the premises of the covered entity. For example, if a hospital employee is the victim of an attack outside of the hospital, but spots the perpetrator sometime later when the perpetrator seeks medical care at the hospital, the workforce member who was attacked may notify law enforcement of the perpetrator's location and other identifying information. We do not permit, however, the disclosure of protected health information other than that described in § 164.512(f)(2).

Section 164.504—Uses and Disclosures—Organizational Requirements—Component Entities, Affiliated Entities, Business Associates and Group Health Plans

Section 164.504(a)-(c)—Health Care Component (Component Entities)

In the preamble to the proposed rule we introduced the concept of a "component entity" to differentiate the health care unit of a larger organization from the larger organization. In the proposal we noted that some organizations that are primarily involved in non-health care activities do provide health care services or operate health plans or health care clearinghouses. Examples included a school with an on-site health clinic and an employer that self administers a sponsored health plan. In such cases, the proposal said that the health care component of the entity would be considered the covered entity, and any release of information from that component to another office or person in the organization would be a regulated disclosure. We would have required

such entities to create barriers to prevent protected health information from being used or disclosed for activities not authorized or permitted under the proposal.

We discuss group health plans and their relationships with plan sponsors below under "Requirements for Group Health Plans."

In the final rule we address the issue of differentiating health plan, covered health care provider and health care clearinghouse activities from other functions carried out by a single legal entity in paragraphs (a)-(c) of § 164.504. We have created a new term, "hybrid entity", to describe the situation where a health plan, health care provider, or health care clearinghouse is part of a larger legal entity; under the definition, a "hybrid entity" is "a single legal entity that is a covered entity and whose covered functions are not its primary functions." The term "covered functions" is discussed above under § 164.501. By "single legal entity" we mean a legal entity, such as a corporation or partnership, that cannot be further differentiated into units with their own legal identities. For example, for purposes of this rule a multinational corporation composed of multiple subsidiary companies would not be a single legal entity, but a small manufacturing firm and its health clinic, if not separately incorporated, could be a single legal entity.

The health care component rules are designed for the situation in which the health care functions of the legal entity are not its dominant mission. Because some part of the legal entity meets the definition of a health plan or other covered entity, the legal entity as a whole could be required to comply with the rules below. However, in such a situation, it makes sense not to require the entire entity to comply with the requirements of the rules below, when most of its activities may have little or nothing to do with the provision of health care; rather, as a practical matter, it makes sense for such an entity to focus its compliance efforts on the component that is actually performing the health care functions. On the other hand, where most of what the covered entity does consist of covered functions, it makes sense to require the entity as a whole to comply with the rules. The provisions at §§ 164.504(a)-(c) provide that for a hybrid entity, the rules apply only to the part of the entity that is the health care component. At the same time, the lack of corporate boundaries increases the risk that protected health information will be used in a manner that would not otherwise be permitted by these rules. Thus, we require that the covered entity erect firewalls to protect against the improper use or disclosure within or by the organization. See § 164.504(c)(2).

The term "primary functions" in the definition of "hybrid entity" is not meant to operate with mathematical precision. Rather, we intend that a more common sense evaluation take place: Is most of what the covered entity does related to its health care functions? If so, then the whole entity should be covered. Entities with different insurance lines, if not separately incorporated, present a particular issue with respect to this analysis. Because the definition of "health plan" excludes many types of insurance products (in the exclusion under paragraph (2)(i) of the definition), we would consider an entity that has one or more of these lines of insurance in addition to its health insurance lines to come within the definition of "hybrid entity," because the other lines of business constitute substantial parts of the total business operation and are required to be separate from the health plan(s) part of the business.

An issue that arises in the hybrid entity situation is what records are covered in the case of an office of the hybrid entity that performs support functions for both the health care component of the entity and for the rest of the entity. For example, this situation could arise in the context of a company with an onsite clinic (which we will assume is a covered health care provider), where the company's business office maintains both clinic records and the company's personnel records. Under the definition of the term "health care component," the business office is part of the health care component (in this hypothetical, the clinic) "to the extent that" it is performing covered functions on behalf of the clinic involving the use or disclosure of protected health information that it receives from, creates or maintains for the clinic. Part of the business office, therefore, is part of the ***82503** health care component, and part of the business office is outside the health care component. This means that the non-health care component part of the business office is not covered by the rules below. Under our hypothetical, then, the business office would not be required to handle its personnel records in accordance with the rules below. The hybrid entity would be required to establish firewalls with respect to these record systems, to ensure that the clinic records were handled in accordance with the rules.

With respect to excepted benefits, the rules below operate as follows. (Excepted benefits include accident, disability income, liability, workers' compensation and automobile medical payment insurance.) Excepted benefit programs are excluded from the health care component (or components) through the definition of "health plan." If a particular organizational unit performs both excepted benefits functions and covered functions, the activities associated with the excepted benefits program may not be part of the health care component. For example, an accountant who works for a covered entity with both a health plan and a life insurer would have his or her accounting functions performed for the health plan as part of the component, but not the life insurance accounting function. See § 164.504(c)(2)(iii). We require this segregation of excepted benefits because HIPAA does not cover such programs, policies and plans, and we do not permit any use or disclosure of protected health information for the purposes of operating or performing the functions of the excepted benefits without authorization from the individual, except as otherwise permitted in this rule.

In § 164.504(c)(2) we require covered entities with a health care component to establish safeguard policies and procedures to prevent any access to protected health information by its other organizational units that would not be otherwise permitted by this rule. We note that section 1173(d)(1)(B) of HIPAA requires policies and procedures to isolate the activities of a health care clearinghouse from a "larger organization" to prevent unauthorized access by the larger organization. This safeguard provision is consistent with the statutory requirement and extends to any covered entity that performs "non-covered entity functions" or operates or conducts functions of more than one type of covered entity.

Because, as noted, the covered entity in the hybrid entity situation is the legal entity itself, we state explicitly what is implicitly the case, that the covered entity (legal entity) remains responsible for compliance vis-a-vis subpart C of part 160. See § 164.504(c)(3)(i). We do this simply to make these responsibilities clear and to avoid confusion on this point. Also, in the hybrid entity situation the covered entity/legal entity has control over the entire workforce, not just the workforce of the health care component. Thus, the covered entity is in a position to implement policies and procedures to ensure that the part of its workforce that is doing mixed or non-covered functions does not impermissibly use or disclose protected health information. Its responsibility to do so is clarified in § 164.504(c)(3)(ii).

Section 164.504(d)—Affiliated Entities

Some legally distinct covered entities may share common administration of organizationally differentiated but similar activities (for example, a hospital chain). In § 164.504(d) we permit legally distinct covered entities that share common ownership or control to designate themselves, or their health care components, together to be a single covered entity. Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity. Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Such organizations may promulgate a single shared notice of information practices and a consent form. For example, a corporation with hospitals in twenty states may designate itself as a covered entity and, therefore, able to merge information for joint marketplace analyses. The requirements that apply to a covered entity also apply to an affiliated covered entity. For example, under the minimum necessary provisions, a hospital in one state could not share protected health information about a particular patient with another hospital if such a use is not necessary for treatment, payment or health care operations. The covered entities that together make up the affiliated covered entity are separately subject to liability under this rule. The safeguarding requirements for affiliated covered entities track the requirements that apply to health care components.

Section 164.504(e)—Business Associates

In the NPRM, we proposed to require a contract between a covered entity and a business associate, except for disclosures of protected health information by a covered entity that is a health care provider to another health care provider for the purposes of consultation or referral. A covered entity would have been in violation of this rule if the covered entity knew or reasonably should have known of a material breach of the contract by a business associate and it failed to take reasonable steps to cure the breach or terminate the contract. We proposed in the preamble that when a covered entity acted as a business associate

to another covered entity, the covered entity that was acting as business associate also would have been responsible for any violations of the regulation.

We also proposed that covered health care providers receiving protected health information for consultation or referral purposes would still have been subject to this rule, and could not have used or disclosed such protected health information for a purpose other than the purpose for which it was received (i.e., the consultation or referral). Further, we noted that providers making disclosures for consultations or referrals should be careful to inform the receiving provider of any special limitations or conditions to which the disclosing provider had agreed to impose (e.g., the disclosing provider had provided notice to its patients that it would not make disclosures for research).

We proposed that business associates would not have been permitted to use or disclose protected health information in ways that would not have been permitted of the covered entity itself under these rules, and covered entities would have been required to take reasonable steps to ensure that protected health information disclosed to a business associate remained protected.

In the NPRM (proposed § 164.506(e)(2)) we would have required that the contractual agreement between a covered entity and a business associate be in writing and contain provisions that would:

- Prohibit the business associate from further using or disclosing the protected health information for any purpose other than the purpose stated in the contract.

- Prohibit the business associate from further using or disclosing the protected health information in a manner that would violate the requirements of this proposed rule if it were done by the covered entity.

- Require the business associate to maintain safeguards as necessary to ensure that the protected health information is not used or disclosed except as provided by the contract.

- Require the business associate to report to the covered entity any use or disclosure of the protected health information of which the business ***82504** associate becomes aware that is not provided for in the contract.

- Require the business associate to ensure that any subcontractors or agents to whom it provides protected health information received from the covered entity will agree to the same restrictions and conditions that apply to the business associate with respect to such information.

- Require the business associate to provide access to non-duplicative protected health information to the subject of that information, in accordance with proposed § 164.514(a).

- Require the business associate to make available its internal practices, books and records relating to the use and disclosure of protected health information received from the covered entity to the Secretary for the purposes of enforcing the provisions of this rule.

- Require the business associate, at termination of the contract, to return or destroy all protected health information received from the covered entity that the business associate still maintains in any form to the covered entity and prohibit the business associate from retaining such protected health information in any form.

- Require the business associate to incorporate any amendments or corrections to protected health information when notified by the covered entity that the information is inaccurate or incomplete.

- State that individuals who are the subject of the protected health information disclosed are intended to be third party beneficiaries of the contract.

- Authorize the covered entity to terminate the contract, if the covered entity determines that the business associate has violated a material term of the contract.

We also stated in the preamble to the NPRM that the contract could have included any additional arrangements that did not violate the provisions of this regulation.

We explained in the preamble to the NPRM that a business associate (including business associates that are covered entities) that had contracts with more than one covered entity would have had no authority to combine, aggregate or otherwise use for a single purpose protected health information obtained from more than one covered entity unless doing so would have been a lawful use or disclosure for each of the covered entities that supplied the protected health information that is being combined, aggregated or used. In addition, the business associate would have had to have been authorized through the contract or arrangement with each covered entity that supplied the protected health information to combine or aggregate the information. A covered entity would not have been permitted to obtain protected health information through a business associate that it could not otherwise obtain itself.

In the final rule we retain the overall approach proposed: covered entities may disclose protected health information to persons that meet the rule's definition of business associate, or hire such persons to obtain or create protected health information for them, only if covered entities obtain specified satisfactory assurances from the business associate that it will appropriately handle the information; the regulation specifies the elements of such satisfactory assurances; covered entities have responsibilities when such specified satisfactory assurances are violated by the business associate. We retain the requirement that specified satisfactory assurances must be obtained if a covered entity's business associate is also a covered entity. We note that a master business associate contract or MOU that otherwise meets the requirements regarding specified satisfactory assurances meets the requirements with respect to all the signatories.

A covered entity may disclose protected health information to a business associate, consistent with the other requirements of the final rule, as necessary to permit the business associate to perform functions and activities for or on behalf of the covered entity, or to provide the services specified in the business associate definition to or for the covered entity. As discussed below, a business associate may only use the protected health information it receives in its capacity as a business associate to a covered entity as permitted by its contract or agreement with the covered entity.

We do not attempt to directly regulate business associates, but pursuant to our authority to regulate covered entities we place restrictions on the flow of information from covered entities to non-covered entities. We add a provision to clarify that a violation of a business associate agreement by a covered entity that is a business associate of another covered entity constitutes a violation of this rule.

In the final rule, we make significant changes to the requirements regarding business associates. As explained below in more detail: we make significant changes to the content of the required contractual satisfactory assurances; we include exceptions for arrangements that would otherwise meet the definition of business associate; we make special provisions for government agencies that by law cannot enter into contracts with one another or that operate under other legal requirements incompatible with some aspects of the required contractual satisfactory assurances; we provide a new mechanism for covered entities to hire a third party to aggregate data.

The final rule provides several exception to the business associate requirements, where a business associate relationship would otherwise exist. We substantially expand the exception for disclosure of protected health information for treatment. Rather than allowing disclosures without business associate assurances only for the purpose of consultation or referral, in the final rule we allow covered entities to make any disclosure of protected health information for treatment purposes to a health care provider without a business associate arrangement. This provision includes all activities that fall under the definition of treatment.

We do not require a business associate contract for a group health plan to make disclosures to the plan sponsor, to the extent that the health plan meets the applicable requirements of § 164.504(f).

We also include an exception for certain jointly administered government programs providing public benefits. Where a health plan that is a government program provides public benefits, such as SCHIP and Medicaid, and where eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or where the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and the joint activities are authorized by law, no business associate contract is required with respect to the collection and sharing of individually identifiable health information for the performance of the authorized functions by the health plan and the agency other than the agency administering the health plan. We note that the phrase "government programs providing public benefits" refers to programs offering benefits to specified members of the public and not to programs that offer benefits only to employees or retirees of government agencies.

We note that we do not consider a financial institution to be acting on behalf of a covered entity, and therefore no business associate contract is required, when it processes consumer-conducted financial transactions by debit, credit or other payment card, ***82505** clears checks, initiates or processes electronic funds transfers, or conducts any other activity that directly facilitates or effects the transfer of funds for compensation for health care. A typical consumer-conducted payment transaction is when a consumer pays for health care or health insurance premiums using a check or credit card. In these cases, the identity of the consumer is always included and some health information (e.g., diagnosis or procedure) may be implied through the name of the health care provider or health plan being paid. Covered entities that initiate such payment activities must meet the minimum necessary disclosure requirements described in the preamble to § 164.514.

In the final rule, we reduce the extent to which a covered entity must monitor the actions of its business associate and we make it easier for covered entities to identify the circumstances that will require them to take actions to correct a business associate's material violation of the contract, in the following ways. We delete the proposed language requiring covered entities to "take reasonable steps to ensure" that each business associate complies with the rule's requirements. Additionally, we now require covered entities to take reasonable steps to cure a breach or terminate the contract for business associate behaviors only if they know of a material violation by a business associate. In implementing this standard, we will view a covered entity that has substantial and credible evidence of a violation as knowing of such violation. While this standard relieves the covered entity of the need to actively monitor its business associates, a covered entity nonetheless is expected to investigate when they receive complaints or other information that contain substantial and credible evidence of violations by a business associate, and it must act upon any knowledge of such violation that it possesses. We note that a whistleblowing disclosure by a business associate of a covered entity that meets the requirements of § 164.502(j)(1) does not put the covered entity in violation of this rule, and the covered entity has no duty to correct or cure, or to terminate the relationship.

We also qualify the requirement for terminating contracts with non-compliant business associates. The final rule still requires that the business associate contract authorize the covered entity to terminate the contract, if the covered entity determines that the business associate has violated a material term of the contract, and it requires the covered entity to terminate the contract if steps to cure such a material breach fail. The rule now stipulates, however, that if the covered entity is unable to cure a material breach of the business associate's obligation under the contract, it is expected to terminate the contract, when feasible. This qualification has been added to accommodate circumstances where terminating the contract would be unreasonably burdensome on the covered entity, such as when there are no viable alternatives to continuing a contract with that particular business associate. It does not mean, for instance, that the covered entity can choose to continue the contract with a non-compliant business associate merely because it is more convenient or less costly than contracts with other potential business associates. We also require that if a covered entity determines that it is not feasible to terminate a non-compliant business associate, the covered entity must notify the Secretary.

We retain all of the requirements for a business associate contract that were listed in proposed § 164.506(e)(2), with some modifications. See § 164.504(e)(2).

We retain the requirement that the business associate contract must provide that the business associate will not use or further disclose the information other than as permitted or required by the contract or as required by law. We do not mean by this requirement that the business associate contract must specify each and every use and disclosure of protected health information permitted to the business associate. Rather, the contract must state the purposes for which the business associate may use and disclose protected health information, and must indicate generally the reasons and types of persons to whom the business associate may make further disclosures. For example, attorneys often need to provide information to potential witnesses, opposing counsel, and others in the course of their representation of a client. The business associate contract pursuant to which protected health information is provided to its attorney may include a general statement permitting the attorney to disclose protected health information to these types of people, within the scope of its representation of the covered entity.

We retain the requirement that a business associate contract may not authorize a business associate to use or further disclose protected health information in a manner that would violate the requirements of this subpart if done by the covered entity, but we add two exceptions. First, we permit a covered entity to authorize a business associate to use and disclose protected health information it receives in its capacity as a business associate for its proper management and administration and to carry out its legal responsibilities. The contract must limit further disclosures of the protected health information for these purposes to those that are required by law and to those for which the business associate obtains reasonable assurances that the protected health information will be held confidentially and that it will be notified by the person to whom it discloses the protected health information of any breaches of confidentiality.

Second, we permit a covered entity to authorize the business associate to provide data aggregation services to the covered entity. As discussed above in § 164.501, data aggregation, with respect to protected health information received by a business associate in its capacity as the business associate of a covered entity, is the combining of such protected health information by the business associate with protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit the creation of data for analyses that relate to the health care operations of the respective covered entities. We added this service to the business associate definition to clarify the ability of covered entities to contract with business associates to undertake quality assurance and comparative analyses that involve the protected health information of more than one contracting covered entity. We except data aggregation from the general requirement that a business associate contract may not authorize a business associate to use or further disclose protected health information in a manner that would violate the requirements of this subpart if done by the covered entity in order to permit the combining or aggregation of protected health information received in its capacity as a business associate of different covered entities when it is performing this service. In many cases, the combining of this information for the respective health care operations of the covered entities is not something that the covered entities could do—a covered entity cannot generally disclose protected health information to another covered entity for the disclosing covered entity's health care operations. However, we permit covered entities that enter into business associate contracts with a business associate for data aggregation to permit the business associate to combine or aggregate the protected health information they ***82506** disclose to the business associate for their respective health care operations.

We note that there may be other instances in which a business associate may combine or aggregate protected health information received in its capacity as a business associate of different covered entities, such as when it is performing health care operations on behalf of covered entities that participate in an organized health care arrangement. A business associate that is performing payment functions on behalf of different covered entities also may combine protected health information when it is necessary, such as when the covered entities share financial risk or otherwise jointly bill for services.

In the final rule we clarify that the business associate contract must require the business associate to make available protected health information for amendment and to incorporate such amendments. The business associate contract must also require the business associate to make available the information required to provide an accounting of disclosures. We provide more flexibility to the requirement that all protected health information be returned by the business associate upon termination of the contract. The rule now stipulates that if feasible, the protected health information should be destroyed or returned at the end of a contract. Accordingly, a contract with a business associate must state that if there are reasons that the return or destruction of the

information is not feasible and the information must be retained for specific reasons and uses, such as for future audits, privacy protections must continue after the contract ends, for as long as the business associate retains the information. The contract also must state that the uses of information after termination of the contract must be limited to the specific set of uses or disclosures that make it necessary for the business associate to retain the information.

We also remove the requirement that business associate contracts contain a provision stating that individuals whose protected health information is disclosed under the contract are intended third-party beneficiaries of the contract. Third party beneficiary or similar responsibilities may arise under these business associate arrangements by operation of state law; we do not intend in this rule to affect the operation of such state laws.

We modify the requirement that a business associate contract require the business associate to ensure that agents abide by the provisions of the business associate contract. We clarify that agents includes subcontractors, and we note that a business associate contract must make the business associate responsible for ensuring that any person to whom it delegates a function, activity or service which is within its business associate contract with the covered entity agrees to abide by the restrictions and conditions that apply to the business associate under the contract. We note that a business associate will need to consider the purpose for which protected health information is being disclosed in determining whether the recipient must be bound to the restrictions and conditions of the business associate contract. When the disclosure is a delegation of a function, activity or service that the business associate has agreed to perform for a covered entity, the recipient who undertakes such a function steps into the shoes of the business associate and must be bound to the restrictions and conditions. When the disclosure is to a third party who is not performing business associate functions, activities or services for on behalf of the covered entity, but is the type of disclosure that the covered entity itself could make without giving rise to a business associate relationship, the business associate is not required to ensure that the restrictions or conditions of the business associate contract are maintained.

For example, if a business associate acts as the billing agent of a health care provider, and discloses protected health information on behalf of the hospital to health plans, the business associate has no responsibility with respect to further uses or disclosures by the health plan. In the example above, where a covered entity has a business associate contract with a lawyer, and the lawyer discloses protected health information to an expert witness in preparation for litigation, the lawyer again would have no responsibility under this subpart with respect to uses or disclosures by the expert witness, because such witness is not undertaking the functions, activities or services that the business associate lawyer has agreed to perform. However, if a covered entity contracts with a third party administrator to provide claims management, and the administrator delegates management of the pharmacy benefits to a third party, the business associate third party administrator must ensure that the pharmacy manager abides by the restrictions and conditions in the business associate contract between the covered entity and the third party administrator.

We provide in § 164.504(c)(3) several methods other than a business associate contract that will satisfy the requirement for satisfactory assurances under this section. First, when a government agency is a business associate of another government agency that is a covered entity, we permit memorandum of understanding between the agencies to constitute satisfactory assurance for the purposes of this rule, if the memorandum accomplishes each of the objectives of the business associate contract. We recognize that the relationships of government agencies are often organized as a matter of law, and that it is not always feasible for one agency to contract with another for all of the purposes provided for in this section. We also recognize that it may be incorrect to view one government agency as “acting on behalf of” the other government agency; under law, each agency may be acting to fulfill a statutory mission. We note that in some instances, it may not be possible for the agencies to include the right to terminate the arrangement because the relationship may be established under law. In such instances, the covered entity government agency would need to fulfill the requirement to report known violations of the memorandum to the Secretary.

Where the covered entity is a government agency, we consider the satisfactory assurances requirement to be satisfied if other law contains requirements applicable to the business associate that accomplish each of the objectives of the business associate contract. We recognize that in some cases, covered entities that are government agencies may be able to impose the requirements of this section directly on the persons acting as their business associates. We also recognize that often one government agency is acting as a business associate of another government agency, and either party may have the legal authority to establish

the requirements of this section by regulation. We believe that imposing these requirements directly on business associates provides greater protection than we can otherwise provide under this section, and so we recognize such other laws as sufficient to substitute for a business associate contract.

We also recognize that there may be some circumstances where the relationship between covered entities and business associates is otherwise mandated by law. In the final rule, we provide that where a business associate is required by law to act as a business associate to a covered entity, the covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without ***82507** meeting the requirement to have a business associate contract (or, in the case of government agencies, a memorandum of understanding or law pertaining to the business associate) if it makes a good faith attempt the obtain satisfactory assurances required by this section and, if unable to do so, documents the attempt and the reasons that such assurances cannot be obtained. This provision addresses situations where law requires one party to act as the business associate of another party. The fact that the parties have contractual obligations that may be enforceable is not sufficient to meet the required by law test in this provision.

This provision recognizes that in some instances the law requires that a government agency act as a business associate of a covered entity. For example, the United States Department of Justice is required by law to defend tort suits brought against certain covered entities; in such circumstances, however, the United States, and not the individual covered entity, is the client and is potentially liable. In such situations, covered entities must be able to disclose protected health information needed to carry out the representation, but the particular requirements that would otherwise apply to a business associate relationship may not be possible to obtain. Subsection (iii) makes clear that, where the relationship is required by law, the covered entity complies with the rule if it attempts, in good faith, to obtain satisfactory assurances as are required by this paragraph and, if such attempt fails, documents the attempts and the reasons that such assurances cannot be obtained.

The operation of the final rule maintains the construction discussed in the preamble to the NPRM that a business associate (including a business associate that is a covered entity) that has business associate contracts with more than one covered entity generally may not use or disclose the protected health information that it creates or receives in its capacity as a business associate of one covered entity for the purposes of carrying out its responsibilities as a business associate of another covered entity, unless doing so would be a lawful use or disclosure for each of the covered entities and the business associate's contract with each of the covered entities permits the business associate to undertake the activity. For example, a business associate performing a function under health care operations on behalf of an organized health care arrangement would be permitted to combine or aggregate the protected health information obtained from covered entities participating in the arrangement to the extent necessary to carry out the authorized activity and in conformance with its business associate contracts. As described above, a business associate providing data aggregation services to different covered entities also could combine and use the protected health information of the covered entities to assist with their respective health care operations. A covered entity that is undertaking payment activities on behalf of different covered entities also may use or disclose protected health information obtained as a business associate of one covered entity when undertaking such activities as a business associate of another covered entity where the covered entities have authorized the activities and where they are necessary to secure payment for the entities. For example, when a group of providers share financial risk and contract with a business associate to conduct payment activities on their behalf, the business associate may use the protected health information received from the covered entities to assist them in managing their shared risk arrangement.

Finally, we note that the requirements imposed by this provision are intended to extend privacy protection to situations in which a covered entity discloses substantial amounts of protected health information to other persons so that those persons can perform functions or activities on its behalf or deliver specified services to it. A business associate contract basically requires the business associate to maintain the confidentiality of the protected health information that it receives and generally to use and disclose such information for the purposes for which it was provided. This requirement does not interfere with the relationship between a covered entity and business associate, or require the business associate to subordinate its professional judgment to that of a covered entity. Covered entities may rely on the professional judgment of their business associates as to the type and amount of protected health information that is necessary to carry out a permitted activity. The requirements of this provision

are aimed at securing the continued confidentiality of protected health information disclosed to third parties that are serving the covered entity's interests.

Section 164.504(f)—Group Health Plans

Covered entities under HIPAA include health care clearinghouses, health care providers and health plans. Specifically included in the definition of "health plan" are group health plans (as defined in section 2791(a) of the Public Health Service Act) with 50 or more participants or those of any size that are administered by an entity other than the employer who established and maintains the plan. These group health plans may be fully insured or self-insured. Neither employers nor other group health plan sponsors are defined as covered entities. However, employers and other plan sponsors—particularly those sponsors with self-insured group health plans—may perform certain functions that are integrally related to or similar to the functions of group health plans and, in carrying out these functions, often require access to individual health information held by the group health plan.

Most group health plans are also regulated under the Employee Retirement Income Security Act of 1974 (ERISA). Under ERISA, a group health plan must be a separate legal entity from its plan sponsor. ERISA-covered group health plans usually do not have a corporate presence, in other words, they may not have their own employees and sometimes do not have their own assets (i.e., they may be fully insured or the benefits may be funded through the general assets of the plan sponsor, rather than through a trust). Often, the only tangible evidence of the existence of a group health plan is the contractual agreement that describes the rights and responsibilities of covered participants, including the benefits that are offered and the eligible recipients.

ERISA requires the group health plan to identify a "named fiduciary," a person responsible for ensuring that the plan is operated and administered properly and with ultimate legal responsibility for the plan. If the plan documents under which the group health plan was established and is maintained permit, the named fiduciary may delegate certain responsibilities to trustees and may hire advisors to assist it in carrying out its functions. While generally the named fiduciary is an individual, it may be another entity. The plan sponsor or employees of the plan sponsor are often the named fiduciaries. These structural and operational relationships present a problem in our ability to protect health information from being used inappropriately in employment-related decisions. On the one hand, the group health plan, and any health insurance issuer or HMO providing health insurance or health coverage to the group health plan, are covered entities under the regulation and may only disclose protected health information as authorized under the ***82508** regulation or with individual consent. On the other hand, plan sponsors may need access to protected health information to carry out administration functions on behalf of the plan, but under circumstances in which securing individual consent is impractical. We note that we sometimes refer in the rule and preamble to health insurance issuers and HMOs that provide health insurance or health coverage to a group health plan as health insurance issuers or HMOs with respect to a group health plan.

The proposed rule used the health care component approach for employers and other plan sponsors. Under this approach, only the component of an employer or other plan sponsor would be treated as a covered entity. The component of the plan sponsor would have been able to use protected health information for treatment, payment, and health care operations, but not for other purposes, such as discipline, hiring and firing, placement and promotions. We have modified the final rule in a number of ways.

In the final rule, we recognize plan sponsors' legitimate need for health information in certain situations while, at the same time, protecting health information from being used for employment-related functions or for other functions related to other employee benefit plans or other benefits provided by the plan sponsor. We do not attempt to directly regulate employers or other plan sponsors, but pursuant to our authority to regulate health plans, we place restrictions on the flow of information from covered entities to non-covered entities.

The final rule permits group health plans, and allows them to authorize health insurance issuers or HMOs with respect to the group health plan, to disclose protected health information to plan sponsors if the plan sponsors voluntarily agree to use and disclose the information only as permitted or required by the regulation. The information may be used only for plan administration functions performed on behalf of the group health plan which are specified in plan documents. The group health

plan is not required to have a business associate contract with the plan sponsor to disclose the protected health information or allow the plan sponsor to create protected health information on its behalf, if the conditions of § 164.504(e) are met.

In order for the group health plan to disclose protected health information to a plan sponsor, the plan documents under which the plan was established and is maintained must be amended to: (1) Describe the permitted uses and disclosures of protected health information; (2) specify that disclosure is permitted only upon receipt of a certification from the plan sponsor that the plan documents have been amended and the plan sponsor has agreed to certain conditions regarding the use and disclosure of protected health information; and (3) provide adequate firewalls to: identify the employees or classes of employees who will have access to protected health information; restrict access solely to the employees identified and only for the functions performed on behalf of the group health plan; and provide a mechanism for resolving issues of noncompliance.

Any employee of the plan sponsor who receives protected health information for payment, health care operations or other matters related to the group health plan must be identified in the plan documents either by name or function. We assume that since individuals employed by the plan sponsor may change frequently, the group health plan would likely describe such individuals in a general manner. Any disclosure to employees or classes of employees not identified in the plan documents is not a permissible disclosure. To the extent a group health plan does have its own employees separate from the plan sponsor's employees, as the workforce of a covered entity (i.e. the group health plan), they also are bound by the permitted uses and disclosures of this rule.

The certification that must be given to the group health plan must state that the plan sponsor agrees to: (1) Not use or further disclose protected health information other than as permitted or required by the plan documents or as required by law; (2) ensure that any subcontractors or agents to whom the plan sponsor provides protected health information agree to the same restrictions; (3) not use or disclose the protected health information for employment-related actions; (4) report to the group health plan any use or disclosure that is inconsistent with the plan documents or this regulation; (5) make the protected health information accessible to individuals; (6) allow individuals to amend their information; (7) provide an accounting of its disclosures; (8) make its practices available to the Secretary for determining compliance; (9) return and destroy all protected health information when no longer needed, if feasible; and (10) ensure that the firewalls have been established.

We have included this certification requirement in part, as a way to reduce the burden on health insurance issuers and HMOs. Without a certification, health insurance issuers and HMOs would need to review the plan documents in order to ensure that the amendments have been made before they could disclose protected health information to plan sponsors. The certification, however, is a simple statement that the amendments have been made and that the plan sponsor has agreed to certain restrictions on the use and disclosure of protected health information. The receipt of the certification therefore, is sufficient basis for the health insurance issuer or HMO to disclose protected health information to the plan sponsor.

Many activities included in the definitions of health care operations and payment are commonly referred to as plan administration functions in the ERISA group health plan context. For purposes of this rule, plan administration activities are limited to activities that would meet the definition of payment or health care operations, but do not include functions to modify, amend, or terminate the plan or solicit bids from prospective issuers. Plan administration functions include quality assurance, claims processing, auditing, monitoring, and management of carve-out plans—such as vision and dental. Under the final rule, “plan administration” does not include any employment-related functions or functions in connection with any other benefits or benefit plans, and group health plans may not disclose information for such purposes absent an authorization from the individual. For purposes of this rule, enrollment functions performed by the plan sponsor on behalf of its employees are not considered plan administration functions.

Plan sponsors have access to protected health information only to the extent group health plans have access to protected health information and plan sponsors are permitted to use or disclose protected health information only as would be permitted by group health plans. That is, a group health plan may permit a plan sponsor to have access to or to use protected health information only for purposes allowed by the regulation.

As explained above, where a group health plan purchases insurance or coverage from a health insurance issuer or HMO, the provision of insurance or coverage by the health insurance issuer or HMO to the group health plan does not make the health insurance issuer or HMO a business associate. In such case, the activities of the health insurance issuer or HMO are on their own behalf and not on the behalf of the group ***82509** health plan. We note that where a group health plan contracts with a health insurance issuer or HMO to perform functions or activities or to provide services that are in addition to or not directly related to the provision of insurance, the health insurance issuer or HMO may be a business associate with respect to those additional functions, activities, or services. In addition, group health plans that provide health benefits only through an insurance contract and do not create, maintain, or receive protected health information (except for summary information described below or information that merely states whether an individual is enrolled in or has been disenrolled from the plan) do not have to meet the notice requirements of § 164.520 or the administrative requirements of § 164.530, except for the documentation requirement in § 164.530(j), because these requirements are satisfied by the issuer or HMO that is providing benefits under the group health plan. A group health plan, however, may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor unless the notice required in 164.520 indicate such disclosure may occur.

The final rule also permits a health plan that is providing insurance to a group health plan to provide summary information to the plan sponsor to permit the plan sponsor to solicit premium bids from other health plans or for the purpose of modifying, amending, or terminating the plan. The rule provides that summary information is information that summarizes claims history, claims expenses, or types of claims experienced by individuals for whom the plan sponsor has provided health benefits under a group health plan, provided that specified identifiers are not included. Summary information may be disclosed under this provision even if it does not meet the definition of de-identified information. As part of the notice requirements in § 164.520, health plans must inform individuals that they may disclose protected health information to plan sponsors. The provision to allow summaries of claims experience to be disclosed to plan sponsors that purchase insurance will allow them to shop for replacement coverage, and get meaningful bids from prospective issuers. It also permits a plan sponsor to get summary information as part of its consideration of whether or not to change the benefits that are offered or employees or whether or not to terminate a group health plan.

We note that a plan sponsor may perform enrollment functions on behalf of its employees without meeting the conditions above and without using the standard transactions described in the Transactions Rule.

Section 164.504(g)—Multiple Covered Function Entities

Although not addressed in the proposed rule, this final rule also recognizes that a covered entity may as a single legal entity, affiliated entity, or other arrangement combine the functions or operations of health care providers, health plans and health care clearinghouses (for example, integrated health plans and health care delivery systems may function as both health plans and health care providers). The rule permits such covered entities to use or disclose the protected health information of its patients or members for all covered entity functions, consistent with the other requirements of this rule. The health care component must meet the requirements of this rule that apply to a particular type of covered entity when it is functioning as that entity; e.g., when a health care component is operating as a health care provider it must meet the requirements of this rule applicable to a health care provider. However, such covered entities may not use or disclose the protected health information of an individual who is not involved in a particular covered entity function for that function, and such information must be segregated from any joint information systems. For example, an HMO may integrate data about health plan members and clinic services to members, but a health care system may not share information about a patient in its hospital with its health plan if the patient is not a member of the health plan.

Section 164.506—Uses and Disclosures for Treatment, Payment, and Health Care Operations

Introduction: "Consent" versus "Authorization"

In the proposed rule, we used the term "authorization" to describe the individual's written permission for a covered entity to use and disclose protected health information, regardless of the purpose of the use or disclosure. Authorization would have been required for all uses and disclosures that were not otherwise permitted or required under the NPRM.

We proposed to permit covered entities, subject to limited exceptions for psychotherapy notes and research information unrelated to treatment, to use and disclose protected health information to carry out treatment, payment, and health care operations without authorization. See proposed § 164.506(a)(1).

We also proposed to prohibit covered entities from requiring individuals to sign authorizations for uses and disclosures of protected health information for treatment, payment, and health care operations, unless required by other applicable law. See proposed § 164.508(a)(iv). We instead proposed requiring covered entities to produce a notice describing their information practices, including practices with respect to uses and disclosures to carry out treatment, payment, and health care operations.

In the final rule, we retain the requirement for covered entities to obtain the individual's written permission (an "authorization") for uses and disclosures of protected health information that are not otherwise permitted or required under the rule. However, under the final rule, we add a second type of written permission for use or disclosure of protected health information: a "consent" for uses and disclosures to carry out treatment, payment, and health care operations. In the final rule, we permit, and in some cases require, covered entities to obtain the individual's written permission for the covered entity to use or disclose protected health information other than psychotherapy notes to carry out treatment, payment, and health care operations. We refer to this written permission as a "consent."

The "consent" and the "authorization" do not overlap. The requirement to obtain a "consent" applies in different circumstances than the requirement to obtain an authorization. In content, a consent and an authorization differ substantially from one another.

As described in detail below, a "consent" allows use and disclosure of protected health information only for treatment, payment, and health care operations. It is written in general terms and refers the individual to the covered entity's notice for further information about the covered entity's privacy practices. It allows use and disclosure of protected health information by the covered entity seeking the consent, not by other persons. Most persons who obtain a consent will be health care providers; health plans and health care clearinghouses may also seek a consent. The consent requirements appear in § 164.506 and are described in this section of the preamble.

With a few exceptions, an "authorization" allows use and disclosure of protected health information for purposes other than treatment, payment, and health care ***82510** operations. In order to make uses and disclosures that are not covered by the consent requirements and not otherwise permitted or required under the final rule, covered entities must obtain the individual's "authorization." An "authorization" must be written in specific terms. It may allow use and disclosure of protected health information by the covered entity seeking the authorization, or by a third party. In some instances, a covered entity may not refuse to treat or cover individuals based on the fact that they refuse to sign an authorization. See § 164.508 and the corresponding preamble discussion regarding authorization requirements.

Section 164.506(a)—Consent Requirements

We make significant changes in the final rule with respect to uses and disclosures of protected health information to carry out treatment, payment, and health care operations. We do not prohibit covered entities from seeking an individual's written permission for use or disclosure of protected health information to carry out treatment, payment, or health care operations.

Except as described below, we instead require covered health care providers to obtain the individual's consent prior to using or disclosing protected health information to carry out treatment, payment, or health care operations. If the covered provider does not obtain the individual's consent, the provider is prohibited from using or disclosing protected health information about the individual for purposes of treating the individual, obtaining payment for health care delivered to the individual, or for the provider's health care operations. See § 164.506(a)(1).

We except two types of health care providers from this consent requirement. First, covered health care providers that have an indirect treatment relationship with an individual are not required to obtain the individual's consent prior to using or disclosing protected health information about the individual to carry out treatment, payment, and health care operations. An "indirect treatment relationship" is defined in § 164.501 and described in the corresponding preamble. These providers may use and disclose protected health information as otherwise permitted under the rule and consistent with their notice of privacy practices (see § 164.520 regarding notice requirements and § 164.502(i) regarding requirements to adhere to the notice). For example, a covered provider that provides consultation services to another provider without seeing the patient would have an indirect treatment relationship with that patient and would not be required to obtain the patient's consent to use protected health information about the patient for the consultation. These covered providers are, however, permitted to obtain consent, as described below.

Second, covered health care providers that create or receive protected health information in the course of providing health care to inmates of a correctional institution are not required to obtain the inmate's consent prior to using or disclosing protected health information about the inmate to carry out treatment, payment, and health care operations. See § 164.501 and the corresponding preamble discussion regarding the definitions of "correctional institution" and "inmate." These providers may use and disclose protected health information as otherwise permitted under the rule. These providers are permitted, however, to obtain consent, as described below.

In addition, we permit covered health care providers to use and disclose protected health information, without consent, to carry out treatment, payment, and health care operations, if the protected health information was created or received in certain treatment situations. In the treatment situations described in § 164.506(a)(3) and immediately below, the covered health care provider must attempt to obtain the individual's consent. If the covered provider is unable to obtain consent, but documents the attempt and the reason consent was not obtained, the covered provider may, without consent, use and disclose the protected health information resulting from the treatment as otherwise permitted under the rule. All other protected health information about that individual that the covered health care provider creates or receives, however, is subject to the consent requirements.

This exception to the consent requirement applies to protected health information created or received in any of three treatment situations. First, the exception applies to protected health information created or received in emergency treatment situations. In these situations, covered providers must attempt to obtain the consent as soon as reasonably practicable after the delivery of the emergency treatment. Second, the exception applies to protected health information created or received in situations where the covered health care provider is required by law to treat the individual (for example, certain publicly funded providers) and the covered health care provider attempts to obtain such consent. Third, the exception applies to protected health information created or received in treatment situations where there are substantial barriers to communicating with the individual and, in the exercise of professional judgment, the covered provider clearly infers from the circumstances the individual's consent to receive treatment. For example, there may be situations in which a mentally incapacitated individual seeks treatment from a health care provider but is unable to provide informed consent to undergo such treatment and does not have a personal representative available to provide such consent on the individual's behalf. If the covered provider, in her professional judgment, believes she can legally provide treatment to that individual, we also permit the provider to use and disclose protected health information resulting from the treatment without the individual's consent. We intend covered health care providers that legally provide treatment without the individual's consent to that treatment to be able to use and disclose protected health information resulting from that treatment to carry out treatment, payment, or health care operations without obtaining the individual's consent for such use or disclosure. We do not intend to impose unreasonable barriers to individuals' ability to receive, and health care providers' ability to provide, health care.

Under § 164.506(a)(4), covered health care providers that have an indirect treatment relationship with an individual, as well as health plans and health care clearinghouses, may elect to seek consent for their own uses and disclosures to carry out treatment, payment, and health care operations. If such a covered entity seeks consent for these purposes, the consent must meet the minimum requirements described below.

If a covered health care provider with an indirect treatment relationship, a health plan, or a health care clearinghouse does not seek consent, the covered entity may use or disclose protected health information to carry out treatment, payment, and health care operations as otherwise permitted under the rule and consistent with its notice of privacy practices (see § 164.520 regarding notice requirements and § 164.502(i) regarding requirements to adhere to the notice).

If a covered health care provider with an indirect treatment relationship, a health plan, or a health care clearinghouse does ask an individual to sign a consent, and the individual does not do so, the covered entity is ***82511** prohibited under § 164.502(a)(1) from using or disclosing protected health information for the purpose(s) included in the consent. A covered entity that seeks a consent must adhere to the individual's decision.

In § 164.506(a)(5), we specify that a consent obtained by one covered entity is not effective to permit another covered entity to use or disclose protected health information, unless the consent is a joint consent. See § 164.506(f) and the corresponding preamble discussion below regarding joint consents. A consent provides the individual's permission only for the covered entity that obtains the consent to use or disclose protected health information for treatment, payment, and health care operations. A consent under this section does not operate to authorize another covered entity to use or disclose protected health information, except where the other covered entity is operating as a business associate. We note that, where a covered entity is acting as a business associate of another covered entity, the business associate covered entity is acting for or on behalf of the principal covered entity, and its actions for or on behalf of the principal covered entity are authorized by the consent obtained by the principal covered entity. Thus, under this section, a health plan can obtain a consent that permits the health plan and its business associates to use and disclose protected health information that the health plan and its business associates create or receive. That consent cannot, however, permit another covered entity (that is not a business associate) to disclose protected health information to the health plan or to any other person.

If a covered entity wants to obtain the individual's permission for another covered entity to disclose protected health information to it for treatment, payment, or health care operations purposes, it must seek an authorization in accordance with § 164.508(e). For example, when a covered provider asks the individual for written permission to obtain the individual's medical record from another provider for treatment purposes, it must do so with an authorization, not a consent. Since the permission is for disclosure of protected health information by another person, a consent may not be used.

Section 164.506(b)—Consent General Requirements

In the final rule, we permit a covered health care provider to condition the provision of treatment on the receipt of the individual's consent for the covered provider to use and disclose protected health information to carry out treatment, payment, and health care operations. Covered providers may refuse to treat individuals who do not consent to uses and disclosures for these purposes. See § 164.506(b)(1). We note that there are exceptions to the consent requirements for covered health care providers that are required by law to treat individuals. See § 164.506(a)(3), described above.

Similarly, in the final rule, we permit health plans to condition an individual's enrollment in the health plan on the receipt of the individual's consent for the health plan to use and disclose protected health information to carry out treatment, payment, and health care operations, if the consent is sought in conjunction with the enrollment process. If the health plan seeks the individual's consent outside of the enrollment process, the health plan may not condition any services on obtaining such consent.

Under § 164.520, covered entities must produce a notice of privacy practices. A consent may not be combined in a single document with the notice of privacy practices. See § 164.506(b)(3).

Under § 164.506(b)(4), consents for uses and disclosures of protected health information to carry out treatment, payment, and health care operations may be combined in a single document covering all three types of activities and may be combined with other types of legal permission from the individual. For example, a consent to use or disclose protected health information under this rule may be combined with an informed consent to receive treatment, a consent to assign payment of benefits to a provider,

or narrowly tailored consents required under state law for the use or disclosure of specific types of protected health information (e.g., state laws requiring specific consent for any sharing of information related to HIV/AIDS).

Within a single consent document, the consent for use and disclosure of protected health information required or permitted under this rule must be visually and organizationally separate from the other consents or authorizations and must be separately signed by the individual and dated.

Where research includes treatment of the individual, a consent under this rule may be combined with the authorization for the use or disclosure of protected health information created for the research, in accordance with § 164.508(f). (This is the only case in which an authorization under § 164.508 of this rule may be combined with a consent under § 164.506 of this rule. See § 164.508(b)(3).) The covered entity that is creating protected health information for the research may elect to combine the consent required under this section with the research-related authorization required under § 164.508(f). For example, a covered health care provider that provides health care to an individual for research purposes and for non-research purposes must obtain a consent under this section for all of the protected health information it maintains. In addition, it must obtain an authorization in accordance with § 164.508(f) which describes how it will use and disclose the protected health information it creates for the research for purposes of treatment, payment, and health care operations. Section 164.506(b)(4) permits the covered entity to satisfy these two requirements with a single document. See § 164.508(f) and the corresponding preamble discussion for a more detailed description of research authorization requirements.

Under § 164.506(b)(5), individuals may revoke a consent in writing at any time, except to the extent that the covered entity has taken action in reliance on the consent. Upon receipt of the written revocation, the covered entity must stop processing the information for use or disclosure, except to the extent that it has taken action in reliance on the consent. A covered health care provider may refuse, under this rule, to continue to treat an individual that revokes his or her consent. A health plan may disenroll an individual that revokes a consent that was sought in conjunction with the individual's enrollment in the health plan.

Covered entities must document and retain any signed consent as required by § 164.530(j).

Section 164.506(c)—Consent Content Requirements

Under § 164.506(c), the consent must be written in plain language. See the preamble discussion regarding notice of privacy practices for a description of plain language requirements. We do not provide a model consent in this rule. We will provide further guidance on drafting consent documents prior to the compliance date.

Under § 164.506(c)(1), the consent must inform the individual that protected health information may be used and disclosed by the covered entity to carry out treatment, payment, or health care operations. The covered entity must determine which of these elements (use and/or disclosure; treatment, payment, and/or health care operations) to include in the consent ***82512** document, as appropriate for the covered entity's practices.

For covered health care providers that are required to obtain consent, the requirement applies only to the extent the covered provider uses or discloses protected health information. For example, if all of a covered provider's health care operations are conducted by members of the covered provider's own workforce, the covered provider may choose to obtain consent only for uses, not disclosures, of protected health information to carry out health care operations. If an individual pays out of pocket for all services received from the covered provider and the provider will not disclose any information about the patient to a third party payor, the provider may choose not to obtain the individual's consent to disclose information for payment purposes. In order for a covered provider to be able to use and disclose information for all three purposes, however, all three purposes must be included in the consent.

Under §§ 164.506(c)(2) and (3), the consent must refer the individual to the covered entity's notice for additional information about the uses and disclosures of information described in the consent. The consent must also indicate that the individual has the right to review the notice prior to signing the consent. If the covered entity has reserved the right to change its privacy

practices in accordance with § 164.520(b)(1)(v)(C), the consent must indicate that the terms of the notice may change and must describe how the individual may obtain a revised notice. See § 164.520 and the corresponding preamble discussion regarding notice requirements.

Under § 164.506(c)(4), the consent must inform individuals that they have the right to request restrictions on uses and disclosures of protected health information for treatment, payment, and health care operations purposes. It must also state that the covered entity is not required to agree to an individual's request, but that if the covered entity does agree to the request, the restriction is binding on the covered entity. See § 164.522(a) regarding the right to request restrictions.

Under § 164.506(c)(5), the consent must indicate that the individual has the right to revoke the consent in writing, except to the extent that the covered entity has taken action in reliance on the consent.

Under § 164.506(c)(6), the consent must include the individual's signature and the date of signature. Once we adopt the standards for electronic signature, another of the required administrative simplification standards we are required to adopt under HIPAA, an electronic signature that meets those standards will be sufficient under this rule. We do not require any verification of the individual's identity or authentication of the individual's signature. We expect covered health care providers that are required to obtain consent to employ the same level of scrutiny to these signatures as they do to the signature obtained on a document regarding the individual's consent to undergo treatment by the provider.

Section 164.506(d)—Defective Consents

Under § 164.506(d), there is no "consent" within the meaning of the rule if the completed document lacks a required element or if the individual has revoked the consent in accordance with § 164.506(b)(5).

Section 164.506(e)—Resolving Conflicting Consents and Authorizations

Situations may arise where a covered entity that has obtained the individual's consent for the covered entity to use or disclose protected health information to carry out treatment, payment, or health care operations is asked to disclose protected health information pursuant to another written legal permission from the individual, such as an authorization, that was obtained by another person. Under § 164.506(e), when the terms of a covered entity's consent conflict with the terms of another written legal permission from the individual to use or disclose protected health information (such as a consent obtained under state law by another covered entity or an authorization), the covered entity must adhere to the more restrictive document. By conflict, we mean that the consent and authorization contain inconsistencies. In implementing this section, we note that the consent under this section references the notice provided to the individual and the individual's right to request restrictions. In determining whether the covered entity's consent conflicts with another written legal permission provided by the individual, the covered entity must consider any limitations on its uses or disclosures resulting from the notice provided to the individual or from restrictions to which it has agreed. For example, a covered nursing home may elect to ask the patient to sign an authorization for the patient's covered primary care physician to forward the patient's medical records to the nursing home. The physician may have previously obtained the individual's consent for disclosure for treatment purposes. If the authorization obtained by the nursing home grants permission for the physician to disclose particular types of information, such as genetic information, but the consent obtained by the physician excludes such information or the physician has agreed to a restriction on that type of information, the physician may not disclose that information. The physician must adhere to the more restrictive written legal permission from the individual.

When a conflict between a consent and another written legal permission from the individual exists, as described above, the covered entity may attempt to resolve the conflict with the individual by either obtaining a new consent from the individual or by having a discussion or otherwise communicating with the individual to determine the individual's preference regarding the use or disclosure. If the individual's preference is communicated orally, the covered entity must document the individual's preference and act in accordance with that preference. In the example described above, the primary care physician could ask the patient to sign a new consent that would permit the disclosure of the genetic information. Alternatively, the physician could ask

the patient whether the patient intended for the genetic information to be disclosed to the nursing home. If the patient confirms that he or she intended for the genetic information to be shared, the physician can document that fact (e.g., by making a notation in the medical record) and disclose the information to the nursing home.

We believe covered entities will rarely be faced with conflicts between consents and other written legal permission from the individual for uses and disclosures to carry out treatment, payment, and health care operations. Under § 164.506(a)(5), we specify that a consent only permits the covered entity that obtains the consent to use or disclose protected health information. A consent obtained by one covered entity is not effective to permit another different covered entity to use or disclose protected health information. Conflicting consents obtained by covered entities, therefore, are not possible. We expect authorizations that permit another covered entity to use and disclose protected health information for treatment, payment, and health care operations purposes will rarely be necessary, because we expect covered entities that maintain protected health information to obtain consents that permit them to make anticipated uses and disclosures for these purposes. Nevertheless, covered entities are permitted under § 164.508(e) to obtain ***82513** authorization for another covered entity to use or disclose protected health information to carry out treatment, payment, and health care operations. We recognize these authorizations may be useful to demonstrate an individual's intent and relationship to the intended recipient of the information. For example, these authorizations may be useful in situations where a health plan wants to obtain information from one provider in order to determine payment of a claim for services provided by a different provider (e.g., information from a primary care physician that is necessary to determine payment of services provided by a specialist) or where an individual's new physician wants to obtain the individual's medical records from prior physicians. Other persons not covered by this rule may also seek authorizations and state law may require written permission for specific types of information, such as information related to HIV/AIDS or to mental health. Because an individual may sign conflicting documents over time, we clarify that the covered entity maintaining the protected health information to be used or disclosed must adhere to the more restrictive permission the individual has granted, unless the covered entity resolves the conflict with the individual.

Section 164.506(f)—Joint Consents

Covered entities that participate in an organized health care arrangement and that develop a joint notice under § 164.520(d) may develop a joint consent in which the individual consents to the uses and disclosures of protected health information by each of the covered entities in the arrangement to carry out treatment, payment, and/or health care operations. The joint consent must identify with reasonable specificity the covered entities, or class of covered entities, to which the joint consent applies and must otherwise meet the consent requirements. If an individual revokes a joint consent, the covered entity that receives the revocation must inform the other entities covered by the joint consent of the revocation as soon as practicable.

If any one of the covered entities included in the joint consent obtains the individual's consent, as required above, the consent requirement is met for all of the other covered entities to which the consent applies. For example, a covered hospital and the clinical laboratory and emergency departments with which it participates in an organized health care arrangement may produce a joint notice and obtain a joint consent. If the covered hospital obtains the individual's joint consent upon admission, and some time later the individual is readmitted through the associated emergency department, the emergency department's consent requirement will already have been met. These joint consents are the only type of consent by which one covered entity can obtain the individual's permission for another covered entity to use or disclose protected health information to carry out treatment, payment, or health care operations.

Effect of Consent

These consents, as well as the authorizations described in § 164.508, should not be construed to waive, directly or indirectly, any privilege granted under federal, state, or local law or procedure. Consents obtained under this regulation are not appropriate for the disposition of more technical and legal proceedings and may not comport with procedures and standards of federal, state, or local judicial practice. For example, state courts and other decision-making bodies may choose to examine more closely the circumstances and propriety of such consent and may adopt more protective standards for application in their proceedings. In the judicial setting, as in the legislative and executive settings, states may provide for greater protection of privacy. Additionally,

both the Congress and the Secretary have established a general approach to protecting from explicit preemption state laws that are more protective of privacy than the protections set forth in this regulation.

Section 164.508—Uses and Disclosures for Which an Authorization Is Required

Section 164.508(a)—Standard

We proposed to require covered entities to obtain the individual's authorization for all uses and disclosures of protected health information not otherwise permitted or required under the proposed rule. Uses and disclosures that would have been permitted without individual authorization included uses and disclosures for national priority purposes such as public health, law enforcement, and research (see proposed § 164.510) and uses and disclosures of protected health information, other than psychotherapy notes and research information unrelated to treatment, for purposes of treatment, payment, and health care operations (see proposed § 164.506). We also proposed to require covered entities to disclose protected health information to the individual for inspection and copying (see proposed § 164.514) and to the Secretary as required for enforcement of the rule (see proposed § 164.522). Individual authorization would not have been required for these uses and disclosures.

We proposed to require covered entities to obtain the individual's authorization for all other uses and disclosures of protected health information. Under proposed § 164.508(a), uses and disclosures that would have required individual authorization included, but were not limited to, the following:

- Use for marketing of health and non-health items and services by the covered entity;

- Disclosure by sale, rental, or barter;

- Use and disclosure to non-health related divisions of the covered entity, e.g., for use in marketing life or casualty insurance or banking services;

- Disclosure, prior to an individual's enrollment in a health plan, to the health plan or health care provider for making eligibility or enrollment determinations relating to the individual or for underwriting or risk rating determinations;

- Disclosure to an employer for use in employment determinations; and

- Use or disclosure for fundraising.

In the preamble to the proposed rule, we stated that covered entities would be bound by the terms of authorizations. Uses or disclosures by the covered entity for purposes inconsistent with the statements made in the authorization would have constituted a violation of the rule.

In the final rule, under § 164.508(a), as in the proposed rule, covered entities must have authorization from individuals before using or disclosing protected health information for any purpose not otherwise permitted or required by this rule. Specifically, except for psychotherapy notes (see below), covered entities are not required to obtain the individual's authorization to use or disclose protected health information to carry out treatment, payment, and health care operations. (Covered entities may, however, be required to obtain the individual's consent for these uses and disclosures. See the preamble regarding § 164.506 for a discussion of "consent" versus "authorization".) We also do not require covered entities to obtain the individual's authorization for uses and disclosures of protected health information permitted under §§ 164.510 or 164.512, for disclosures to the individual, or for required disclosures to the Secretary under subpart C of part 160 of this subchapter for enforcement of this rule.

In the final rule, we clarify that covered entities are bound by the ***82514** statements provided on the authorization; use or disclosure by the covered entity for purposes inconsistent with the statements made in the authorization constitutes a violation of this rule.

Unlike the proposed rule, we do not include in the regulation examples of the types of uses and disclosures that require individual authorization. We eliminated two examples from the proposed list due to potential confusion as to our intent: disclosure by sale, rental, or barter and use and disclosure to non-health related divisions of the covered entity. We recognize that covered entities sometimes make these types of uses and disclosures for purposes that are permitted under the rule without authorization. For example, a covered health care provider may sell its accounts receivable to a collection agency for payment purposes and a health plan may disclose protected health information to its life insurance component for payment purposes. We do not intend to require authorization for uses and disclosures made by sale, rental, or barter or for disclosures made to non-health related divisions of the covered entity, if those uses or disclosures could otherwise be made without authorization under this rule. As with any other use or disclosure, however, uses and disclosures of protected health information for these purposes do require authorization if they are not otherwise permitted under the rule.

We also eliminated the remaining proposed examples from the final rule due to concern that these examples might be misinterpreted as an exhaustive list of all of the uses and disclosures that require individual authorization. We discuss the examples here, however, to clarify the interaction of the authorization requirements and the provisions of the rule that permit uses and disclosures without authorization and/or with consent. Uses and disclosures for which covered entities must have the individual's authorization include, but are not limited to, the following activities.

Marketing

As in the proposed rule, covered entities must obtain the individual's authorization before using or disclosing protected health information for marketing purposes. In the final rule, we add a new definition of marketing (see § 164.501). For more detail on what activities constitute marketing, see § 164.501, definition of "marketing," and § 164.514(e).

Pre-Enrollment Underwriting

As in the proposed rule, covered entities must obtain the individual's authorization to use or disclose protected health information for the purpose of making eligibility or enrollment determinations relating to an individual or for underwriting or risk rating determinations, prior to the individual's enrollment in a health plan (that is, for purposes of pre-enrollment underwriting). For example, if an individual applies for new coverage with a health plan in the non-group market and the health plan wants to review protected health information from the individual's covered health care providers before extending an offer of coverage, the individual first must authorize the covered providers to share the information with the health plan. If the individual applies for renewal of existing coverage, however, the health plan would not need to obtain an authorization to review its existing claims records about that individual, because this activity would come within the definition of health care operations and be permissible. We also note that under § 164.504(f), a group health plan and a health insurance issuer that provides benefits with respect to a group health plan are permitted in certain circumstances to disclose summary health information to the plan sponsor for the purpose of obtaining premium bids. Because these disclosures fall within the definition of health care operations, they do not require authorization.

Employment Determinations

As in the proposed rule, covered entities must obtain the individual's authorization to use or disclose protected health information for employment determinations. For example, a covered health care provider must obtain the individual's authorization to disclose the results of a pre-employment physical to the individual's employer. The final rule provides that a covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on the provision of authorization for the disclosure of the information to the third party.

Fundraising

Under the proposed regulation, we would have required authorization before a covered entity could have used or disclosed protected health information for fundraising. In the final rule, we narrow the circumstances under which covered entities must obtain the individual's authorization to use or disclose protected health information for fundraising purposes. As provided in § 164.514(f) and described in detail in the corresponding preamble, authorization is not required when a covered entity uses or discloses demographic information and information about the dates of health care provided to an individual for the purpose of raising funds for its own benefit, nor when it discloses such information to an institutionally related foundation to raise funds for the covered entity.

Any use or disclosure for fundraising purposes that does not meet the requirements of § 164.514(f) and does not fall within the definition of health care operations (see § 164.501), requires authorization. Specifically, covered entities must obtain the individual's authorization to use or disclose protected health information to raise funds for any entity other than the covered entity. For example, a covered entity must have the individual's authorization to use protected health information about the individual to solicit funds for a non-profit organization that engages in research, education, and awareness efforts about a particular disease.

Psychotherapy Notes

In the NPRM, we proposed different rules with respect to psychotherapy notes than we proposed with respect to all other protected health information. The proposed rule would have required covered entities to obtain an authorization for any use or disclosure of psychotherapy notes to carry out treatment, payment, or health care operations, unless the use was by the person who created the psychotherapy notes. With respect to all other protected health information, we proposed to prohibit covered entities from requiring authorization for uses and disclosures for these purposes.

We significantly revise our approach to psychotherapy notes in the final rule. With a few exceptions, covered entities must obtain the individual's authorization to use or disclose psychotherapy notes to carry out treatment, payment, or health care operations. A covered entity must obtain the individual's consent, but not an authorization, for the person who created the psychotherapy notes to use the notes to carry out treatment and for the covered entity to use or disclose psychotherapy notes for conducting training programs in which students, trainees, or practitioners in mental health learn under supervision to ***82515** practice or improve their skills in group, joint, family, or individual counseling. A covered entity may also use psychotherapy notes to defend a legal action or other proceeding brought by the individual pursuant to a consent, without a specific authorization. We note that, while this provision allows disclosure of these records to the covered entity's attorney to defend against the action or proceeding, disclosure to others in the course of a judicial or administrative proceeding is governed by § 164.512(e). This special provision is necessary because disclosure of protected health information for purposes of legal representatives may be made under the general consent as part of "health care operations." Because we require an authorization for disclosure of psychotherapy notes for "health care operations," an exception is needed to allow covered entities to use protected health information about an individual to defend themselves against an action threatened or brought by that individual without asking that individual for authorization to do so. Otherwise, a consent under § 164.506 is not sufficient for the use or disclosure of psychotherapy notes to carry out treatment, payment, or health care operations. Authorization is required. We anticipate these authorizations will rarely be necessary, since psychotherapy notes do not include information that covered entities typically need for treatment, payment, or other types of health care operations.

In the NPRM, we proposed to permit covered entities to use and disclose psychotherapy notes for all other purposes permitted or required under the rule without authorization. In the final rule, we specify a more limited set of uses and disclosures of psychotherapy notes that covered entities are permitted to make without authorization. An authorization is not required for use or disclosure of psychotherapy notes when required for enforcement purposes, in accordance with subpart C of part 160 of this subchapter; when mandated by law, in accordance with § 164.512(a); when needed for oversight of the health care provider who created the psychotherapy notes, in accordance with § 164.512(d); when needed by a coroner or medical examiner, in accordance with § 164.512(g)(1); or when needed to avert a serious and imminent threat to health or safety, in accordance with § 164.512(j)(1)(i). We also provide transition provisions in § 164.532 regarding the effect of express legal permission obtained from an individual prior to the compliance date of this rule.

Section 164.508(b)—Implementation Specifications for Authorizations

Valid and Defective Authorizations

We proposed to require a minimum set of elements for authorizations requested by the individual and an additional set of elements for authorizations requested by a covered entity. We would have permitted covered entities to use and disclose protected health information pursuant to authorizations containing the applicable required elements. We would have prohibited covered entities from acting on an authorization if the submitted document had any of the following defects:

- The expiration date had passed;

- The form had not been filled out completely;

- The covered entity knew the authorization had been revoked;

- The completed form lacked a required element; or

- The covered entity knew the information on the form was false.

In § 164.508(b)(1) of the final rule, we specify that an authorization containing the applicable required elements (as described below) is a valid authorization. We clarify that a valid authorization may contain additional, non-required elements, provided that these elements are not inconsistent with the required elements. Covered entities are not required to use or disclose protected health information pursuant to a valid authorization. Our intent is to clarify that a covered entity that uses or discloses protected health information pursuant to an authorization meeting the applicable requirements will be in compliance with this rule.

We retain the provision prohibiting covered entities from acting on an authorization if the submitted document had any of the listed defects, with a few changes. First, in § 164.508(c)(1)(iv) we specify that an authorization may expire upon a certain event or on a specific date. For example, a valid authorization may state that it expires upon acceptance or rejection of an application for insurance or upon the termination of employment (for example, in an authorization for disclosure of protected health information for fitness-for-duty purposes) or similar event. The expiration event must, however, be related to the individual or the purpose of the use or disclosure. An authorization that purported to expire on the date when the stock market reached a specified level would not be valid. Under § 164.508(b)(2)(i), if the expiration event is known by the covered entity to have occurred, the authorization is defective. Second, we clarify that certain compound authorizations, as described below, are defective. We also clarify that authorizations that are not completely filled out with respect to the required elements are defective. Finally, we clarify that an authorization with information that the covered entity knows to be false is defective only if the information is material.

As under the proposed regulation, an authorization that the covered entity knows has been revoked is not a valid authorization. We note that, although an authorization must be revoked in writing, the covered entity may not always "know" that an authorization has been revoked. The writing required for an individual to revoke an authorization may not always trigger the "knowledge" required for a covered entity to consider an authorization defective. Conversely, a copy of the written revocation is not required before a provider "knows" that an authorization has been revoked.

Many authorizations will be obtained by persons other than the covered entity. If the individual revokes an authorization by writing to that other person, and neither the individual nor the other person informs the covered entity of the revocation, the covered entity will not "know" that the authorization has been revoked. For example, a government agency may obtain an individual's authorization for "all providers who have seen the individual in the past year" to disclose protected health information to the agency for purposes of determining eligibility for benefits. The individual may revoke the authorization by writing to the government agency requesting such revocation. We cannot require the agency to inform all covered entities to whom it has presented the authorization that the authorization has been revoked. If a covered entity does not know of the

revocation, the covered entity will not violate this rule by acting pursuant to the authorization. At the same time, if the individual does inform the covered entity of the revocation, even orally, the covered entity "knows" that the authorization has been revoked and can no longer treat the authorization as valid under this rule. Thus, in this example, if the individual tells a covered entity that the individual has revoked the authorization, the covered entity "knows" of the revocation and must consider the authorization defective under § 164.508(b)(2). ***82516**

Compound Authorizations

Except for authorizations requested in connection with a clinical trial, we proposed to prohibit covered entities from combining an authorization for use or disclosure of protected health information for purposes other than treatment, payment, or health care operations with an authorization or consent for treatment (e.g., an informed consent to receive care) or payment (e.g., an assignment of benefits).

We clarify the prohibition on compound authorizations in the final rule. Other than as described below, § 164.508(b)(3) prohibits a covered entity from acting on an authorization required under this rule that is combined with any other document, including any other written legal permission from the individual. For example, an authorization under this rule may not be combined with a consent for use or disclosure of protected health information under § 164.506, with the notice of privacy practices under § 164.520, with any other form of written legal permission for the use or disclosure of protected health information, with an informed consent to participate in research, or with any other form of consent or authorization for treatment or payment.

There are three exceptions to this prohibition. First, under § 164.508(f) (described in more detail, below), an authorization for the use or disclosure of protected health information created for research that includes treatment of the individual may be combined with a consent for the use or disclosure of that protected health information to carry out treatment, payment, or health care operations under § 164.506 and with other documents as provided in § 164.508(f). Second, authorizations for the use or disclosure of psychotherapy notes for multiple purposes may be combined in a single document, but may not be combined with authorizations for the use or disclosure of other protected health information. Third, authorizations for the use or disclosure of protected health information other than psychotherapy notes may be combined, provided that the covered entity has not conditioned the provision of treatment, payment, enrollment, or eligibility on obtaining the authorization. If a covered entity conditions any of these services on obtaining an authorization from the individual, as permitted in § 164.508(b)(4) and described below, the covered entity must not combine the authorization with any other document.

The following are examples of valid compound authorizations: an authorization for the disclosure of information created for clinical research combined with a consent for the use or disclosure of other protected health information to carry out treatment, payment, and health care operations, and the informed consent to participate in the clinical research; an authorization for disclosure of psychotherapy notes for both treatment and research purposes; and an authorization for the disclosure of the individual's demographic information for both marketing and fundraising purposes. Examples of invalid compound authorizations include: an authorization for the disclosure of protected health information for treatment, for research, and for determining payment of a claim for benefits, when the covered entity will refuse to pay the claim if the individual does not sign the authorization; or an authorization for the disclosure of psychotherapy notes combined with an authorization to disclose any other protected health information.

Prohibition on Conditioning Treatment, Payment, Eligibility, or Enrollment

We proposed to prohibit covered entities from conditioning treatment or payment on the provision by the individual of an authorization, except when the authorization was requested in connection with a clinical trial. In the case of authorization for use or disclosure of psychotherapy notes or research information unrelated to treatment, we proposed to prohibit covered entities from conditioning treatment, payment, or enrollment in a health plan on obtaining such an authorization.

We retain this basic approach but refine its application in the final rule. In addition to the general prohibition on conditioning treatment and payment, covered entities are also prohibited (with certain exceptions described below) from conditioning

eligibility for benefits or enrollment in a health plan on obtaining an authorization. This prohibition extends to all authorizations, not just authorizations for use or disclosure of psychotherapy notes. This prohibition is intended to prevent covered entities from coercing individuals into signing an authorization for a use or disclosure that is not necessary to carry out the primary services that the covered entity provides to the individual. For example, a health care provider could not refuse to treat an individual because the individual refused to authorize a disclosure to a pharmaceutical manufacturer for the purpose of marketing a new product.

We clarify the proposed research exception to this prohibition. Covered entities seeking authorization in accordance with § 164.508(f) to use or disclose protected health information created for the purpose of research that includes treatment of the individual, including clinical trials, may condition the research-related treatment on the individual's authorization. Permitting use of protected health information is part of the decision to receive care through a clinical trial, and health care providers conducting such trials should be able to condition research-related treatment on the individual's willingness to authorize the use or disclosure of his or her protected health information for research associated with the trial.

In addition, we permit health plans to condition eligibility for benefits and enrollment in the health plan on the individual's authorization for the use or disclosure of protected health information for purposes of eligibility or enrollment determinations relating to the individual or for its underwriting or risk-rating determinations. We also permit health plans to condition payment of a claim for specified benefits on the individual's authorization for the disclosure of information maintained by another covered entity to the health plan, if the disclosure is necessary to determine payment of the claim. These exceptions do not apply, however, to authorization for the use or disclosure of psychotherapy notes. Health plans may not condition payment, eligibility, or enrollment on the receipt of an authorization for the use or disclosure of psychotherapy notes, even if the health plan intends to use the information for underwriting or payment purposes.

Finally, when a covered entity provides treatment for the sole purpose of providing information to a third party, the covered entity may condition the treatment on the receipt of an authorization to use or disclose protected health information related to that treatment. For example, a covered health care provider may have a contract with an employer to provide fitness-for-duty exams to the employer's employees. The provider may refuse to conduct the exam if an individual refuses to authorize the provider to disclose the results of the exam to the employer. Similarly, a covered health care provider may have a contract with a life insurer to provide pre-enrollment physicals to applicants for life insurance coverage. The provider may refuse to conduct the physical if an individual refuses to authorize the provider to disclose the results of the physical to the life insurer. ***82517**

Revocation of Authorizations

We proposed to allow individuals to revoke an authorization at any time, except to the extent that the covered entity had taken action in reliance on the authorization.

We retain this provision, but specify that the individual must revoke the authorization in writing. When an individual revokes an authorization, a covered entity that knows of such revocation must stop making uses and disclosures pursuant to the authorization to the greatest extent practical. A covered entity may continue to use and disclose protected health information in accordance with the authorization only to the extent the covered entity has taken action in reliance on the authorization. For example, a covered entity is not required to retrieve information that it has already disclosed in accordance with the authorization. (See above for discussion of how written revocation of an authorization and knowledge of that revocation may differ.)

We also include an additional exception. Under § 164.508(b)(5), individuals do not have the right to revoke an authorization if the authorization was obtained as a condition of obtaining insurance coverage and other applicable law provides the insurer that obtained the authorization with the right to contest a claim under the policy. We intend this exception to permit insurers to obtain necessary protected health information during contestability periods under state law. For example, an individual may not revoke an authorization for the disclosure of protected health information to a life insurer for the purpose of investigating material misrepresentation if the individual's policy is still subject to the contestability period.

Documentation

In the final rule, we clarify that a covered entity must document and retain any signed authorization as required by § 164.530(j) (see below).

Section 164.508(c)—Core Elements and Requirements

We proposed to require authorizations requested by individuals to contain a minimum set of elements: a description of the information to be used or disclosed; the name of the covered entity, or class of entities or persons, authorized to make the use or disclosure; the name or types of recipient(s) of the information; an expiration date; the individual's signature and date of signature; if signed by a representative, a description of the representative's authority or relationship to the individual; a statement regarding the individual's right to revoke the authorization; and a statement that the information may no longer be protected by the federal privacy law. We proposed a model authorization form that entities could have used to satisfy the authorization requirements. If the model form was not used, we proposed to require covered entities to use authorization forms written in plain language.

We modify the proposed approach, by eliminating the distinction between authorizations requested by the individuals and authorizations requested by others. Instead, we prescribe a minimum set of elements for authorizations and certain additional elements when the authorization is requested by a covered entity for its own use or disclosure of protected health information it maintains or for receipt of protected health information from another covered entity to carry out treatment, payment, or health care operations.

The core elements are required for all authorizations, not just authorizations requested by individuals. Individuals seek disclosure of protected health information about them to others in many circumstances, such as when applying for life or disability insurance, when government agencies conduct suitability investigations, and in seeking certain job assignments when health status is relevant. Another common instance is tort litigation, when an individual's attorney needs individually identifiable health information to evaluate an injury claim and asks the individual to authorize disclosure of records relating to the injury to the attorney. In each of these situations, the individual may go directly to the covered entity and ask it to send the relevant information to the intended recipient. Alternatively, the intended recipient may ask the individual to complete a form, which the recipient will submit to the covered entity on the individual's behalf, that authorizes the covered entity to disclose the information. Whether the authorization is submitted to the covered entity by the individual or by another person on the individual's behalf, the covered entity maintaining protected health information may not use or disclose it pursuant to an authorization unless the authorization meets the following requirements.

First, the authorization must include a description of the information to be used or disclosed, with sufficient specificity to allow the covered entity to know which information the authorization references. For example, the authorization may include a description of “laboratory results from July 1998” or “all laboratory results” or “results of MRI performed in July 1998.” The covered entity can then use or disclose that information and only that information. If the covered entity does not understand what information is covered by the authorization, the use or disclosure is not permitted unless the covered entity clarifies the request.

There are no limitations on the information that can be authorized for disclosure. If an individual wishes to authorize a covered entity to disclose his or her entire medical record, the authorization can so specify. In order for the covered entity to disclose the entire medical record, the authorization must be specific enough to ensure that the individual has a clear understanding that the entire record will be disclosed. For example, if the Social Security Administration seeks authorization for release of all health information to facilitate the processing of benefit applications, then the description on the authorization form must specify “all health information” or the equivalent.

In some instances, a covered entity may be reluctant to undertake the effort to review the record and select portions relevant to the request (or redact portions not relevant). In such circumstances, covered entities may provide the entire record to the

individual, who may then redact and release the more limited information to the requestor. This rule does not require a covered entity to disclose information pursuant to an individual's authorization.

Second, the authorization must include the name or other specific identification of the person(s) or class of persons that are authorized to use or disclose the protected health information. If an authorization permits a class of covered entities to disclose information to an authorized person, the class must be stated with sufficient specificity so that a covered entity presented with the authorization will know with reasonable certainty that the individual intended the covered entity to release protected health information. For example, a covered licensed nurse practitioner presented with an authorization for “all physicians” to disclose protected health information could not know with reasonable certainty that the individual intended for the practitioner to be included in the authorization.

Third, the authorization must include the name or other specific identification of the person(s) or class of persons to ***82518** whom the covered entity is authorized to make the use or disclosure. The authorization must identify these persons with sufficient specificity to reasonably permit a covered entity responding to the authorization to identify the authorized user or recipient of the protected health information. Often, individuals provide authorizations to third parties, who present them to one or more covered entities. For example, an authorization could be completed by an individual and given to a government agency, authorizing the agency to receive medical information from any health care provider that has treated the individual within a defined period of time. Such an authorization is permissible (subject to the other requirements of this part) if it sufficiently identifies the government entity that is authorized to receive the disclosed protected health information.

Fourth, the authorization must state an expiration date or event. This expiration date or event must either be a specific date (e.g., January 1, 2001), a specific time period (e.g., one year from the date of signature), or an event directly relevant to the individual or the purpose of the use or disclosure (e.g., for the duration of the individual's enrollment with the health plan that is authorized to make the use or disclosure). We note that the expiration date or event is subject to otherwise applicable and more stringent law. For example, the National Association of Insurance Commissioners' Insurance Information and Privacy Protection Model Act, adopted in at least fifteen states, specifies that authorizations signed for the purpose of collecting information in connection with an application for a life, health, or disability insurance policy are permitted to remain valid for no longer than thirty months. In those states, the longest such an authorization may remain in effect is therefore thirty months, regardless of the expiration date or event indicated on the form.

Fifth, the authorization must state that the individual has the right to revoke an authorization in writing, except to the extent that action has been taken in reliance on the authorization or, if applicable, during a contestability period. The authorization must include instructions on how the individual may revoke the authorization. For example, the person obtaining the authorization from the individual can include an address where the individual can send a written request for revocation.

Sixth, the authorization must inform the individual that, when the information is used or disclosed pursuant to the authorization, it may be subject to re-disclosure by the recipient and may no longer be protected by this rule.

Seventh, the authorization must include the individual's signature and the date of the signature. Once we adopt the standards for electronic signature, another of the required administrative simplification standards we are required to adopt under HIPAA, an electronic signature that meets those standards will be sufficient under this rule. We do not require verification of the individual's identity or authentication of the individual's signature.

Finally, if the authorization is signed by a personal representative of the individual, the representative must indicate his or her authority to act for the individual.

As in the proposed rule, the authorization must be written in plain language. See the preamble discussion regarding notice of privacy practices (§ 164.520) for a discussion of the plain language requirement. We do not provide a model authorization in this rule. We will provide further guidance on this issue prior to the compliance date.

Section 164.508(d)—Authorizations Requested by a Covered Entity for Its Own Uses and Disclosures

We proposed to require covered entities to include additional elements in authorizations initiated by the covered entity. Before a covered entity could use or disclose protected health information of an individual pursuant to a request the covered entity made, we proposed to require the entity to obtain an authorization containing the minimum elements described above and the following additional elements: except for authorizations requested for clinical trials, a statement that the entity will not condition treatment or payment on the individual's authorization; a description of the purpose of the requested use or disclosure; a statement that the individual may inspect or copy the information to be used or disclosed and may refuse to sign the authorization; and, if the use or disclosure of the requested information will result in financial gain to the entity, a statement that such gain will result.

We additionally proposed to require covered entities, when requesting an individual's authorization, to request only the minimum amount of information necessary to accomplish the purpose for which the request was made. We also proposed to require covered entities to provide the individual with a copy of the executed authorization.

We retain the proposed approach, but apply these additional requirements when the covered entity requests the individual's authorization for the entity's own use or disclosure of protected health information maintained by the covered entity itself. For example, a health plan may ask individuals to authorize the plan to disclose protected health information to a subsidiary to market life insurance to the individual. A pharmaceutical company may also ask a covered provider to recruit patients for drug research; if the covered provider asks patients to sign an authorization for the provider to disclose protected health information to the pharmaceutical company for this research, this is also an authorization requested by a covered entity for disclosure of protected health information maintained by the covered entity. When covered entities initiate the authorization by asking individuals to authorize the entity to use or disclose protected health information that the entity maintains, the authorization must include all of the elements required above as well as several additional elements.

Authorizations requested by covered entities for the covered entity's own use or disclosure of protected health information must state, as applicable under § 164.508(b)(4), that the covered entity will not condition treatment, payment, enrollment, or eligibility on the individual's authorization for the use or disclosure. For example, if a health plan asks an individual to sign an authorization for the health plan to disclose protected health information to a non-profit advocacy group for the advocacy group's fundraising purposes, the authorization must contain a statement that the health plan will not condition treatment, payment, enrollment in the health plan, or eligibility for benefits on the individual providing the authorization.

Authorizations requested by covered entities for their own uses and disclosures of protected health information must also identify each purpose for which the information is to be used or disclosed. The required statement of purpose(s) must provide individuals with the facts they need to make an informed decision whether to allow release of the information. We prohibit the use of broad or blanket authorizations requesting the use or disclosure of protected health information for a wide range of unspecified purposes. Both the information that is to be used or disclosed and the specific purpose(s) for such uses or disclosures must be stated in the authorization. ***82519**

Authorizations requested by covered entities for their own uses and disclosures must also advise individuals of certain rights available to them under this rule. The authorization must state that the individual may inspect or copy the information to be used or disclosed as provided in § 164.524 regarding access for inspection and copying and that the individual may refuse to sign the authorization.

We alter the proposed requirements with respect to authorizations for which the covered entity will receive financial gain. When the covered entity initiates the authorization and the covered entity will receive direct or indirect remuneration from a third party (rather than financial gain, as proposed) in exchange for using or disclosing the protected health information, the authorization must include a statement that such remuneration will result. For example, a health plan may wish to sell or rent its enrollee mailing list or a pharmaceutical company may offer a covered provider a discount on its products if the provider obtains authorization to disclose the demographic information of patients with certain diagnoses so that the company can market new

drugs to them directly. In each case, the covered entity must obtain the individual's authorization, and the authorization must include a statement that the covered entity will receive remuneration.

In § 164.508(d)(2), we continue to require a covered entity that requests an authorization for its own use or disclosure of protected health information to provide the individual with a copy of the signed authorization. While we eliminate from this section the provision requiring covered entities to obtain authorization for use or disclosure of the minimum necessary protected health information, § 164.514(d)(4) requires covered entities to request only the minimum necessary protected health information to accomplish the purpose for which the request is made. This requirement applies to these authorizations, as well as other requests.

Section 164.508(e)—Authorizations Requested by a Covered Entity for Disclosures by Others

In the proposed rule, we would have prohibited all covered entities from requiring the individual's written legal permission (as proposed, an "authorization") for the use or disclosure of protected health information to carry out treatment, payment, or health care operations. We generally eliminate this prohibition in the final rule, except to specify that a consent obtained by one covered entity is not effective to permit another covered entity to use or disclose protected health information. See § 164.506(a)(5) and the corresponding preamble discussion.

In the final rule, if a covered entity seeks the individual's written legal permission to obtain protected health information about the individual from another covered entity for any purpose, it must obtain the individual's authorization for the covered entity that maintains the protected health information to make the disclosure. If the authorization is for the purpose of obtaining protected health information for purposes other than treatment, payment, or health care operations, the authorization need only contain the core elements required by § 164.508(c) and described above.

If the authorization, however, is for the purpose of obtaining protected health information to carry out treatment, payment, or health care operations, the authorization must meet the requirements of § 164.508(e). We expect such authorizations will rarely be necessary, because we expect covered entities that maintain protected health information to obtain consents that permit them to make anticipated uses and disclosures for these purposes. An authorization obtained by another covered entity that authorizes the covered entity maintaining the protected health information to make a disclosure for the same purpose, therefore, would be unnecessary.

We recognize, however, that these authorizations may be useful to demonstrate an individual's intent and relationship to the intended recipient of the information when the intent or relationship is not already clear. For example, a long term care insurer may need information from an individual's health care providers about the individual's ability to perform activities of daily living in order to determine payment of a long term care claim. The providers that hold the information may not be providing the long term care and may not, therefore, be aware of the individual's coverage under the policy or that the individual is receiving long term care services. An authorization obtained by the long term care insurer will help to demonstrate these facts to the providers holding the information, which will make them more confident that the individual intends for the information to be shared. Similarly, an insurer with subrogation obligations may need health information from the enrollee's providers to assess or prosecute the claim. A patient's new physician may also need medical records from the patient's prior providers in order to treat the patient. Without an authorization that demonstrates the patient's intent for the information to be shared, the covered entity that maintains the protected health information may be reluctant to provide the information, even if that covered entity's consent permits such disclosure to occur.

These authorizations may also be useful to accomplish clinical coordination and integration among covered entities that do not meet the definitions of affiliated covered entities or organized health care arrangements. For example, safety-net providers that participate in the Community Access Program (CAP) may not qualify as organized health care arrangements but may want to share protected health information with each other in order to develop and expand integrated systems of care for uninsured people. An authorization under this section would permit such providers to receive protected health information from other CAP participants to engage in such activities.

Because of such concerns, we permit a covered entity to request the individual's authorization to obtain protected health information from another covered entity to carry out treatment, payment, and health care operations. In these situations, the authorization must contain the core elements described above and must also describe each purpose of the requested disclosure.

With one exception, the authorization must also indicate that the authorization is voluntary. It must state that the individual may refuse to sign the authorization and that the covered entity requesting the authorization will not condition the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits on obtaining the individual's authorization. If the authorization is for a disclosure of information that is necessary to determine payment of a claim for specified benefits, however, the health plan requesting the authorization may condition the payment of the claim on obtaining the authorization from the individual. See § 164.508(b)(4)(iii). In this case, the authorization does not have to state that the health plan will not condition payment on obtaining the authorization.

The covered entity requesting the authorization must provide the individual with a copy of the signed authorization. We note that the covered entity requesting the authorization is also subject to the requirements in ***82520** § 164.514 to request only the minimum necessary information needed for the purpose of the authorization.

We additionally note that, when the covered entity that maintains the protected health information has already obtained a consent for disclosure of protected health information to carry out treatment, payment, and/or health care operations under § 164.506, and that consent conflicts with an authorization obtained by another covered entity under § 164.508(e), the covered entity maintaining the protected health information is bound by the more restrictive document. See § 164.506(e) and the corresponding preamble discussion for further explanation.

Section 164.508(f)—Authorizations for Uses and Disclosures of Protected Health Information Created for Research that Includes Treatment of Individuals

In the proposed rule, we would have required individual authorization for any use or disclosure of research information unrelated to treatment. In the final rule, we eliminate the special rules for this category of information and, instead, require covered entities to obtain an authorization for the use or disclosure of protected health information the covered entity creates for the purpose of research that includes treatment of individuals, except as otherwise permitted by § 164.512(i).

The intent of this provision is to permit covered entities that conduct research involving treatment to bind themselves to a more limited scope of uses and disclosures of research information than they would otherwise be permitted to make with non-research information. Rather than creating a single definition of "research information," we allow covered entities the flexibility to define that subset of protected health information they create during clinical research that is not necessary for treatment, payment, or health care operations and that the covered entity will use or disclose under more limited circumstances than it uses or discloses other protected health information. In designing their authorizations, we expect covered entities to be mindful of the often highly sensitive nature of research information and the impact of individuals' privacy concerns on their willingness to participate in research.

Covered entities seeking authorization to use or disclose protected health information they create for the purpose of research that includes treatment of individuals, including clinical trials, must include in the authorization (in addition to the applicable elements required above) a description of the extent to which some or all of the protected health information created for the research will also be used or disclosed for purposes of treatment, payment, and health care operations. For example, if the covered entity intends to seek reimbursement from the individual's health plan for the routine costs of care associated with the research protocol, it must explain in the authorization the types of information that it will provide to the health plan for this purpose. This information, and the circumstances under which disclosures will be made for treatment, payment, and health care operations, may be more limited than the information and circumstances described in the covered entity's general consent and notice of privacy practices. To the extent the covered entity limits itself to a subset of uses or disclosures that are otherwise permissible under the rule and the covered entity's consent and notice, the covered entity is bound by the statements made in

the research-related authorization. In these circumstances, the authorization must indicate that the authorization, not the general consent and notice, controls.

If the covered entity's primary interaction with the individual is through the research, the covered entity may combine the general consent for treatment, payment, and health care operations required under § 164.506 with this research authorization and need not obtain an additional consent under § 164.506. If the entity has already obtained, or intends to obtain, a separate consent as required under § 164.506, the research authorization must refer to that consent and state that the practices described in the research-related authorization are binding on the covered entity as to the information covered by the research-related authorization. The research-related authorization may also be combined in the same document as the informed consent for participation in the research. This is an exception to the general rule in § 164.508(b)(3) that an authorization under this section may not be combined with any other document (see above).

The covered entity must also include in the authorization a description of the extent to which it will not use or disclose the protected health information it obtains in connection with the research protocol for purposes that are permitted without individual authorization under this rule (under §§ 164.510 and 164.512). To the extent that the entity limits itself to a subset of uses or disclosures that are otherwise permissible under the rule and the entity's notice, the entity is bound by the statements made in the research authorization. In these circumstances, the authorization must indicate that the authorization, not the notice, controls. The covered entity may not, however, purport to preclude itself from making uses or disclosures that are required by law or that are necessary to avert a serious and imminent threat to health or safety.

In some instances, the covered entity may wish to make a use or disclosure of the research information that it did not include in its general consent or notice or for which authorization is required under this rule. To the extent the entity includes uses or disclosures in the research authorization that are otherwise not permissible under the rule and the entity's consent and notice of information practices, the entity must include all of the elements required by §§ 164.508(c) and (d) in the research-related authorization. The covered entity is bound by these statements.

Research that involves the delivery of treatment to participants sometimes relies on existing health information, such as to determine eligibility for the trial. We note that under § 164.508(b)(3)(iii), the covered entity may combine the research-related authorization required under § 164.508(f) with any other authorization for the use or disclosure of protected health information (other than psychotherapy notes), provided that the covered entity does not condition the provision of treatment on the individual signing the authorization. For example, a covered health care provider that had a treatment relationship with an individual prior to the individual's enrollment in a clinical trial, but that is now providing research-related treatment to the individual, may elect to request a compound authorization from the individual: an authorization under § 164.508(d) for the provider to use the protected health information it created prior to the initiation of the research that involves treatment, combined with an authorization under § 164.508(f) regarding use and disclosure of protected health information the covered provider will create for the purpose of the clinical trial. This compound authorization would be valid, provided the covered provider did not condition the research-related treatment on obtaining the authorization required under § 164.508(f), as permitted in § 164.508(b)(4)(i).

However, we anticipate that covered entities will almost always, if not always, condition the provision of research-related treatment on the individual signing the authorization under § 164.508(f) for the covered ***82521** entity's use or disclosure of protected health information created for the research. Therefore, we expect that the vast majority of covered providers who wish to use or disclose protected health information about an individual that will be created for research that includes treatment and wish to use existing protected health information about that individual for the research that includes treatment, will be required to obtain two authorizations from the individual: (1) an authorization for the use and disclosure of protected health information to be created for the research that involves treatment of the individual (as required under § 164.508(f)), and (2) an authorization for the use of existing protected health information for the research that includes treatment of the individual (as required under § 164.508(d)).

Effect of Authorization

As noted in the discussion about consents in the preamble to § 164.506, authorizations under this rule should not be construed to waive, directly or indirectly, any privilege granted under federal, state, or local laws or procedures.

Section 164.510—Uses and Disclosures Requiring an Opportunity for the Individual To Agree or To Object

Introduction

Section 164.510 of the NPRM proposed the uses and disclosures of protected health information that covered entities could make for purposes other than treatment, payment, or health care operations and for which an individual authorization would not have been required. These allowable uses and disclosures were designed to permit and promote key national health care priorities, and to promote the smooth operation of the health care system. In each of these areas, the proposal permitted, but would not have required, covered entities to use or disclose protected health information.

We proposed to require covered entities to obtain the individual's oral agreement before making a disclosure to a health care facility's directory or to the individual's next-of-kin or to another person involved in the individual's health care. Because there is an expectation in these two areas that individuals will have some input into a covered entity's decision to use or disclose protected health information, we decided to place disclosures to health facility directories and to persons involved in an individual's care in a separate section. In the final rule, requirements regarding disclosure of protected health information for facility directories and to others involved in an individual's care are included in § 164.510(a) and § 164.510(b), respectively. In the final rule, we include in § 164.510(b) provisions to address a type of disclosure not addressed in the NPRM: disclosures to entities providing relief and assistance in disasters such as floods, fires, and terrorist attacks. Requirements for most of the remaining categories of disclosures addressed in proposed § 164.510 of the NPRM are included in a new § 164.512 of the final rule, as discussed below.

Section 164.510 of the final rule addresses situations in which the interaction between the covered entity and the individual is relatively informal and agreements are made orally, without written authorizations for use or disclosure. In general, under the final rule, to disclose or use protected health information for these purposes, covered entities must inform individuals in advance and must provide a meaningful opportunity for the individual to prevent or restrict the disclosure. In exceptional circumstances, where even this informal discussion cannot practicably take place, covered entities are permitted to make decisions regarding disclosure or use based on the exercise of professional judgment of what is in the individual's best interest.

Section 164.510(a)—Use and Disclosure for Facility Directories

The NPRM proposed to allow covered health care providers to disclose through an inpatient facility's directory a patient's name, location in the facility, and general health condition, provided that the individual had agreed to the disclosure. The NPRM would have allowed this agreement to be oral. Pursuant to the NPRM, when making decisions about incapacitated individuals, a covered health care provider could have disclosed such information at the entity's discretion and consistent with good medical practice and any prior expressions of patient preference of which the covered entity was aware.

The preamble to the NPRM listed several factors that we encouraged covered entities to take into account when making decisions about whether to include an incapacitated patient's information in the directory. These factors included: (1) Whether disclosing that an individual is in the facility could reasonably cause harm or danger to the individual (e.g., if it appeared that an unconscious patient had been abused and disclosing the information could give the attacker sufficient information to seek out the person and repeat the abuse); (2) whether disclosing a patient's location within a facility implicitly would give information about the patient's condition (e.g., whether a patient's room number revealed that he or she was in a psychiatric ward); (3) whether it was necessary or appropriate to give information about patient status to family or friends (e.g., if giving information to a family member about an unconscious patient could help a physician administer appropriate medications); and (4) whether an individual had, prior to becoming incapacitated, expressed a preference not to be included in the directory. The preamble stated that if a covered entity learned of such a preference, it would be required to act in accordance with the preference.

The preamble to the NPRM said that when individuals entered a facility in an incapacitated state and subsequently gained the ability to make their own decisions, health facilities should ask them within a reasonable time period for permission to include their information in the facility's directory.

In the final rule, we change the NPRM's opt-in authorization requirement to an opt-out approach for inclusion of patient information in a health care facility's directory. The final rule allows covered health care providers—which in this case are health care facilities—to include patient information in their directory only if: (1) They inform incoming patients of their policies regarding the directory; (2) they give patients a meaningful opportunity to opt out of the directory listing or to restrict some or all of the uses and disclosures that can be included in the directory; and (3) the patient does not object to being included in the directory. A patient must be allowed, for example, to have his or her name and condition included in the directory while not having his or her religious affiliation included. The facility's notice and the individual's opt-out or restriction may be oral.

Under the final rule, subject to the individual's right to object, or known prior expressed preferences, a covered health care provider may disclose the following information to persons who inquire about the individual by name: (1) The individual's general condition in terms that do not communicate specific medical information about the individual (e.g., fair, critical, stable, etc.); and (2) location in the facility. This approach represents a slight change to the NPRM, which did not require members of the general public to ask for a patient by name in order to obtain directory information and which, ***82522** in fact, would have allowed covered entities to disclose the individual's name as part of directory information.

Under the final rule, we also establish provisions for disclosure of directory information to clergy that are slightly different from those which apply for disclosure to the general public. Subject to the individual's right to object or restrict the disclosure, the final rule permits a covered entity to disclose to a member of the clergy: (1) The individual's name; (2) the individual's general condition in terms that do not communicate specific medical information about the individual; (3) the individual's location in the facility; and (4) the individual's religious affiliation. A disclosure of directory information may be made to members of the clergy even if they do not inquire about an individual by name. We note that the rule in no way requires a covered health care provider to inquire about the religious affiliation of an individual, nor must individuals supply that information to the facility. Individuals are free to determine whether they want their religious affiliation disclosed to clergy through facility directories.

We believe that allowing clergy to access patient information pursuant to this section does not violate the Establishment Clause of the First Amendment, which prohibits laws “respecting an establishment of religion.” Courts traditionally turn to the Lemon test when evaluating laws that might raise Establishment Clause concerns. A law does not violate the Clause if it has a secular purpose, is not primarily to advance religion, and does not cause excessive government entanglement with religion. The privacy regulation passes this test because its purpose is to protect the privacy of individuals—regardless of their religious affiliation—and it does not cause excessive government entanglement.

More specifically, although this section provides a special rule for members of the clergy, it does so as an accommodation to patients who seek to engage in religious conduct. For example, restricting the disclosure of an individual's religious affiliation, room number, and health status to a priest could cause significant delay that would inhibit the ability of a Catholic patient to obtain sacraments provided during the last rites. We believe this accommodation does not violate the Establishment Clause, because it avoids a government-imposed restriction on the disclosure of information that could disproportionately affect the practice of religion. In that way, it is no different from accommodations upheld by the U.S. Supreme Court, such as exceptions to laws banning the use of alcohol in religious ceremonies.

The final rule expands the circumstances under which health care facilities can disclose specified health information to the patient directory without the patient's agreement. Besides allowing such disclosures when patients are incapacitated, as the NPRM would have allowed, the final rule allows such disclosures in emergency treatment circumstances. For example, when a patient is conscious and capable of making a decision, but is so seriously injured that asking permission to include his or her information in the directory would delay treatment such that the patient's health would be jeopardized, health facilities can make decisions about including the patient's information in the directory according to the same rules that apply when the

patient is incapacitated. The final rule modifies the NPRM requirements for cases in which an incapacitated patient is admitted to a health care facility. Whereas the NPRM would have allowed health care providers to disclose an incapacitated patient's information to the facility's directory "at its discretion and consistent with good medical practice and any prior expressions of preference of which the covered entity [was] aware," the final rule states that in these situations (and in other emergency treatment circumstances), covered health care providers must make the decision on whether to include the patient's information in the facility's directory in accordance with professional judgment as to the patient's best interest. In addition, when making decisions involving incapacitated patients and patients in emergency situations, covered health care providers may decide to include some portions of the patient's information (such as name) but not other information (such as location in the facility) in order to protect patient interests.

As in the preamble to the NPRM, we encourage covered health care providers to take into account the four factors listed above when making decisions about whether to include patient information in a health care facility's directory when patients are incapacitated or are in an emergency treatment circumstance. In addition, we retain the requirement stated in the preamble of the NPRM that if a covered health care provider learns of an incapacitated patient's prior expression of preference not to be included in a facility's directory, the facility must not include the patient's information in the directory. For cases involving patients admitted to a health care facility in an incapacitated or emergency treatment circumstance who during the course of their stay become capable of decisionmaking, the final rule takes an approach similar to that described in the NPRM. The final rule states that when an individual who was incapacitated or in an emergency treatment circumstance upon admission to an inpatient facility and whose condition stabilizes such that he or she is capable of decisionmaking, a covered health care provider must, when it becomes practicable, inform the individual about its policies regarding the facility's directory and provide the opportunity to object to the use or disclosure of protected health information about themselves for the directory.

Section 164.510(b)—Uses and Disclosures for Involvement in the Individual's Care and Notification Purposes

In cases involving an individual with the capacity to make health care decisions, the NPRM would have allowed covered entities to disclose protected health information about the individual to a next-of-kin, to other family members, or to close personal friends of the individual if the individual had agreed orally to such disclosure. If such agreement could not practicably or reasonably be obtained (e.g., when the individual was incapacitated), the NPRM would have allowed disclosure of protected health information that was directly relevant to the person's involvement in the individual's health care, consistent with good health professional practices and ethics. The NPRM defined next-of-kin as defined under state law.

Under the final rule, we specify that covered entities may disclose to a person involved in the current health care of the individual (such as a family member, other relative, close personal friend, or any other person identified by the individual) protected health information directly related to the person's involvement in the current health care of an individual or payment related to the individual's health care. Such persons involved in care and other contact persons might include, for example: blood relatives; spouses; roommates; boyfriends and girlfriends; domestic partners; neighbors; and colleagues. Inclusion of this list is intended to be illustrative only, and it is not intended to change current practices with respect to: (1) Involvement of other persons in individuals' treatment decisions; (2) informal information-sharing among individuals involved in a person's care; or (3) sharing of protected health ***82523** information to contact persons during a disaster. The final rule also includes new language stating that covered entities may use or disclose protected health information to notify or assist in notification of family members, personal representatives, or other persons responsible for an individual's care with respect to an individual's location, condition, or death. These provisions allow, for example, covered entities to notify a patient's adult child that his father has suffered a stroke and to tell the person that the father is in the hospital's intensive care unit.

The final rule includes separate provisions for situations in which the individual is present and for when the individual is not present at the time of disclosure. When the individual is present and has the capacity to make his or her own decisions, a covered entity may disclose protected health information only if the covered entity: (1) Obtains the individual's agreement to disclose to the third parties involved in their care; (2) provides the individual with an opportunity to object to such disclosure and the individual does not express an objection; or (3) reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure. Situations in which covered providers may infer an individual's

agreement to disclose protected health information pursuant to option (3) include, for example, when a patient brings a spouse into the doctor's office when treatment is being discussed, and when a colleague or friend has brought the individual to the emergency room for treatment.

We proposed that when a covered entity could not practicably obtain oral agreement to disclose protected health information to next-of-kin, relatives, or those with a close personal relationship to the individual, the covered entity could make such disclosures consistent with good health professional practice and ethics. In such instances, we proposed that covered entities could disclose only the minimum information necessary for the friend or relative to provide the assistance he or she was providing. For example, health care providers could not disclose to a friend or relative simply driving a patient home from the hospital extensive information about the patient's surgery or past medical history when the friend or relative had no need for this information.

The final rule takes a similar approach. Under the final rule, when an individual is not present (for example, when a friend of a patient seeks to pick up the patient's prescription at a pharmacy) or when the opportunity to agree or object to the use or disclosure cannot practicably be provided due to the individual's incapacity or an emergency circumstance, covered entities may, in the exercise of professional judgment, determine whether the disclosure is in the individual's best interests and if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care. For example, this provision allows covered entities to inform relatives or others involved in a patient's care, such as the person who accompanied the individual to the emergency room, that a patient has suffered a heart attack and to provide updates on the patient's progress and prognosis when the patient is incapacitated and unable to make decisions about such disclosures. In addition, this section allows covered entities to disclose functional information to individuals assisting in a patient's care; for example, it allows hospital staff to give information about a person's mobility limitations to a friend driving the patient home from the hospital. It also allows covered entities to use professional judgment and experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on an individual's behalf to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information. Thus, under this provision, pharmacists may release a prescription to a patient's friend who is picking up the prescription for him or her. Section 164.510(b) is not intended to disrupt most covered entities' current practices or state law with respect to these types of disclosures.

This provision is intended to allow disclosures directly related to a patient's current condition and should not be construed to allow, for example, disclosure of extensive information about the patient's medical history that is not relevant to the patient's current condition and that could prove embarrassing to the patient. In addition, if a covered entity suspects that an incapacitated patient is a victim of domestic violence and that a person seeking information about the patient may have abused the patient, covered entities should not disclose information to the suspected abuser if there is reason to believe that such a disclosure could cause the patient serious harm. In all of these situations regarding possible disclosures of protected health information about an patient who is not present or is unable to agree to such disclosures due to incapacity or other emergency circumstance, disclosures should be in accordance with the exercise of professional judgment as to the patient's best interest.

This section is not intended to provide a loophole for avoiding the rule's other requirements, and it is not intended to allow disclosures to a broad range of individuals, such as journalists who may be curious about a celebrity's health status. Rather, it should be construed narrowly, to allow disclosures to those with the closest relationships with the patient, such as family members, in circumstances when a patient is unable to agree to disclosure of his or her protected health information. Furthermore, when a covered entity cannot practicably obtain an individual's agreement before disclosing protected health information to a relative or to a person involved in the individual's care and is making decisions about such disclosures consistent with the exercise of professional judgment regarding the individual's best interest, covered entities must take into account whether such a disclosure is likely to put the individual at risk of serious harm.

Like the NPRM, the final rule does not require covered entities to verify the identity of relatives or other individuals involved in the individual's care. Rather, the individual's act of involving the other persons in his or her care suffices as verification of their identity. For example, the fact that a person brings a family member into the doctor's office when treatment information will be discussed constitutes verification of the involved person's identity for purposes of this rule. Likewise, the fact that a friend

arrives at a pharmacy and asks to pick up a specific prescription for an individual effectively verifies that the friend is involved in the individual's care, and the rule allows the pharmacist to give the filled prescription to the friend.

We also clarify that the final rule does not allow covered entities to assume that an individual's agreement at one point in time to disclose protected health information to a relative or to another person assisting in the individual's care implies agreement to disclose protected health information indefinitely in the future. We encourage the exercise of professional judgment in determining the scope of the person's involvement in the individual's care and the time period for which the individual is agreeing to the other person's involvement. For example, if a friend simply picks up a patient from the hospital but has played no other role ***82524** in the individual's care, hospital staff should not call the friend to disclose lab test results a month after the initial encounter with the friend. However, if a patient routinely brings a spouse into the doctor's office when treatment is discussed, a physician can infer that the spouse is playing a long-term role in the patient's care, and the rule allows disclosure of protected health information to the spouse consistent with his or her role in the patient's care, for example, discussion of treatment options.

The NPRM did not specifically address situations in which disaster relief organizations may seek to obtain protected health information from covered entities to help coordinate the individual's care, or to notify family or friends of an individual's location or general condition in a disaster situation. In the final rule, we account for disaster situations in this paragraph. Specifically, we allow covered entities to use or disclose protected health information without individual agreement to federal, state, or local government agencies engaged in disaster relief activities, as well as to private disaster relief or disaster assistance organizations (such as the Red Cross) authorized by law or by their charters to assist in disaster relief efforts, to allow these organizations to carry out their responsibilities in a specific disaster situation. Covered entities may make these disclosures to disaster relief organizations, for example, so that these organizations can help family members, friends, or others involved in the individual's care to locate individuals affected by a disaster and to inform them of the individual's general health condition. This provision also allows disclosure of information to disaster relief or disaster assistance organizations so that these organizations can help individuals obtain needed medical care for injuries or other health conditions caused by a disaster.

We encourage disaster relief organizations to protect the privacy of individual health information to the extent practicable in a disaster situation. However, we recognize that the nature of disaster situations often makes it impossible or impracticable for disaster relief organizations and covered entities to seek individual agreement or authorization before disclosing protected health information necessary for providing disaster relief. Thus, we note that we do not intend to impede disaster relief organizations in their critical mission to save lives and reunite loved ones and friends in disaster situations.

Section 164.512—Uses and Disclosures for Which Consent, an Authorization, or Opportunity To Agree or Object Is Not Required

Introduction

The final rule's requirements regarding disclosures for directory information and to family members or others involved in an individual's care are in a section separate from that covering disclosures allowed for other national priority purposes. In the final rule, we place most of the other disclosures for national priority purposes in a new § 164.512.

As in the NPRM, in § 164.512 of the final rule, we allow covered entities to make these national priority uses and disclosures without individual authorization. As in the NPRM, these uses and disclosures are discretionary. Covered entities are free to decide whether or not to use or disclose protected health information for any or all of the permitted categories. However, as in the NPRM, nothing in the final rule provides authority for a covered entity to restrict or refuse to make a use or disclosure mandated by other law.

The new § 164.512 includes paragraphs on: Uses and disclosures required by law; uses and disclosures for public health activities; disclosures about victims of abuse, neglect, or domestic violence; uses and disclosures for health oversight activities; disclosures for judicial and administrative proceedings; disclosures for law enforcement purposes; uses and disclosures about decedents; uses and disclosures for cadaveric donation of organs, eyes, or tissues; uses and disclosures for research purposes;

uses and disclosures to avert a serious threat to health or safety (which we had called "emergency circumstances" in the NPRM); uses and disclosures for specialized government functions (referred to as "specialized classes" in the NPRM); and disclosures to comply with workers' compensation laws.

Section 164.512(c) in the final rule, which addresses uses and disclosures regarding adult victims of abuse, neglect and domestic violence, is new, although it incorporates some provisions from proposed § 164.510 of the NPRM. In the final rule we also eliminate proposed § 164.510(g) on government health data systems and proposed § 164.510(i) on banking and payment processes. These changes are discussed below.

Approach to Use of Protected Health Information

Proposed § 164.510 of the NPRM included specific subparagraphs addressing uses of protected health information by covered entities that were also public health agencies, health oversight agencies, government entities conducting judicial or administrative proceedings, or government heath data systems. Such covered entities could use protected health information in all instances for which they could disclose the information for these purposes. In the final rule, as discussed below, we retain this language in the paragraphs on public health activities and health oversight. However, we eliminate this clause with respect to uses of protected health information for judicial and administrative proceedings, because we no longer believe that there would be any situations in which a covered entity would also be a judicial or administrative tribunal. Proposed § 164.510(e) of the NPRM, regarding disclosure of protected health information to coroners, did not include such a provision. In the final rule we have added it because we believe there are situations in which a covered entity, for example, a public hospital conducting post-mortem investigations, may need to use protected health information for the same purposes for which it would have disclosed the information to a coroner.

While the right to request restrictions under § 164.522 and the consents required under § 164.506 do not apply to the use and disclosure of protected health information under § 164.512, we do not intend to preempt any state or other restrictions, or any right to enforce such agreements or consents under other law.

We note that a covered entity may use or disclose protected health information as permitted by and in accordance with one of the paragraphs of § 164.512, regardless of whether that use or disclosure fails to meet the requirements for use or disclosure under a different paragraph in § 164.512 or elsewhere in the rule.

Verification for Disclosures Under § 164.512

In § 164.510(a) of the NPRM, we proposed that covered entities verify the identity and authority of persons to whom they made disclosure under the section. In the final rule, we generally have retained the proposed requirements. Verification requirements are discussed in § 164.514 of the final rule.

Section 164.512(a)—Uses and Disclosures Required by Law

In the NPRM we would have allowed covered entities to use or disclose protected health information without individual authorization where such use ***82525** or disclosure was required by other law, as long as the use or disclosure met all relevant requirements of such law. However, a legally mandated use or disclosure which fell into one or more of the national priority purposes expressly identified in proposed § 164.510 of the NPRM would have been subject to the terms and conditions specified by the applicable paragraph of proposed § 164.510. Thus, a disclosure required by law would have been allowed only to the extent it was not otherwise prohibited or restricted by another provision in proposed § 164.510. For example, mandatory reporting to law enforcement officials would not have been allowed unless such disclosures conformed to the requirements of proposed § 164.510(f) of the NPRM, on uses and disclosures for law enforcement purposes. As explained in the NPRM, this provision was not intended to obstruct access to information deemed important enough by federal, state or other government authorities to require it by law.

In § 164.512(a) of the final rule, we retain the proposed approach, and we permit covered entities to comply with laws requiring the use or disclosure of protected health information, provided the use or disclosure meets and is limited to the relevant requirements of such other laws. To more clearly address where the substantive and procedural requirements of other provisions in this section apply, we have deleted the general sentence from the NPRM which stated that the provision "does not apply to uses or disclosures that are covered by paragraphs (b) through (m)" of proposed § 164.510. Instead, in § 164.512 (a)(2) we list the specific paragraphs that have additional requirements with which covered entities must comply. They are disclosures about victims of abuse, neglect or domestic violence (§ 164.512(c)), for judicial and administrative proceedings (§ 164.512(e)), and for law enforcement purposes (§ 164.512(f)). We include a new definition of "required by law." See § 164.501. We clarify that the requirements provided for in § 164.514(h) relating to verification apply to disclosures under this paragraph. Those provisions require covered entities to verify the identity and authority of persons to whom they make disclosures. We note that the minimum necessary requirements of § 164.514(d) do not apply to disclosures made under this paragraph.

We note that this rule does not affect what is required by other law, nor does it compel a covered entity to make a use or disclosure of protected health information required by the legal demands or reporting requirements listed in the definition of "required by law." Covered entities will not be sanctioned under this rule for responding in good faith to such legal process and reporting requirements. However, nothing in this rule affects, either by expanding or contracting, a covered entity's right to challenge such process or reporting requirements under other laws. The only disclosures of protected health information compelled by this rule are disclosures to an individual (or the personal representative of an individual) or to the Secretary for the purposes of enforcing this rule.

Uses and disclosures permitted under this paragraph must be limited to the protected health information necessary to meet the requirements of the law that compels the use or disclosure. For example, disclosures pursuant to an administrative subpoena are limited to the protected health information authorized to be disclosed on the face of the subpoena.

Section 164.512(b)—Uses and Disclosures for Public Health Activities

The NPRM would have allowed covered entities to disclose protected health information without individual authorization to: (1) A public health authority authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; (2) a public health authority or other appropriate authority authorized by law to receive reports of child abuse or neglect; (3) a person or entity other than a governmental authority that could demonstrate or demonstrated that it was acting to comply with requirements or direction of a public health authority; or (4) a person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition and was authorized by law to be notified as necessary in the conduct of a public health intervention or investigation.

In the final rule, we broaden the scope of permissible disclosures pursuant to item (1) listed above. We narrow the scope of disclosures permissible under item (3) of this list, and we add language to clarify the scope of permissible disclosures with respect to item (4) on the list. We broaden the scope of allowable disclosures regarding item (1) by allowing covered entities to disclose protected health information not only to U.S. public health authorities but also, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority. For example, we allow covered entities to disclose protected health information to a foreign government agency that is collaborating with the Centers for Disease Control and Prevention to limit the spread of infectious disease.

We narrow the conditions under which covered entities may disclose protected health information to non-government entities. We allow covered entities to disclose protected health information to a person subject to the FDA's jurisdiction, for the following activities: to report adverse events (or similar reports with respect to food or dietary supplements), product defects or problems, or biological product deviations, if the disclosure is made to the person required or directed to report such information to the FDA; to track products if the disclosure is made to a person required or directed by the FDA to track the product; to enable product recalls, repairs, or replacement, including locating and notifying individuals who have received products regarding

product recalls, withdrawals, or other problems; or to conduct post-marketing surveillance to comply with requirements or at the direction of the FDA.

The terms included in § 164.512(b)(iii) are intended to have both their commonly understood meanings, as well as any specialized meanings, pursuant to the Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.). For example, "post-marketing surveillance" is intended to mean activities related to determining the safety or effectiveness of a product after it has been approved and is in commercial distribution, as well as certain Phase IV (post-approval) commitments by pharmaceutical companies. With respect to devices, "post-marketing surveillance" can be construed to refer to requirements of section 522 of the Food, Drug, and Cosmetic Act regarding certain implanted, life-sustaining, or life-supporting devices. The term "track" includes, for example, tracking devices under section 519(e) of the Food, Drug, and Cosmetic Act, units of blood or other blood products, as well as trace-backs of contaminated food.

In § 164.512(b)(iii), the term "required" refers to requirements in statute, regulation, order, or other ***82526** legally binding authority exercised by the FDA. The term "directed," as used in this section, includes other official agency communications such as guidance documents.

We note that under this provision, a covered entity may disclose protected health information to a non-governmental organization without individual authorization for inclusion in a private data base or registry only if the disclosure is otherwise for one of the purposes described in this provision (e.g., for tracking products pursuant to FDA direction or requirements, for post-marketing surveillance to comply with FDA requirements or direction.)

To make a disclosure that is not for one of these activities, covered entities must obtain individual authorization or must meet the requirements of another provision of this rule. For example, covered entities may disclose protected health information to employers for inclusion in a workplace surveillance database only: with individual authorization; if the disclosure is required by law; if the disclosure meets the requirements of § 164.512(b)(v); or if the disclosure meets the conditions of another provision of this regulation, such as § 154.512(i) relating to research. Similarly, if a pharmaceutical company seeks to create a registry containing protected health information about individuals who had taken a drug that the pharmaceutical company had developed, covered entities may disclose protected health information without authorization to the pharmaceutical company pursuant to FDA requirements or direction. If the pharmaceutical company's registry is not for any of these purposes, covered entities may disclose protected health information to it only with patient authorization, if required by law, or if disclosure meets the conditions of another provision of this rule.

The final rule continues to permit covered entities to disclose protected health information without individual authorization directly to public health authorities, such as the Food and Drug Administration, the Occupational Safety and Health Administration, the Centers for Disease Control and Prevention, as well as state and local public health departments, for public health purposes as specified in the NPRM.

The final rule retains the NPRM provision allowing covered entities to disclose protected health information to public health authorities or other appropriate government authorities authorized by law to receive reports of child abuse or neglect. In addition, we clarify the NPRM's provision regarding disclosure of protected health information to persons who may have been exposed to a communicable disease or who may otherwise be at risk of contracting or spreading a disease or condition. Under the final rule, covered entities may disclose protected health information to such individuals when the covered entity or public health authority is authorized by law to notify these individuals as necessary in the conduct of a public health intervention or investigation.

In addition, as in the NPRM, under the final rule, a covered entity that is acting as a public health authority—for example, a public hospital conducting infectious disease surveillance in its role as an arm of the public health department—may use protected health information in all cases for which it is allowed to disclose such information for public health activities as described above.

The proposed rule did not contain a specific provision relating to disclosures by covered health care providers to employers concerning work-related injuries or illnesses or workplace medical surveillance. Under the proposed rule, a covered entity would have been permitted to disclose protected health information without individual authorization for public health purposes to private person if the person could demonstrate that it was acting to comply with requirements or at the direction of a public health authority.

As discussed above, in the final rule we narrow the scope of this paragraph as it applies to disclosures to persons other than public health authorities. To ensure that covered health care providers may make disclosures of protected health information without individual authorization to employers when appropriate under federal and state laws addressing work-related injuries and illnesses or workplace medical surveillance, we include a new provision in the final rule. The provision permits covered health care providers who provide health care as a workforce member of or at the request of an employer to disclose to that employer protected health information concerning work-related injuries or illnesses or workplace medical surveillance in situations where the employer has a duty under the Occupational Safety and Health Act, the Federal Mine Safety and Health Act, or under a similar state law, to keep records on or act on such information. For example, OSHA regulations in 29 CFR part 1904 require employers to record work-related injuries and illnesses if medical treatment is necessary; MSHA regulations at 30 CFR part 50 require mine operators to report injuries and illnesses experienced by miners. Similarly, OSHA rules require employers to monitor employees' exposure to certain substances and to remove employees from exposure when toxic thresholds have been met. To obtain the relevant health information necessary to determine whether an injury or illness should be recorded, or whether an employee must be medically removed from exposure at work, employers must refer employees to health care providers for examination and testing.

OSHA and MSHA rules do not impose duties directly upon health care providers to disclose health information pertaining to recordkeeping and medical monitoring requirements to employers. Rather, these rules operate on the presumption that health care providers who provide services at the request of an employer will be able to disclose to the employer work-related health information necessary for the employer to fulfill its compliance obligations. This new provision permits covered entities to make disclosures necessary for the effective functioning of OSHA and MSHA requirements, or those of similar state laws, by permitting a health care provider to make disclosures without the authorization of the individual concerning work-related injuries or illnesses or workplace medical surveillance in situations where the employer has a duty under OSHA and MSHA requirements, or under a similar state laws, to keep records on or act on such information.

We require health care providers who make disclosures to employers under this provision to provide notice to individuals that it discloses protected health information to employers relating to the medical surveillance of the workplace and work-related illnesses and injuries. The notice required under this provision is separate from the notice required under § 164.520. The notice required under this provision may be met giving a copy of the notice to the individual at the time it provides the health care services, or, if the health care services are provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care services are provided.

This provision applies only when a covered health care provider provides health care services as a workforce member of or at the request of an employer and for the purposes discussed above. The provision does not affect the application of this rule to other health care provided to ***82527** individuals or to their relationship with health care providers that they select.

Section 164.512(c)—Disclosures About Victims of Abuse, Neglect or Domestic Violence

The NPRM included two provisions related to disclosures about persons who are victims of abuse. In the NPRM, we would have allowed covered entities to report child abuse to a public health authority or other appropriate authority authorized by law to receive reports of child abuse or neglect. In addition, under proposed § 164.510(f)(3) of the NPRM, we would have allowed covered entities to disclose protected health information about a victim of a crime, abuse or other harm to a law enforcement official under certain circumstances. The NPRM recognized that most, if not all, states had laws that mandated reporting of child abuse or neglect to the appropriate authorities. Moreover, HIPAA expressly carved out state laws on child abuse and neglect from preemption or any other interference. The NPRM further acknowledged that most, but not all, states had laws mandating

the reporting of abuse, neglect or exploitation of the elderly or other vulnerable adults. We did not intend to impede reporting in compliance with these laws.

The final rule includes a new paragraph, § 164.512(c), which allows covered entities to report protected health information to specified authorities in abuse situations other than those involving child abuse and neglect. In the final rule, disclosures of protected health information related to child abuse continues to be addressed in the paragraph allowing disclosure for public health activities (§ 164.512(b)), as described above. Because HIPAA addresses child abuse specifically in connection with a state's public health activities, we believe it would not be appropriate to include child abuse-related disclosures in this separate paragraph on abuse. State laws continue to apply with respect to child abuse, and the final rule does not in any way interfere with a covered entity's ability to comply with these laws.

In the final rule, we address disclosures about other victims of abuse, neglect and domestic violence in § 164.512(c) rather than in the law enforcement paragraph. Section 164.512(c) establishes conditions for disclosure of protected health information in cases involving domestic violence other than child abuse (e.g., spousal abuse), as well as those involving abuse or neglect (e.g., abuse of nursing home residents or residents of facilities for the mentally retarded). This paragraph addresses reports to law enforcement as well as to other authorized public officials. The provisions of this paragraph supersede the provisions of § 164.512(a) and § 164.512(f)(1)(i) to the extent that those provisions address the subject matter of this paragraph.

Under the circumstances described below, the final rule allows covered entities to disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence. In this paragraph, references to “individual” should be construed to mean the individual believed to be the victim. The rule allows such disclosure to any governmental authority authorized by law to receive reports of such abuse, neglect, or domestic violence. These entities may include, for example, adult protective or social services agencies, state survey and certification agencies, ombudsmen for the aging or those in long-term care facilities, and law enforcement or oversight.

The final rule specifies three circumstances in which disclosures of protected health information is allowed in order to report abuse, neglect or domestic violence. First, this paragraph allows disclosure of protected health information related to abuse if required by law and the disclosure complies with and is limited to the relevant requirements of such law. As discussed below, the final rule requires covered entities that make such disclosures pursuant to a state's mandatory reporting law to inform the individual of the report.

Second, this paragraph allows covered entities to disclose protected health information related to abuse if the individual has agrees to such disclosure. When considering the possibility of disclosing protected health information in an abuse situation pursuant to this section, we encourage covered entities to seek the individual's agreement whenever possible.

Third, this paragraph allows covered entities to disclose protected health information about an individual without the individual's agreement if the disclosure is expressly authorized by statute or regulation and either: (1) The covered entity, in the exercise of its professional judgment, believes that the disclosure is necessary to prevent serious harm to the individual or to other potential victims; or (2) if the individual is unable to agree due to incapacity, a law enforcement or other public official authorized to received the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual, and that an immediate enforcement activity that depends on the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

We emphasize that disclosure under this third part of the paragraph also may be made only if it is expressly authorized by statute or regulation. We use this formulation, rather than the broader “required by law,” because of the heightened privacy and safety concerns in these situations. We believe it appropriate to defer to other public determinations regarding reporting of this information only where a legislative or executive body has determined the reporting to be of sufficient importance to warrant enactment of a law or promulgation of a regulation. Law and regulations reflect a clear decision to authorize the particular

disclosure of protected health information, and reflect greater public accountability (e.g., through the required public comment process or because enacted by elected representatives).

For example, a Wisconsin law (Wis. Stat § 46.90(4)) states that any person may report to a county agency or state official that he or she believes that abuse or neglect has occurred. Pursuant to § 164.512(c)(1)(iii), a covered entity may make a report only if the specific type or subject matter of the report (e.g., abuse or neglect of the elderly) is included in the law authorizing the report, and such a disclosure may only be made to a public authority specifically identified in the law authorizing the report. Furthermore, we note that disclosures under this part of the paragraph are further limited to two circumstances. In the first case, a covered entity, in the exercise of professional judgment, must believe that the disclosure is necessary to prevent serious harm to the individual or to other potential victims. The second case addresses situations in which an individual who is a victim of abuse, neglect or domestic violence is unable to agree due to incapacity and a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate law enforcement activity that depends on the disclosure would be materially and adversely affected by waiting until the individual if able to agree to the disclosure. We note that, in this second case, a covered entity may exercise discretion, consistent with professional judgment as to the patient's ***82528** best interest, in deciding whether to make the requested disclosure.

The rules governing disclosure in this third set of circumstances are different from those governing disclosures pursuant to § 164.512(f)(3) regarding disclosure to law enforcement about victims of crime and other harm. We believe that in abuse situations —to a greater extent than in situations involving crime victims in general—there is clear potential for abusers to cause further serious harm to the victim or to others, such as other family members in a household or other residents of a nursing home. The provisions allowing reporting of abuse when authorized by state law, as described above, are consistent with principles articulated by the AMA's Council on Ethical and Judicial Affairs, which state that when reporting abuse is voluntary under state law, it is justified when necessary to prevent serious harm to a patient. Through the provisions of § 164.512(c), we recognize the unique circumstances surrounding abuse and domestic violence, and we seek to provide an appropriate balance between individual privacy interests and important societal interests such as preventing serious harm to other individuals. We note that here we are relying on covered entities, in the exercise of professional judgment, to determine what is in the best interests of the patient.

Finally, we require covered entities to inform the individual in all of the situations described above that the covered entity has disclosed protected health information to report abuse, neglect, or domestic violence. We allow covered entities to provide this information orally. We do not require written notification, nor do we encourage it, due to the sensitivity of abuse situations and the potential for the abuser to cause further harm to the individual if, for example, a covered entity sends written notification to the home of the individual and the abuser. Whenever possible, covered entities should inform the individual at the same time that they determine abuse has occurred and decide that the abuse should be reported. In cases involving patient incapacity, we encourage covered entities to inform the individual of such disclosures as soon as it is practicable to do so.

The rule provides two exceptions to the requirement to inform the victim about a report to a government authority, one based on concern for future harm and one based on past harm. First, a covered entity need not inform the victim if the covered entity, in the exercise of professional judgment, believes that informing the individual would place the individual at risk of serious harm. We believe that this exception is necessary to address the potential for future harm, either physical or emotional, that the individual may face from knowing that the report has been made. Second, a covered entity may choose not to meet the requirement for informing the victim, if the covered entity actually would be informing a personal representative (such as a parent of a minor) and the covered entity reasonably believes that such person is responsible for the abuse, neglect, or other injury that has already occurred and that informing that person would not be in the individual's best interests.

Section 164.512(d)—Uses and Disclosures for Health Oversight Activities

Under § 164.510(c) of the NPRM, we proposed to permit covered entities to disclose protected health information to health oversight agencies for oversight activities authorized by law, including audit, investigation, inspection, civil, criminal, or

administrative proceeding or action, or other activity necessary for appropriate oversight of: (i) the health care system; (ii) government benefit programs for which health information is relevant to beneficiary eligibility; or (iii) government regulatory programs for which health information is necessary for determining compliance with program standards.

In § 164.512(d) of the final rule, we modify the proposed language to include civil and criminal investigations. In describing "other activities necessary for oversight" of particular entities, we add the phrase "entities subject to civil rights laws for which health information is necessary for determining compliance." In addition, in the final rule, we add "licensure or disciplinary actions" to the list of oversight activities authorized by law for which covered entities may disclose protected health information to health oversight agencies. The NPRM's definition of "health oversight agency" (in proposed § 164.504) included this phrase, but it was inadvertently excluded from the regulation text at proposed § 164.510(c). We make this change in the regulation text of the final rule to conform to the NPRM's definition of health oversight agency and to reflect the full range of activities for which we intend to allow covered entities to disclose protected health information to health oversight agencies.

The NPRM would have allowed, but would not have required, covered entities to disclose protected health information to public oversight agencies and to private entities acting under grant of authority from or under contract with oversight agencies for oversight purposes without individual authorization for health oversight activities authorized by law. When a covered entity was also an oversight agency, it also would have been permitted to use protected health information in all cases in which it would have been allowed to disclose such information for health oversight purposes. The NPRM would not have established any new administrative or judicial process prior to disclosure for health oversight, nor would it have permitted disclosures forbidden by other law. The proposed rule also would not have created any new right of access to health records by oversight agencies, and it could not have been used as authority to obtain records not otherwise legally available to the oversight agency.

The final rule retains this approach to health oversight. As in the NPRM, the final rule provides that when a covered entity is also an oversight agency, it is allowed to use protected health information in all cases in which it is allowed to disclose such information for health oversight purposes. For example, if a state insurance department is acting as a health plan in operating the state's Medicaid managed care program, the final rule allows the insurance department to use protected health information in all cases for which the plan can disclose the protected health information for health oversight purposes. For example, the state insurance department in its capacity as the state Medicaid managed care plan can use protected health information in the process of investigating and disciplining a state Medicaid provider for attempting to defraud the Medicaid system. As in the NPRM, the final rule does not establish any new administrative or judicial process prior to disclosure for health oversight, nor does it prohibit covered entities from making any disclosures for health oversight that are otherwise required by law. Like the NPRM, it does not create any new right of access to health records by oversight agencies and it cannot be used as authority to obtain records not otherwise legally available to the oversight agency.

Overlap Between Law Enforcement and Oversight

Under the NPRM, the proposed definitions of law enforcement and oversight, and the rules governing disclosures for these purposes ***82529** overlapped. Specifically, this overlap occurred because: (1) The NPRM preamble, but not the NPRM regulation text, indicated that agencies conducting both oversight and law enforcement activities would be subject to the oversight requirements when conducting oversight activities; and (2) the NPRM addressed some disclosures for investigations of health care fraud in the law enforcement paragraph (proposed § 164.510(f)(5)(i)), while health care fraud investigations are central to the purpose of health care oversight agencies (covered under proposed § 164.510(c)). In the final rule, we make substantial changes to these provisions, in an attempt to prevent confusion.

In § 164.512(d)(2), we include explicit decision rules indicating when an investigation is considered law enforcement and when an investigation is considered oversight under this regulation. An investigation or activity is not considered health oversight for purposes of this rule if: (1) The individual is the subject of the investigation or activity; and (2) The investigation or activity does not arise out of and is not directly related to: (a) The receipt of health care; (b) a claim for public benefits related to health; or (c) qualification for, or receipt of public benefits or services where a patient's health is integral to the claim for benefits or services. In such cases, where the individual is the subject of the investigation and the investigation does not relate to issues (a)

through (c), the rules regarding disclosure for law enforcement purposes (see § 164.512(f)) apply. For the purposes of this rule, we intend for investigations regarding issues (a) through (c) above to mean investigations of health care fraud.

Where the individual is not the subject of the activity or investigation, or where the investigation or activity relates to the subject matter in (a) through (c) of the preceding sentence, a covered entity may make a disclosure pursuant to § 164.512(d)(1). For example, when the U.S. Department of Labor's Pension and Welfare Benefits Administration (PWBA) needs to analyze protected health information about health plan enrollees in order to conduct an audit or investigation of the health plan (i.e., the enrollees are not subjects of the investigation) to investigate potential fraud by the plan, the health plan may disclose protected health information to the PWBA under the health oversight rules. These rules and distinctions are discussed in greater detail in our responses to comments.

To clarify further that health oversight disclosure rules apply generally in health care fraud investigations (subject to the exception described above), in the final rule, we eliminate proposed § 164.510(f)(5)(i), which would have established requirements for disclosure related to health care fraud for law enforcement purposes. All disclosures of protected health information that would have been permitted under proposed § 164.510(f)(5)(i) are permitted under § 164.512(d).

In the final rule, we add new language (§ 164.512(d)(3)) to address situations in which health oversight activities are conducted in conjunction with an investigation regarding a claim for public benefits not related to health (e.g., claims for Food Stamps). In such situations, for example, when a state Medicaid agency is working with the Food Stamps program to investigate suspected fraud involving Medicaid and Food Stamps, covered entities may disclose protected health information to the entities conducting the joint investigation under the health oversight provisions of the rule.

In the proposed rule, the definitions of “law enforcement proceeding” and “oversight activity” both included the phrase “criminal, civil, or administrative proceeding.” For reasons explained below, the final rule retains this phrase in both definitions. The final rule does not attempt to distinguish between these activities based on the agency undertaking them or the applicable enforcement procedures. Rather, as described above, the final rule carves out certain activities which must always be considered law enforcement for purposes of disclosure of protected health information under this rule.

Additional Considerations

We note that covered entities are permitted to initiate disclosures that are permitted under this paragraph. For example, a covered entity could disclose protected health information in the course of reporting suspected health care fraud to a health oversight agency.

We delete language in the NPRM that would have allowed disclosure under this section only to law enforcement officials conducting or supervising an investigation, official inquiry, or a criminal, civil or administrative proceeding authorized by law. In some instances, a disclosure by a covered entity under this section will initiate such an investigation or proceeding, but it will not already be ongoing at the time the disclosure is made.

Section 164.512(e)—Disclosures and Uses for Judicial and Administrative Proceedings

Section 164.512(e) addresses when a covered entity is permitted to disclose protected health information in response to requests for protected health information that are made in the course of judicial and administrative proceedings—for example, when a non-party health care provider receives a subpoena (under Federal Rule of Civil Procedure Rule 45 or similar provision) for medical records from a party to a law suit. In the NPRM we would have allowed covered entities to disclose protected health information in the course of any judicial or administrative proceeding: (1) In response to an order of a court or administrative tribunal; or (2) where an individual was a party to the proceeding and his or her medical condition or history was at issue and the disclosure was pursuant to lawful process or otherwise authorized by law. Under the NPRM, if the request for disclosure of protected health information was accompanied by a court order, a covered entity could have disclosed that protected health information which the court order authorized to be disclosed. If the request for disclosure of protected health information were

not accompanied by a court order, covered entities could not have disclosed the information requested unless a request authorized by law had been made by the agency requesting the information or by legal counsel representing a party to litigation, with a written statement certifying that the protected health information requested concerned a litigant to the proceeding and that the health condition of the litigant was at issue at the proceeding.

In § 164.512(e) of the final rule, we permit covered entities to disclose protected health information in a judicial or administrative proceeding if the request for such protected health information is made through or pursuant to an order from a court or administrative tribunal or in response to a subpoena or discovery request from, or other lawful process by a party to the proceeding. When a request is made pursuant to an order from a court or administrative tribunal, a covered entity may disclose the information requested without additional process. For example, a subpoena issued by a court constitutes a disclosure which is required by law as defined in this rule, and nothing in this rule is intended to interfere with the ability of the covered entity to comply with such subpoena. ***82530**

However, absent an order of, or a subpoena issued by, a court or administrative tribunal, a covered entity may respond to a subpoena or discovery request from, or other lawful process by, a party to the proceeding only if the covered entity obtains either: (1) Satisfactory assurances that reasonable efforts have been made to give the individual whose information has been requested notice of the request; or (2) satisfactory assurances that the party seeking such information has made reasonable efforts to secure a protective order that will guard the confidentiality of the information. In meeting the first test, a covered entity is considered to have received satisfactory assurances from the party seeking the information if that party demonstrates that it has made a good faith effort (such as by sending a notice to the individual's last known address) to provide written notice to the individual whose information is the subject of the request, that the written notice included sufficient information about the proceeding to permit the individual to raise an objection, and that the time for the individual to raise objections to the court or administrative tribunal has elapsed and no objections were filed or any objections filed by the individual have been resolved.

Unless required to do so by other law, the covered entity is not required to explain the procedures (if any) available for the individual to object to the disclosure. Under the rule, the individual exercises the right to object before the court or other body having jurisdiction over the proceeding, and not to the covered entity. The provisions in this paragraph are not intended to disrupt current practice whereby an individual who is a party to a proceeding and has put his or her medical condition at issue will not prevail without consenting to the production of his or her protected health information. In such cases, we presume that parties will have ample notice and an opportunity to object in the context of the proceeding in which the individual is a party.

As described above, in this paragraph we also permit a covered entity to disclose protected health information in response to a subpoena, discovery request, or other lawful process if the covered entity receives satisfactory assurances that the party seeking the information has made reasonable efforts to seek a qualified protective order that would protect the privacy of the information. A “qualified protective order” means an order of a court or of an administrative tribunal or a stipulation that: (1) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which the records are requested; and (2) requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding. Satisfactory assurances of reasonable efforts to secure a qualified protective order are a statement and documentation that the parties to the dispute have agreed to a protective order and that it has been submitted to the court or administrative tribunal with jurisdiction, or that the party seeking the protected health information has requested a qualified protective order from such court or tribunal. We encourage the development of “model” protective orders that will facilitate adherence with this subpart.

In the final rule we also permit the covered entity itself to satisfy the requirement to make reasonable efforts to notify the individual whose information has been requested or to seek a qualified protective order. We intend this to be a permissible activity for covered entities: we do not require covered entities to undertake these efforts in response to a subpoena, discovery request, or similar process (other than an order from a court or administrative tribunal). If a covered entity receives such a request without receiving the satisfactory assurances described above from the party requesting the information, the covered entity is free to object to the disclosure and is not required to undertake the reasonable efforts itself.

We clarify that the provisions of this paragraph do not supersede or otherwise invalidate other provisions of this rule that permit uses and disclosures of protected health information. For example, the fact that protected health information is the subject of a matter before a court or tribunal does not prevent its disclosure under another provision of the rule, such as §§ 164.512(b), 164.512(d), or 164.512(f), even if a public agency's method of requesting the information is pursuant to an administrative proceeding. For example, where a public agency commences a disciplinary action against a health professional, and requests protected health information as part of its investigation, the disclosure made be made to the agency under paragraph (d) of this section (relating to health oversight) even if the method of making the request is through the proceeding. As with any request for disclosure under this section, the covered entity will need to verify the authority under which the request is being made, and we expect that public agencies will identify their authority when making such requests. We note that covered entities may reasonably rely on assertions of authority made by government agencies.

Additional Considerations

Where a disclosure made pursuant to this paragraph is required by law, such as in the case of an order from a court or administrative tribunal, the minimum necessary requirements in § 164.514(d) do not apply to disclosures made under this paragraph. A covered entity making a disclosure under this paragraph, however, may of course disclose only that protected health information that is within the scope of the permitted disclosure. For instance, in response to an order of a court or administrative tribunal, the covered entity may disclose only the protected health information that is expressly authorized by such an order. Where a disclosure is not considered under this rule to be required by law, the minimum necessary requirements apply, and the covered entity must make reasonable efforts to limit the information disclosed to that which is reasonably necessary to fulfill the request. A covered entity is not required to second guess the scope or purpose of the request, or take action to resist the request because they believe that it is over broad. In complying with the request, however, the covered entity must make reasonable efforts not to disclose more information than is requested. For example, a covered entity may not provide a party free access to its medical records under the theory that the party can identify the information necessary for the request. In some instances, it may be appropriate for a covered entity, presented with a relatively broad discovery request, to permit access to a relatively large amount of information in order for a party to identify the relevant information. This is permissible as long as the covered entity makes reasonable efforts to circumscribe the access as appropriate.

The NPRM indicated that when a covered entity was itself a government agency, the covered entity could use protected health information in all cases in which it would have been allowed to disclose such information in the course of any judicial or administrative proceeding. As explained above, the final rule does not include this provision. ***82531**

Section 164.512(f)—Disclosure for Law Enforcement Purposes

Disclosures Pursuant to Process and as Otherwise Required by Law

In the NPRM we would have allowed covered entities to disclose protected health information without individual authorization as required by other law. However, as explained above, if a legally mandated use or disclosure fell into one or more of the national priority purposes expressly identified in other paragraphs of proposed § 164.510, the disclosure would have been subject to the terms and conditions specified by the applicable paragraph of proposed § 164.510. For example, mandatory reporting to law enforcement officials would not have been allowed unless such disclosures conformed to the requirements of proposed § 164.510(f) of the NPRM. Proposed § 164.510(f) did not explicitly recognize disclosures required by other laws, and it would not have permitted covered entities to comply with some state and other mandatory reporting laws that require covered entities to disclose protected health information to law enforcement officials, such as the reporting of gun shot wounds, stab wounds, and/or burn injuries.

We did not intend to preempt generally state and other mandatory reporting laws, and in § 164.512(f)(1)(i) of the final rule, we explicitly permit covered entities to disclose protected health information for law enforcement purposes as required by other law. This provision permits covered entities to comply with these state and other laws. Under this provision, to the extent that

a mandatory reporting law falls under the provisions of § 164.512(c)(1)(i) regarding reporting of abuse, neglect, or domestic violence, the requirements of those provisions supersede.

In the final rule, we specify that covered entities may disclose protected health information pursuant to this provision in compliance with and as limited by the relevant requirements of legal process or other law. In the NPRM, for the purposes of this portion of the law enforcement paragraph, we proposed to define "law enforcement inquiry or proceeding" as an investigation or official proceeding inquiring into a violation of or failure to comply with law; or a criminal, civil or administrative proceeding arising from a violation of or failure to comply with law. In the final rule, we do not include this definition in § 164.512(f), because it is redundant with the definition of "law enforcement official" in § 164.501.

Proposed § 164.510(f)(1) of the NPRM would have authorized disclosure of protected health information to a law enforcement official conducting or supervising a law enforcement inquiry or proceeding authorized by law pursuant to process, under three circumstances.

First, we proposed to permit such disclosures pursuant to a warrant, subpoena, or other order issued by a judicial officer that documented a finding by the officer. The NPRM did not specify requirements for the nature of the finding. In the final rule, we eliminate the requirement for a "finding," and we make changes to the list of orders in response to which covered entities may disclose under this provision. Under the final rule, covered entities may disclose protected health information in compliance with and as limited by relevant requirements of: a court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer. We made this change to the list to conform to the definition of "required by law" in § 164.501.

Second, we proposed to permit such disclosures pursuant to a state or federal grand jury subpoena. In the final rule, we leave this provision of the NPRM unchanged.

Third, we proposed to permit such disclosures pursuant to an administrative request, including an administrative subpoena or summons, a civil investigative demand, or similar process, under somewhat stricter standards than exist today for such disclosures. We proposed to permit a covered entity to disclose protected health information pursuant to an administrative request only if the request met three conditions, as follows: (i) The information sought was relevant and material to a legitimate law enforcement inquiry; (ii) the request was as specific and narrowly drawn as reasonably practicable; and (iii) de-identified information could not reasonably have been used to meet the purpose of the request.

The final rules generally adopts this provision of the NPRM. In the final rule, we modify the list of orders in response to which covered entities may disclose protected health information, to include administrative subpoenas or summons, civil or authorized investigative demands, or similar process authorized by law. We made this change to the list to conform with the definition of "required by law" in § 164.501. In addition, we slightly modify the second of the three conditions under which covered entities may respond to such requests, to allow disclosure if the request is specific and is limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought.

Limited Information for Identification and Location Purposes

The NPRM would have allowed covered entities to disclose "limited identifying information" for purposes of identifying a suspect, fugitive, material witness, or missing person, in response to a law enforcement request. We proposed to define "limited identifying information" as (i) name; (ii) address; (iii) Social Security number; (iv) date of birth; (v) place of birth; (vi) type of injury or other distinguishing characteristic; and (vii) date and time of treatment.

The final rules generally adopts this provision of the NPRM with a few modifications. In the final rule, we expand the circumstances under which limited information about suspects, fugitives, material witnesses, and missing persons may be disclosed, to include not only cases in which law enforcement officials are seeking to identify such individuals, but also cases in which law enforcement officials are seeking to locate such individuals. In addition, the final rule modifies the list of data elements that may be disclosed under this provision, in several ways. We expand the list of elements that may be disclosed under

these circumstances, to include ABO blood type and Rh factor, as well as date and time of death, if applicable. We remove "other distinguishing characteristic" from the list of items that may be disclosed for the location and identification purposes described in this paragraph, and instead allow covered entities to disclose only a description of distinguishing physical characteristics, such as scars and tattoos, height, weight, gender, race, hair and eye color, and the presence or absence of facial hair such as a beard or moustache. In addition, in the final rule, protected health information associated with the following cannot be disclosed pursuant to § 164.512(f)(2): DNA data and analyses; dental records; or typing, samples or analyses of tissues or bodily fluids other than blood (e.g., saliva). If a covered entity discloses additional information under this provision, the covered entity will be out of compliance and subject to sanction.

We clarify our intent not to allow covered entities to initiate disclosures of limited identifying information to law enforcement in the absence of a law enforcement request; a covered entity may disclose protected health information under this provision only in response to a request from law enforcement. We allow a "law enforcement official's request" to be ***82532** made orally or in writing, and we intend for it to include requests by a person acting on behalf of law enforcement, for example, requests by a media organization making a television or radio announcement seeking the public's assistance in identifying a suspect. Such a request also may include a "Wanted" poster and similar postings.

Disclosure About a Victim of Crime

The NPRM would have allowed covered entities to disclose protected health information about a victim of a crime, abuse or other harm to a law enforcement official, if the law enforcement official represented that: (i) The information was needed to determine whether a violation of law by a person other than the victim had occurred; and (ii) immediate law enforcement activity that depended on obtaining the information may have been necessary.

The final rule modifies the conditions under which covered entities can disclose protected health information about victims. In addition, as discussed above, the final rule includes a new § 164.512(c), which establishes conditions for disclosure of protected health information about victims of abuse, neglect or domestic violence. In addition, as discussed above, we have added § 164.512(f)(1)(i) to this paragraph to explicitly recognize that in some cases, covered entities' disclosure of protected health information is mandated by state or other law. The rule's requirements for disclosure in situations not covered under mandatory reporting laws are different from the rule's provisions regarding disclosure pursuant to a mandatory reporting law.

The final rule requires covered entities to obtain individual agreement as a condition of disclosing the protected health information about victims to law enforcement, unless the disclosure is permitted under § 164.512(b) or (c) or § 164.512(f)(1) above. The required agreement may be obtained orally, and does not need to meet the requirements of § 164.508 of this rule (regarding authorizations). The rule waives the requirement for individual agreement if the victim is unable to agree due to incapacity or other emergency circumstance and: (1) The law enforcement official represents that the protected health information is needed to determine whether a violation of law by a person other than the victim has occurred and the information is not intended to be used against the victim; (2) the law enforcement official represents that immediate law enforcement activity that depends on such disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and (3) the covered entity, in the exercise of professional judgment, determines that the disclosure is in the individual's best interests. We intend that assessing the individual's best interests includes taking into account any further risk of harm to the individual. This provision does not allow covered entities to initiate disclosures of protected health information to law enforcement; the disclosure must be in response to a request from law enforcement.

We do not intend to create a new legal duty on the part of covered entities with respect to the safety of their patients. Rather, we intend to ensure that covered entities can continue to exercise their professional judgment in these circumstances, on a case-by-case basis, as they do today.

In some cases, a victim may also be a fugitive or suspect. For example, an individual may receive a gunshot wound during a robbery and seek treatment in a hospital emergency room. In such cases, when law enforcement officials are requesting protected health information because the individual is a suspect (and thus the information may be used against the individual), covered

entities may disclose the protected health information pursuant to § 164.512(f)(2) regarding suspects and not pursuant to § 164.512(f)(3) regarding victims. Thus, in these situations, covered entities may disclose only the limited identifying information listed in § 164.512(f)(2)—not all of the protected health information that may be disclosed under § 164.512(f)(3).

The proposed rule did not address whether a covered entity could disclose protected health information to a law enforcement official to alert the official of the individual's death.

Disclosures About Decedents

In the final rule, we add a new provision § 164.512(f)(4) in which we permit covered entities to disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death if the covered entity has a suspicion that such death may have resulted from criminal conduct. In such circumstances consent of the individual is not available and it may be difficult to determine the identity of a personal representative and gain consent for disclosure of protected health information. Permitting disclosures in this circumstance will permit law enforcement officials to begin their investigation into the death more rapidly, increasingly the likelihood of success.

Intelligence and National Security Activities

Section 164.510(f)(4) of the NPRM would have allowed covered entities to disclose protected health information to a law enforcement official without individual authorization for the conduct of lawful intelligence activities conducted pursuant to the National Security Act of 1947 (50 U.S.C. 401 et seq.) or in connection with providing protective services to the President or other individuals pursuant to section 3056 of title 18, United States Code. In the final rule, we move provisions regarding disclosures of protected health information for intelligence and protective services activities to § 164.512(k) regarding uses and disclosures for specialized government functions.

Criminal Conduct on the Premises of a Covered Entity

The NPRM would have allowed covered entities on their own initiative to disclose to law enforcement officials protected health information that the covered entity believed in good faith constituted evidence of criminal conduct that arose out of and was directly related to: (A) The receipt of health care or payment for health care, including a fraudulent claim for health care; (B) qualification for or receipt of benefits, payments, or services based on a fraudulent statement or material misrepresentation of the health of the individual; that occurred on the covered entity's premises or was witnessed by a member of the covered entity's workforce.

In the final rule, we modify this provision substantially, by eliminating language allowing disclosures already permitted in other sections of the regulation. The proposed provision overlapped with other sections of the NPRM, in particular proposed § 164.510(c) regarding disclosure for health oversight activities. In the final regulation, we clarify that this provision applies only to disclosures to law enforcement officials of protected health information that the covered entity believes in good faith constitutes evidence of a crime committed on the premises. We eliminate proposed § 164.510(f)(5)(i) regarding health care fraud from the law enforcement section, because all disclosures that would have been allowed under that provision are allowed under § 164.512(d) of the final rule (health oversight). Similarly, in the final rule, we eliminate proposed ***82533** § 164.510(f)(5)(iii) on disclosure of protected health information to law enforcement officials regarding criminal activity witnessed by a member of a health plan workforce. All disclosures that would have been permitted by that provision are included in § 164.512(f)(5), which allows disclosure of information to report a crime committed on the covered entity's premises, and by § 164.502, which provides that a covered entity is not in violation of the rule when a member of its workforce or person working for a business associate uses or discloses protected health information while acting as a “whistle blower.” Thus, § 164.512(f)(5) allows covered entities to disclose health information only on the good faith belief that it constitutes evidence of a crime on their premises. The preamble to the NPRM said that if the covered entity disclosed protected health information in good faith but was wrong in its belief that the information was evidence of a violation of law, the covered entity would not be subject to sanction under this regulation. The final rule retains this approach.

Reporting Crime in Emergencies

The proposed rule did not address disclosures by emergency medical personnel to a law enforcement official intended to alert law enforcement about the commission of a crime. Because the provisions of proposed rule were limited to individually identifiable health information that was reduced to electronic form, many communications that occur between emergency medical personnel and law enforcement officials at the scene of a crime would not have been covered by the proposed provisions.

In the final rule we include a new provision § 164.512(f)(6) that addresses "911" calls for emergency medical technicians as well as other emergency health care in response to a medical emergency. The final rule permits a covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, to disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to (1) the commission and nature of a crime, (2) the location of such crime or of the victim(s) of such crime, and (3) the identity, description, and location of the perpetrator of such crime. A disclosure is not permitted under this section if health care provider believes that the medical emergency is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care. In such cases, disclosures to law enforcement would be governed by paragraph (c) of this section.

This added provision recognizes the special role of emergency medical technicians and other providers who respond to medical emergencies. In emergencies, emergency medical personnel often arrive on the scene before or at the same time as police officers, firefighters, and other emergency response personnel. In these cases, providers may be in the best position, and sometimes be the only ones in the position, to alert law enforcement about criminal activity. For instance, providers may be the first persons aware that an individual has been the victim of a battery or an attempted murder. They may also be in the position to report in real time, through use of radio or other mechanism, information that may immediately contribute to the apprehension of a perpetrator of a crime.

We note that disclosure under this provision is at the discretion of the health care provider. Disclosures in some instances may be governed more strictly, such as by applicable ethical standards and state and local laws.

Finally, the NPRM also included a proposed § 164.510(f)(5), which duplicated proposed § 164.510(f)(3). The final rule does not include this duplicate provision.

Additional Considerations

As stated in the NPRM, this paragraph is not intended to limit or preclude a covered entity from asserting any lawful defense or otherwise contesting the nature or scope of the process when the procedural rules governing the proceeding so allow. At the same time, it is not intended to create a basis for appealing to federal court concerning a request by state law enforcement officials. Each covered entity will continue to have available legal procedures applicable in the appropriate jurisdiction to contest such requests where warranted.

As was the case with the NPRM, this rule does not create any new affirmative requirement for disclosure of protected health information. Similarly, this section is not intended to limit a covered entity from disclosing protected health information to law enforcement officials where other sections of the rule permit such disclosure, e.g., as permitted by § 164.512(j) to avert an imminent threat to health or safety, for health oversight activities, to coroners or medical examiners, and in other circumstances permitted by the rule. For additional provisions permitting covered entities to disclose protected health information to law enforcement officials, see § 164.512(j)(1)(i) and (ii).

Under the NPRM and under the final rule, to obtain protected health information, law enforcement officials must comply with whatever other law is applicable. In certain circumstances, while this provision could authorize a covered entity to disclose protected health information to law enforcement officials, there could be additional applicable statutes or rules that further

govern the specific disclosure. If the preemption provisions of this regulation do not apply, the covered entity must comply with the requirements or limitations established by such other law, regulation or judicial precedent. See §§ 160.201 through 160.205. For example, if state law permits disclosure only after compulsory process with court review, a provider or payor is not allowed to disclose information to state law enforcement officials unless the officials have complied with that requirement. Similarly, disclosure of substance abuse patient records subject to, 42 U.S.C. 290dd-2, and the implementing regulations, 42 CFR part 2, continue to be governed by those provisions.

In some instances, disclosure of protected health information to law enforcement officials will be compelled by other law, for example, by compulsory judicial process or compulsory reporting laws (such as laws requiring reporting of wounds from violent crimes, suspected child abuse, or suspected theft of controlled substances). As discussed above, disclosure of protected health information under such other mandatory law is permitted under § 164.512(a).

In the responses to comments we clarify that items such as cells and tissues are not protected health information, but that analyses of them is. The same treatment would be given other physical items, such as clothing, weapons, or a bloody knife. We note, however, that while these items are not protected health information and may be disclosed, some communications that could accompany the disclosure will be protected health information under the rule. For example, if a person provides cells to a researcher, and tells the researcher that these are an identified individual's cancer cells, that accompanying statement is protected health information about that individual. Similarly, if a person provides a bullet to law enforcement, and tells law enforcement that the bullet was extracted from an identified ***82534** individual, the person has disclosed the fact that the individual was treated for a wound, and the additional statement is a disclosure of protected health information.

To be able to make the additional statement accompanying the provision of the bullet, a covered entity must look to the rule to find a provision under which a disclosure may be made to law enforcement. Section 164.512(f) of the rule addresses disclosures for law enforcement purposes. Under § 164.512(f)(1), the additional statement may be disclosed to a law enforcement official if required by law or with appropriate process. Under § 164.512(f)(2), we permit covered entities to disclose limited identifying information without legal process in response to a request from a law enforcement official for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person. Thus, in the case of bullet described above, the covered entity may, in response to a law enforcement request, provide the extracted bullet and such additional limited identifying information as is permitted under § 164.512(f)(2).

Section 164.512(g)—Uses and Disclosures About Decedents

In the NPRM we proposed to allow covered entities to disclose protected health information without individual authorization to coroners and medical examiners, consistent with applicable law, for identification of a deceased person or to determine cause of death.

In § 164.512(g) of the final rule, we permit covered entities to disclose protected health information to coroners, medical examiners, and funeral directors as part of a new paragraph on disclosures related to death. The final rule retains the NPRM approach regarding disclosure of protected health information to coroners and medical examiners, and it allows the information disclosed to coroners and medical examiners to include identifying information about other persons that may be included in the individual's medical record. Redaction of such names is not required prior to disclosing the individual's record to coroners or medical examiners. Since covered entities may also perform duties of a coroner or medical examiner, where a covered entity is itself a coroner or medical examiner, the final rule permits the covered entity to use protected health information in all cases in which it is permitted to disclose such information for its duties as a coroner or medical examiner.

Section 164.512(g) allows covered entities to disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to a decedent. For example, the rule allows hospitals to disclose to funeral directors the fact that an individual has donated an organ or tissue, because this information has implications for funeral home staff duties associated with embalming. When necessary for funeral directors to carry out their duties, covered entities may disclose protected health information prior to and in reasonable anticipation of the individual's death.

Whereas the NPRM did not address the issue of disclosure of psychotherapy notes without individual authorization to coroners and medical examiners, the final rule allows such disclosures.

The NPRM did not include in proposed § 164.510(e) language stating that where a covered entity was itself a coroner or medical examiner, it could use protected health information for the purposes of engaging in a coroner's or a medical examiner's activities. The final rule includes such language to address situations such as where a public hospital performs medical examiner functions. In such cases, the hospital's on-staff coroners can use protected health information while conducting post-mortem investigations, and other hospital staff can analyze any information associated with these investigations, for example, as part of the process of determining the cause of the individual's death.

Section 164.512(h)—Uses and Disclosures for Cadaveric Donation of Organs, Eyes, or Tissues

In the NPRM we proposed to include the procurement or banking of blood, sperm, organs, or any other tissue for administration to patients in the definition of "health care" (described in proposed § 160.103). The NPRM's proposed approach did not differentiate between situations in which the donor was competent to consent to the donation—for example, when an individual is donating blood, sperm, a kidney, or a liver or lung lobe—and situations in which the donor was deceased, for example, when cadaveric organs and tissues were being donated. We also proposed to allow use and disclosure of protected health information for treatment without consent.

In the final rule, we take a different approach. In § 164.512(h), we permit covered entities to disclose protected health information without individual authorization to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for donation and transplantation. This provision is intended to address situations in which an individual has not previously indicated whether he or she seeks to donate organs, eyes, or tissues (and therefore authorized release of protected health information for this purpose). In such situations, this provision is intended to allow covered entities to initiate contact with organ and tissue donation and transplantation organizations to facilitate transplantation of cadaveric organs, eyes, and tissues.

Disclosures and Uses for Government Health Data Systems

In the NPRM we proposed to permit covered entities to disclose protected health information to a government agency, or to a private entity acting on behalf of a government agency, for inclusion in a government health data system collecting health data for analysis in support of policy, planning, regulatory, or management functions authorized by law. The NPRM stated that when a covered entity was itself a government agency collecting health data for these functions, it could use protected health information in all cases for which it was permitted to disclose such information to government health data systems.

In the final rule, we eliminate the provision that would have allowed covered entities to disclose protected health information to government health data systems without authorization. Thus, under the final rule, covered entities cannot disclose protected health information without authorization to government health data systems—or to private health data systems—unless the disclosure is permissible under another provision of the rule.

Disclosures for Payment Processes

In the NPRM we proposed to permit covered entities to disclose, in connection with routine banking activities or payment by debit, credit, or other payment card, or other payment means, the minimum amount of protected health information necessary to complete a banking or payment activity to financial institutions or to entities acting on behalf of financial institutions to authorize, process, clear, settle, bill, transfer, reconcile, or collect payments for financial institutions.

The preamble to the NPRM clarified the proposed rule's intent regarding disclosure of diagnostic and treatment information along with payment ***82535** information to financial institutions. The preamble to the proposed rule said that diagnostic and

treatment information never was necessary to process a payment transaction. The preamble said we believed that in most cases, the permitted disclosure would include only: (1) The name and address of the account holder; (2) the name and address of the payor or provider; (3) the amount of the charge for health services; (4) the date on which health services were rendered; (5) the expiration date for the payment mechanism, if applicable; and (6) the individual's signature. The preamble noted that the proposed regulation text did not include an exclusive list of information that could lawfully be disclosed to process payments, and it solicited comments on whether more elements would be needed for banking and payment transactions and on whether including a specific list of protected health information that could be disclosed was an appropriate approach.

The preamble also noted that under section 1179 of HIPAA, certain activities of financial institutions were exempt from this rule, to the extent that these activities constituted authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments for health care or health plan premiums.

In the final rule, we eliminate the NPRM's provision on “banking and payment processes.” All disclosures that would have been allowed pursuant to proposed § 164.510(i) are allowed under § 164.502(a) of the final rule, regarding disclosure for payment purposes.

Section 164.512(i)—Uses and Disclosures for Research Purposes

The NPRM would have permitted covered entities to use and disclose protected health information for research—regardless of funding source—without individual authorization, provided that the covered entity obtained documentation of the following:

(1) A waiver, in whole or in part, of authorization for the use or disclosure of protected health information was approved by an Institutional Review Board (IRB) or a privacy board that was composed as stipulated in the proposed rule;

(2) The date of approval of the waiver, in whole or in part, of authorization by an IRB or privacy board;

(3) The IRB or privacy board had determined that the waiver, in whole or in part satisfied the following criteria:

(i) The use or disclosure of protected health information involves no more than minimal risk to the subjects;

(ii) The waiver will not adversely affect the rights and welfare of the subjects;

(iii) The research could not practicably be conducted without the waiver;

(iv) Whenever appropriate, the subjects will be provided with additional pertinent information after participation;

(v) The research could not practicably be conducted without access to and use of the protected health information;

(vi) The research is of sufficient importance so as to outweigh the intrusion of the privacy of the individual whose information is subject to the disclosure;

(vii) There is an adequate plan to protect the identifiers from improper use and disclosure; and

(viii) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers; and

(4) The written documentation was signed by the chair of, as applicable, the IRB or the privacy board.

The NPRM also proposed that IRBs and privacy boards be permitted to adopt procedures for "expedited review" similar to those provided in the Common Rule (Common Rule §__.110) for records research that involved no more than minimal risk. However, this provision for expedited review was not included in the proposed regulation text.

The board that would determine whether the research protocol met the eight specified criteria for waiving the patient authorization requirements (described above), could have been an IRB constituted as required by the Common Rule, or a privacy board, whose proposed composition is described below. The NPRM proposed no requirements for the location or sponsorship of the IRB or privacy board. Under the NPRM, the covered entity could have created such a board and could have relied on it to review research proposals for uses and disclosures of protected health information for research. A covered entity also could have relied on the necessary documentation from an outside researcher's own university IRB or privacy board. In addition, a covered entity could have engaged the services of an outside IRB or privacy board to obtain the necessary documentation.

Absent documentation that the requirements described above had been met, the NPRM would have required individuals' authorization for the use or disclosure of protected health information for research, pursuant to the authorization requirements in proposed § 164.508. For research conducted with patient authorization, documentation of IRB or privacy board approval would not have been required.

The final rule retains the NPRM's proposed framework for permitting uses and disclosures of protected health information for research purposes, although we are making several important changes for the final rule. These changes are discussed below:

Documentation Requirements of IRB or Privacy Board Approval of Waiver

The final rule retains these documentation requirements, but modifies some of them and includes two additional documentation requirements. The final rule's modifications to the NPRM's proposed documentation requirements are described first, followed by a description of the three documentation requirements added in the final rule.

The final rule makes the following modifications to the NPRM's proposed documentation requirements for the waiver of individual authorization:

1. IRB and privacy board membership. The NPRM stipulated that to meet the requirements of proposed § 164.510(j), the documentation would need to indicate that the IRB had been composed as required by the Common Rule (§__. 107), and the privacy board had been composed as follows: "(A) Has members with varying backgrounds and appropriate professional competency as necessary to review the research protocol; (B) Includes at least one member who is not affiliated with the entity conducting the research, or related to a person who is affiliated with such entity; and (C) Does not have any member participating in a review of any project in which the member has a conflict of interest" (§ 164.510(j)(1)(ii)).

The final rule modifies the first of the requirements for the composition of a privacy board to focus on the effect of the research protocol on the individual's privacy rights and related interests. Therefore, under the final rule, the required documentation must indicate that the privacy board has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests.

In addition, the final rule further restricts the NPRM's proposed requirement that the privacy board include at least one member who was ***82536** not affiliated with the entity conducting the research, or related to a person who is affiliated with such entity. Under the final rule, the board must include at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with such entities.

The other documentation requirements for the composition of an IRB and privacy board remain the same.

2. Waiver of authorization criteria. The NPRM proposed to prohibit the use or disclosure of protected health information for research without individual authorization as stipulated in proposed § 164.508 unless the covered entity had documentation indicating that an IRB or privacy board had determined that the following waiver criteria had been met:

(i) The use or disclosure of protected health information involves no more than minimal risk to the subjects;

(ii) The waiver will not adversely affect the rights and welfare of the subjects;

(iii) The research could not practicably be conducted without the waiver;

(iv) Whenever appropriate, the subjects will be provided with additional pertinent information after participation;

(v) The research could not be practicably be conducted without access to and use of the protected health information;

(vi) The research is of sufficient importance so as to outweigh the intrusion of the privacy of the individual whose information is subject to the disclosure;

(vii) There is an adequate plan to protect the identifiers from improper use and disclosure; and

(viii) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers.

The final rule continues to permit the documentation of IRB or privacy board approval of a waiver of an authorization as required by § 164.508, to indicate that only some or all of the § 164.508 authorization requirements have been waived. In addition, the final rule clarifies that the documentation of IRB or privacy board approval may indicate that the authorization requirements have been altered. Also, for all of the proposed waiver of authorization criteria that used the term "subject," we replace this term with the term "individual" in the final rule.

In addition, the final rule (1) eliminates proposed waiver criterion iv, (2) modifies proposed waiver criteria ii, iii, vi, and viii, and (3) adds a waiver criterion.

Proposed waiver criterion ii (waiver criterion § 164.512(i)(2)(ii)(B) in the final rule) is revised as follows to focus more narrowly on the privacy interests of individuals, and to clarify that it also pertains to alterations of individual authorization: "the alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals." Under criterion § 164.512(i)(2)(ii)(B), the question is whether the alteration or waiver of individual authorization would adversely affect the privacy rights and the welfare of individuals, not whether the research project itself would adversely affect the privacy rights or the welfare of individuals.

Proposed waiver criterion iii (waiver criterion § 164.512(i)(2)(ii)(C) in the final rule) is revised as follows to clarify that it also pertains to alterations of individual authorization: "the research could not practicably be conducted without the alteration or waiver."

Proposed waiver criterion vi (waiver criterion § 164.512(i)(2)(ii)(E) in the final rule) is revised as follows to be more consistent with one of the Common Rule's requirements for the approval of human subjects research (Common Rule, §__.111(a)(2)): "the privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to anticipated benefits if any to individuals, and the importance of the knowledge that may reasonably be expected to result from the research." Under criterion § 164.512(i)(2)(ii)(E), the question is whether the risks to an individual's privacy from participating in the research are reasonable in relation to the anticipated benefits from the research. This criterion is unlike waiver criterion

§ 164.512(i)(2)(ii)(B) in that it focuses on the privacy risks and benefits of the research project more broadly, not on the waiver of individual authorization.

Proposed waiver criterion viii (waiver criterion § 164.512(i)(2)(ii)(G) in the final rule) is revised as follows: "there is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law."

In addition, the final rule includes another waiver criterion: waiver criterion § 164.512(i)(2)(ii)(H). The NPRM proposed no restriction on a researcher's further use or disclosure of protected health information that had been received under proposed § 164.510(j). The final rule requires that the covered entity obtain written agreement from the person or entity receiving protected health information under § 164.512(i) not to re-use or disclose protected health information to any other person or entity, except: (1) As required by law, (2) for authorized oversight of the research project, or (3) for other research for which the use or disclosure of protected health information would be permitted by this subpart. For instance, in assessing whether this criterion has been met, we encourage IRBs and privacy boards to obtain adequate assurances that the protected health information will not be disclosed to an individual's employer for employment decisions without the individual's authorization.

3. Required signature. The rule broadens the types of individuals who are permitted to sign the required documentation of IRB or privacy board approval. The final rule requires the documentation of the alteration or waiver of authorization to be signed by (1) the chair of, as applicable, the IRB or the privacy board, or (2) a member of the IRB or privacy board, as applicable, who is designated by the chair to sign the documentation.

Furthermore, the final rule makes the following three additions to the proposed documentation requirements for the alteration or waiver of authorization:

1. Identification of the IRB or privacy board. The NPRM did not propose that the documentation of waiver include a statement identifying the IRB or privacy board that approved the waiver of authorization. In the final rule we require that such a statement be included in the documentation of alteration or waiver of individual authorization. By this requirement we mean that the name of the IRB or privacy board must be included in such documentation, not the names of individual members of the board.

2. Description of protected health information approved for use or disclosure. The NPRM did not propose that the documentation of waiver include a description of the protected health information that the IRB or privacy board had approved for use or disclosure without individual authorization. In considering waiver of authorization criterion § 164.512(i)(2)(ii)(D), we expect the IRB or privacy board to consider the amount of information that is minimally needed for the study. The final rule requires that the documentation of IRB or ***82537** privacy board approval of the alteration or waiver of authorization describe the protected health information for which use or access has been determined to be necessary for the research by the IRB or privacy board. For example, if the IRB or privacy board approves only the use or disclosure of certain information from patients' medical records, and not patients' entire medical record, this must be stated on the document certifying IRB or privacy board approval.

3. Review and approval procedures. The NPRM would not have required documentation of IRBs' or privacy boards' review and approval procedures. In the final rule, the documentation of the alteration or waiver of authorization must state that the alteration or waiver has been reviewed and approved by: (1) an IRB that has followed the voting requirements stipulated in the Common Rule (§__.108(b)), or the expedited review procedures as stipulated in §__.110(b); or (2) a privacy board that has reviewed the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any such entities, and the alteration or waiver of authorization is approved by the majority of privacy board members present at the meeting, unless an expedited review procedure is used.

For documentation of IRB approval that used an expedited review procedure, the covered entity must ensure that the documentation indicates that the IRB followed the expedited review requirements of the Common Rule (§__.110). For

documentation of privacy board approval that used an expedited review procedure, the covered entity must ensure that the documentation indicates that the privacy board met the expedited review requirements of the privacy rule. In the final rule, a privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which disclosure is being sought. If a privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair. Use of the expedited review mechanism permits review by a single member of the IRB or privacy board, but continues to require that the covered entity obtain documentation that all of the specified waiver criteria have been met.

Reviews Preparatory to Research

Under the NPRM, if a covered entity used or disclosed protected health information for research, but the researcher did not record the protected health information in a manner that persons could be identified, such an activity would have constituted a research use or disclosure that would have been subject to either the individual authorization requirements of proposed § 164.508 or the documentation of the waiver of authorization requirements of proposed § 164.510(j).

The final rule permits the use and disclosure of protected health information for research without requiring authorization or documentation of the alteration or waiver of authorization, if the research is conducted in such a manner that only de-identified protected health information is recorded by the researchers and the protected health information is not removed from the premises of the covered entity. For such uses and disclosures of protected health information, the final rule requires that the covered entity obtain from the researcher representations that use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research, no protected health information is to be removed from the covered entity by the researcher in the course of the review, and the protected health information for which use or access is sought is necessary for the research purposes. The intent of this provision is to permit covered entities to use and disclose protected health information to assist in the development of a research hypothesis and aid in the recruitment of research participants. We understand that researchers sometimes require access to protected health information to develop a research protocol, and to determine whether a specific covered entity has protected health information of prospective research participants that would meet the eligibility criteria for enrollment into a research study. Therefore, this provision permits covered entities to use and disclose protected health information for these preliminary research activities without individual authorization and without documentation that an IRB or privacy board has altered or waived individual authorization.

Research on Protected Health Information of the Deceased

The NPRM would have permitted the use and disclosure of protected health information of deceased persons for research without the authorization of a legal representative, and without the requirement for written documentation of IRB or privacy board approval in proposed § 164.510(j). In the final rule, we retain the exception for uses and disclosures for research purposes but in addition require that the covered entity take certain protective measures prior to release of the decedent's protected health information for such purposes. Specifically, the final rule requires that the covered entity obtain representation that the use or disclosure is sought solely for research on the protected health information of decedent, and representation that the protected health information for which use or disclosure is sought is necessary for the research purposes. In addition, the final rule allows covered entities to request from the researcher documentation of the death of the individuals about whom protected health information is being sought.

Good Faith Reliance

The final rule clarifies that covered entities are allowed to rely on the IRB's or privacy board's representation that the research proposal meets the documentation requirements of § 164.512(i)(1)(i) and the minimum necessary requirements of § 164.514.

In addition, when using or disclosing protected health information for reviews preparatory to research (§ 164.512(i)(1)(ii)) or for research solely on the protected health information of decedents (§ 164.512)(1)(iii)), the final rule clarifies that the covered entity may rely on the requesting researcher's representation that the purpose of the request is for one of these two purpose, and that the request meets the minimum necessary requirements of § 164.514. Therefore, the covered entity has not violated the rule if the requesting researcher misrepresents his or her intended use of the protected health information to the covered entity.

Additional Research Provisions

Research Including Treatment

To the extent that a researcher provided treatment to persons as part of a research study, the NPRM would have covered such researchers as health care providers for purposes of that treatment, and required that the researcher comply with all of the provisions of the rule that ***82538** would be applicable to health care providers. The final rule retains this requirement.

Individual Access to Research Information

Under proposed § 164.514, the NPRM would have applied the proposed provision regarding individuals' access to records to research that includes the delivery of treatment. The NPRM proposed an exception to individuals' right to access protected health information for clinical trials, where (1) protected health information was obtained by a covered entity in the course of clinical trial, (2) the individual agreed to the denial of access when consenting to participate in the trial (if the individual's consent to participate was obtained), and (3) the trial was still in progress.

Section 164.524 of the final rule retains this exception to access for research that includes treatment. In addition, the final rule requires that participants in such research be informed that their right of access to protected health information about them will be reinstated once the research is complete.

Obtaining the Individual's Authorization for Research

The NPRM would have required covered entities obtaining individuals' authorization for the use or disclosure of information for research to comply with the requirements applicable to individual authorization for the release of protected health information (proposed § 164.508(a)(2)). If an individual had initiated the use or disclosure of his/her protected health information for research, or any other purpose, the covered entity would have been required to obtain a completed authorization for the use or disclosure of protected health information as proposed in § 164.508(c).

The final rule retains these requirements for research conducted with authorization, as required by § 164.508. In addition, for the use and disclosure of protected health information created by a covered entity for the purpose, in whole or in part, of research that includes treatment of the individual, the covered entity must meet the requirements of § 164.508(f).

Interaction with the Common Rule

The NPRM stated that the proposed rule would not override the Common Rule. Where both the NPRM and the Common Rule would have applied to research conducted by the covered entity—either with or without individuals' authorization—both sets of regulations would have needed to be followed. This statement remains true in the final rule. In addition, we clarify that FDA's human subjects regulations must also be followed if applicable.

Section 164.512(j)—Uses and Disclosures to Avert a Serious Threat to Health or Safety

In the NPRM we proposed to allow covered entities to use or disclose protected health information without individual authorization—consistent with applicable law and ethics standards—based on a reasonable belief that use or disclosure of the protected health information was necessary to prevent or lessen a serious and imminent threat to health or safety of an individual or of the public. Pursuant to the NPRM, covered entities could have used or disclosed protected health information in these

emergency circumstances to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat. The NPRM stated that covered entities that made disclosures in these circumstances were presumed to have acted under a reasonable belief if the disclosure was made in good faith, based on credible representation by a person with apparent knowledge or authority. The NPRM did not include verification requirements specific to this paragraph.

In § 164.512(j) of the final rule, we retain the NPRM's approach to uses and disclosures made to prevent or lessen serious and imminent threats to health or safety, as well as its language regarding the presumption of good faith. We also clarify that: (1) Rules governing these situations, which the NPRM referred to as "emergency circumstances," are not intended to apply to emergency care treatment, such as health care delivery in a hospital emergency room; and (2) the "presumption of good faith belief" is intended to apply only to this provision and not to all disclosures permitted without individual authorization. The final rule allows covered entities to use or disclose protected health information without an authorization on their own initiative in these circumstances, when necessary to prevent or lessen a serious and imminent threat, consistent with other applicable ethical or legal standards.

The rule's approach is consistent with the "duty to warn" third persons at risk, which has been established through case law. In Tarasoff v. Regents of the University of California (17 Cal. 3d 425 (1976)), the Supreme Court of California found that when a therapist's patient had made credible threats against the physical safety of a specific person, the therapist had an obligation to use reasonable care to protect the intended victim of his patient against danger, including warning the victim of the danger. Many states have adopted, through either statutory or case law, versions of the Tarasoff duty to warn. The rule is not intended to create a duty to warn or disclose. Rather, it permits disclosure to avert a serious and imminent threat to health or safety consistent with other applicable legal or ethical standards. If disclosure in these circumstances is prohibited by state law, this rule would not allow the disclosure.

As indicated above, in some situations (for example, when a person is both a fugitive and a victim and thus covered entities could disclose protected health information pursuant either to § 164.512(f)(2) regarding fugitives or to § 164.512(f)(3) establishing conditions for disclosure about victims), more than one section of this rule potentially could apply with respect to a covered entity's potential disclosure of protected health information. Similarly, in situations involving a serious and imminent threat to public health or safety, law enforcement officials may be seeking protected health information from covered entities to locate a fugitive. In the final rule, we clarify that if a situation fits one section of the rule (for example, § 164.512(j) on serious and imminent threats to health or safety), covered entities may disclose protected health information pursuant to that section, regardless of whether the disclosure also could be made pursuant to another section (e.g., § 164.512(f)), regarding disclosure to law enforcement officials).

The proposed rule did not address situations in which covered entities could make disclosures to law enforcement officials about oral statements admitting participation in violent conduct or about escapees.

In the final rule we permit, but do not require, covered entities to use or disclose protected health information, consistent with applicable law and standards of ethical conduct, in specific situations in which the covered entity, in good faith, believes the use or disclosure is necessary to permit law enforcement authorities to identify or apprehend an individual. Under paragraph (j)(1)(ii)(A) of this section, a covered entity may take such action because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have resulted in serious physical harm to the victim. The ***82539** protected health information that is disclosed in this case is limited to the statement and to the protected health information included under the limited identifying and location information in § 164.512(f)(2), such as name, address, and type of injury. Under paragraph (j)(1)(ii)(B) of this section, a covered entity may take such action where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody.

A disclosure may not be made under paragraph (j)(1)(ii)(A) for a statement admitting participation in a violent crime if the covered entity learns the information in the course of counseling or therapy. Similarly, such a disclosure is not permitted if the covered entity learns the information in the course of treatment to affect the propensity to commit the violent crimes that are

described in the individual's statements. We do not intend to discourage individuals from speaking accurately in the course of counseling or therapy sessions, or to discourage other treatment that specifically seeks to reduce the likelihood that someone who has acted violently in the past will do so again in the future. This prohibition on disclosure is triggered once an individual has made a request to initiate or be referred to such treatment, therapy, or counseling.

The provision permitting use and disclosure has been added in light of the broadened definition in the final rule of protected health information. Under the NPRM, protected health information meant individually identifiable health information that is or has been electronically transmitted or electronically maintained by a covered entity. Under the final rule, protected health information includes information transmitted by electronic media as well as such information transmitted or maintained in any other form or medium. The new definition includes oral statements to covered entities as well as individually identifiable health information transmitted "in any other form."

The definition of protected health information, for instance, would now apply to a statement by a patient that is overheard by a hospital security guard in a waiting room. Such a statement would have been outside the scope of the proposed rule (unless it was memorialized in an electronic record), but is within the scope of the final rule. For the example with the hospital guard, the new provision permitting disclosure of a statement by an individual admitting participation in a violent crime would have the same effect as the proposed rule—the statement could be disclosed to law enforcement, so long as the other aspects of the regulation are followed. Similarly, where it appears from all the circumstances that the individual has escaped from prison, the expanded definition of protected health information should not prevent the covered entity from deciding to report this information to law enforcement.

The disclosures that covered entities may elect to make under this paragraph are entirely at their discretion. These disclosures to law enforcement are in addition to other disclosure provisions in the rule. For example, under paragraph § 164.512(f)(2) of this section, a covered entity may disclose limited categories of protected health information in response to a request from a law enforcement official for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person. Paragraph § 164.512(f)(1) of this section permits a covered entity to make disclosures that are required by other laws, such as state mandatory reporting laws, or are required by legal process such as court orders or grand jury subpoena.

Section 164.512(k)—Uses and Disclosures for Specialized Government Functions

Application to Military Services

In the NPRM we would have permitted a covered entity providing health care to Armed Forces personnel to use and disclose protected health information for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, where the appropriate military authority had published by notice in the Federal Register (In the NPRM, we proposed that the Department of Defense would publish this Federal Register notice in the future.) The final rule takes a similar approach while making some modifications to the NPRM. One modification concerns the information that will be required in the Federal Register notice. The NPRM would have required a listing of (i) appropriate military command authorities; (ii) the circumstances for which use or disclosure without individual authorization would be required; and (iii) activities for which such use or disclosure would occur in order to assure proper execution of the military mission. In the final rule, we eliminate the third category and also slightly modify language in the second category to read: "the purposes for which the protected health information may be used or disclosed."

An additional modification concerns the rule's application to foreign military and diplomatic personnel. The NPRM would have excluded foreign diplomatic and military personnel, as well as their dependents, from the proposed definition of "individual," thereby excluding any protected health information created about these personnel from the NPRM's privacy protections. Foreign military and diplomatic personnel affected by this provision include, for example, allied military personnel who are in the United States for training. The final rule applies a more limited exemption to foreign military personnel only (Foreign diplomatic personnel will have the same protections granted to all other individuals under the rule). Under the final rule, foreign military personnel are not excluded from the definition of "individual." Covered entities will be able to use and disclose protected

health information of foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for U.S. Armed Forces personnel under the notice to be published in the Federal Register. Foreign military personnel do have the same rights of access, notice, right to request privacy protection, copying, amendment, and accounting as do other individuals pursuant to §§ 164.520-164.526 (sections on access, notice, right to request privacy protection for protected health information, amendment, inspection, copying) of the rule.

The NPRM likewise would have exempted overseas foreign national beneficiaries from the proposed rule's requirements by excluding them from the definition of "individual." Under the final rule, these beneficiaries no longer are exempt from the definition of "individual." However, the rule's provisions do not apply to the individually identifiable health information of overseas foreign nationals who receive care provided by the Department of Defense, other federal agencies, or by non-governmental organizations incident to U.S. sponsored missions or operations.

The final rule includes a new provision to address separation or discharge from military service. The preamble to the NPRM noted that upon completion of individuals' military service, DOD and the Department of Transportation routinely transfer entire military service records, including protected health information to the Department of Veterans Affairs so that ***82540** the file can be retrieved quickly if the individuals or their dependents apply for veterans benefits. The NPRM would have required consent for such transfers. The final rule no longer requires consent in such situations. Thus, under the final rule, a covered entity that is a component of DOD or the Department of Transportation may disclose to DVA the protected health information of an Armed Forces member upon separation or discharge from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

Department of Veterans Affairs

Under the NPRM, a covered entity that is a component of the Department of Veterans Affairs could have used and disclosed protected health information to other components of the Department that determine eligibility for, or entitlement to, or that provide benefits under the laws administered by the Secretary of Veterans Affairs. In the final rule, we retain this approach.

Application to Intelligence Community

The NPRM would have provided an exemption from its proposed requirements to the intelligence community. As defined in section 4 of the National Security Act, 50 U.S.C. 401a, the intelligence community includes: the Office of the Director of Central Intelligence Agency; the Office of the Deputy Director of Central Intelligence; the National Intelligence Council and other such offices as the Director may designate; the Central Intelligence Agency; the National Security Agency; the Defense Intelligence Agency; the National Imagery and Mapping Agency ; the National Reconnaissance Office; other offices within the DOD for the collection of specialized national intelligence through reconnaissance programs; the intelligence elements of the Army, the Navy, the Air Force, the Marine Corps, the Federal Bureau of Investigation, the Department of the Treasury, and the Department of Energy; the Bureau of Intelligence and Research of the Department of State; and such other elements of any other department or agency as may be designated by the President, or designated jointly by the Director of Central Intelligence and the head of the department or agency concerned, as an element of the intelligence community. It would have allowed a covered entity to use without individual authorization protected health information of employees of the intelligence community, and of their dependents, if such dependents were being considered for posting abroad. The final rule does not include such an exemption. Rather, the final rule does not except intelligence community employees and their dependents from the general rule requiring an authorization in order for protected health information to be used and disclosed.

National Security and Intelligence Activities

The NPRM included a provision, in § 164.510(f)—Disclosure for Law Enforcement Purposes—that would allow covered entities to disclose protected health information without consent for the conduct of lawful intelligence activities under the National Security Act, and in connection with providing protective services to the President or to foreign heads of state pursuant to 18 U.S.C. 3056 and 22 U.S.C. 2709(a)(3) respectively. The final rule preserves these exemptions, with slight modifications,

but moves them from proposed § 164.510(f) to § 164.512(k). It also divides this area into two paragraphs—one called "National Security and Intelligence Activities" and the second called "Protective services for the President and Others."

The final rule, with modifications, allows a covered entity to disclose protected health information to an authorized federal official for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act and implementing authority (e.g., Executive Order 1233). The references to "counter-intelligence and other national security activities" are new to the final rule. The reference to "implementing authority (e.g. Executive Order 12333)" is also new. The final rule also adds specificity to the provision on protective services. It states that a covered entity may disclose protected health information to authorized federal officials for the provision of protective services to the President or other persons as authorized by 18 U.S.C. 3056, or to foreign heads of state or other persons as authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

Application to the State Department

The final rule creates a narrower exemption for Department of State for uses and disclosures of protected health information (1) for purposes of a required security clearance conducted pursuant to Executive Orders 10450 and 12698; (2) as necessary to meet the requirements of determining worldwide availability or availability for mandatory service abroad under Sections 101(a)(4) and 504 of the Foreign Service Act; and (3) for a family member to accompany a Foreign Service Officer abroad, consistent with Section 101(b)(5) and 904 of the Foreign Service Act.

Regarding security clearances, nothing prevents any employer from requiring that individuals provide authorization for the purpose of obtaining a security clearance. For the Department of State, however, the final rule provides a limited exemption that allows a component of the Department of State without an authorization to (1) use protected health information to make medical suitability determinations and (2) to disclose whether or not the individual was determined to be medically suitable to authorized officials in the Department of State for the purpose of a security clearance investigation conducted pursuant to Executive Order 10450 and 12698.

Sections 101(a)(4) and 504 of the Foreign Service Act require that Foreign Service members be available to serve in assignments throughout the world. The final rule permits disclosures to officials who need protected health information to determine availability for duty worldwide.

Section 101(b)(5) of the Foreign Service Act requires the Department of State to mitigate the impact of hardships, disruptions, and other unusual conditions on families of Foreign Service Officers. Section 904 requires the Department to establish a health care program to promote and maintain the physical and mental health of Foreign Service member family members. The final rule permits disclosure of protected health information to officials who need protected health information for a family member to accompany a Foreign Service member abroad.

This exemption does not permit the disclosure of specific medical conditions, diagnoses, or other specific medical information. It permits only the disclosure of the limited information needed to determine whether the individual should be granted a security clearance or whether the Foreign Service member of his or her family members should be posted to a certain overseas assignment.

Application to Correctional Facilities

The NPRM would have excluded the individually identifiable health information of correctional facility inmates and detention facility detainees from the definition of protected health information. Thus, none of the NPRM's ***82541** proposed privacy protections would have applied to correctional facility inmates or to detention facility detainees while they were in these facilities or after they had been released.

The final rule takes a different approach. First, to clarify that we are referring to individuals who are incarcerated in correctional facilities that are part of the criminal justice system or in the lawful custody of a law enforcement official—and not to individuals who are "detained" for non-criminal reasons, for example, in psychiatric institutions—§ 164.512(k) covers disclosure of protected health information to correctional institutions or law enforcement officials having such lawful custody. In addition, where a covered health care provider is also a health care component of a correctional institution, the final rule permits the covered entity to use protected health information in all cases in which it is permitted to disclose such information.

We define correctional institution as defined pursuant to 42 U.S.C. 13725(b)(1), as a "prison, jail, reformatory, work farm, detention center, or halfway house, or any other similar institution designed for the confinement or rehabilitation of criminal offenders." The rules regarding disclosure and use of protected health information specified in § 164.512(k) cover individuals who are in transitional homes, and other facilities in which they are required by law to remain for correctional reasons and from which they are not allowed to leave. This section also covers individuals who are confined to psychiatric institutions for correctional reasons and who are not allowed to leave; however, it does not apply to disclosure of information about individuals in psychiatric institutions for treatment purposes only, who are not there due to a crime or under a mandate from the criminal justice system. The disclosure rules described in this section do not cover release of protected health information about individuals in pretrial release, probation, or on parole, such persons are not considered to be incarcerated in a correctional facility.

As described in § 164.512(k), correctional facility inmates' individually identifiable health information is not excluded from the definition of protected health information. When individuals are released from correctional facilities, they will have the same privacy rights that apply to all other individuals under this rule.

Section 164.512(k) of the final rule states that while individuals are in a correctional facility or in the lawful custody of a law enforcement official, covered entities (for example, the prison's clinic) can use or disclose protected health information about these individuals without authorization to the correctional facility or the law enforcement official having custody as necessary for: (1) The provision of health care to such individuals; (2) the health and safety of such individual or other inmates; (3) the health and safety of the officers of employees of or others at the correctional institution; and (4) the health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution or facility to another; (5) law enforcement on the premises of the correctional institution; and (6) the administration and maintenance of the safety, security, and good order of the correctional institution. This section is intended to allow, for example, a prison's doctor to disclose to a van driver transporting a criminal that the individual is a diabetic and frequently has seizures, as well as information about the appropriate action to take if the individual has a seizure while he or she is being transported.

We permit covered entities to disclose protected health information about these individuals if the correctional institution or law enforcement official represents that the protected health information is necessary for these purposes. Under 164.514(h), a covered entity may reasonably rely on the representation of such public officials.

Application to Public Benefits Programs Required to Share Eligibility Information

We create a new provision for covered entities that are a government program providing public benefits. This provision allows the following disclosures of protected health information.

First, where other law requires or expressly authorizes information relating to the eligibility for, or enrollment in more than one public program to be shared among such public programs and/or maintained in a single or combined data system, a public agency that is administering a health plan may maintain such a data base and may disclose information relating to such eligibility or enrollment in the health plan to the extent authorized by such other law.

Where another public entity has determined that the appropriate balance between the need for efficient administration of public programs and public funds and individuals' privacy interests is to allow information sharing for these limited purposes, we do not upset that determination. For example, section 1137 of the Social Security Act requires a variety of public programs, including the Social Security program, state medicaid programs, the food stamp program, certain unemployment compensation programs,

and others, to participate in a joint income and eligibility verification system. Similarly, section 222 of the Social Security Act requires the Social Security Administration to provide information to certain state vocational rehabilitation programs for eligibility purposes. In some instances, it is a covered entity that first collects or creates the information that is then disclosed for these systems. We do not prohibit those disclosures.

This does not authorize these entities to share information for claims determinations or ongoing administration of these public programs. This provision is limited to the agencies and activities described above.

Second, § 164.512(k)(6) permits a covered entity that is a government agency administering a government program providing public benefits to disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs.

The second provision permits covered entities that are government program providing public benefits that serve the same or similar populations to share protected health information for the purposes of coordinating covered functions of the programs and for general management and administration relating to the covered functions of the programs. Often, similar government health programs are administered by different government agencies. For example, in some states, the Medicaid program and the State Children's Health Insurance Program are administered by different agencies, although they serve similar populations. Many states coordinate eligibility for these two programs, and sometimes offer services through the same delivery systems and contracts. This provision would permit the covered entities administering these programs to share protected health information of program participants to coordinate enrollment and services and to generally improve the health care operations of the programs. We note that this provision does not authorize the ***82542** agencies to use or disclose the protected health information that is shared for purposes other than as provided for in this paragraph.

Section 164.512(l)—Disclosures For Workers' Compensation

The NPRM did not contain special provisions permitting covered entities to disclose protected health information for the purpose of complying with workers' compensation and similar laws. Under HIPAA, workers' compensation and certain other forms of insurance (such as automobile or disability insurance) are “excepted benefits.” Insurance carriers that provide this coverage are not covered entities even though they provide coverage for health care services. To carry out their insurance functions, these non-covered insurers typically seek individually identifiable health information from covered health care providers and group health plans. In drafting the proposed rule, the Secretary was faced with the challenge of trying to carry out the statutory mandate of safeguarding the privacy of individually identifiable health information by regulating the flow of such information from covered entities while at the same time respecting the Congressional intent to shield workers' compensation carriers and other excepted benefit plans from regulation as covered entities.

In the proposed rule we allowed covered entities to disclose protected health information without individual consent for purposes of treatment, payment or health care operations—even when the disclosure was to a non-covered entity such as a workers' compensation carrier. In addition, we allowed protected health information to be disclosed if required by state law for purposes of determining eligibility for coverage or fitness for duty. The proposed rule also required that whenever a covered entity disclosed protected health information to a non-covered entity, even though authorized under the rule, the individual who was the subject of the information must be informed that the protected health information was no longer subject to privacy protections.

Like other disclosures under the proposed rule, the information provided to workers' compensation carriers for treatment, payment or health care operations was subject to the minimum necessary standard. However, to the extent that protected health information was disclosed to the carrier because it was required by law, it was not subject to the minimum necessary standard. In addition, individuals were entitled to an accounting when protected health information was disclosed for purposes other than treatment, payment or health care operations.

In the final rule, we include a new provision in this section that clarifies the ability of covered entities to disclose protected health information without authorization to comply with workers' compensation and similar programs established by law that provide benefits for work-related illnesses or injuries without regard to fault. Although most disclosures for workers' compensation would be permissible under other provisions of this rule, particularly the provisions that permit disclosures for payment and as required by law, we are aware of the significant variability among workers' compensation and similar laws, and include this provision to ensure that existing workers' compensation systems are not disrupted by this rule. We note that the minimum necessary standard applies to disclosures under this paragraph.

Under this provision, a covered entity may disclose protected health information regarding an individual to a party responsible for payment of workers' compensation benefits to the individual, and to an agency responsible for administering and/or adjudicating the individual's claim for workers' compensation benefits. For purposes of this paragraph, workers' compensation benefits include benefits under programs such as the Black Lung Benefits Act, the federal Employees' Compensation Act, the Longshore and Harbor Workers' Compensation Act, and the Energy Employees' Occupational Illness Compensation Program Act.

Additional Considerations

We have included a general authorization for disclosures under workers' compensation systems to be consistent with the intent of Congress, which defined workers' compensation carriers as excepted benefits under HIPAA. We recognize that there are significant privacy issues raised by how individually identifiable health information is used and disclosed in workers' compensation systems, and believe that states or the federal government should enact standards that address those concerns.

Section 164.514—Other Procedural Requirements Relating To Uses and Disclosures of Protected Health Information

Section 164.514(a)-(c)—De-identification

In § 164.506(d) of the NPRM, we proposed that the privacy standards would apply to "individually identifiable health information," and not to information that does not identify the subject individual. The statute defines individually identifiable health information as certain health information:

(i) Which identifies the individual, or

(ii) With respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

As we pointed out in the NPRM, difficulties arise because, even after removing obvious identifiers (e.g., name, social security number, address), there is always some probability or risk that any information about an individual can be attributed to that individual.

The NPRM proposed two alternative methods for determining when sufficient identifying information has been removed from a record to render the information de-identified and thus not subject to the rule. First, the NPRM proposed the establishment of a "safe harbor": if all of a list of 19 specified items of information had been removed, and the covered entity had no reason to believe that the remaining information could be used to identify the subject of the information (alone or in combination with other information), the covered entity would have been presumed to have created de-identified information. Second, the NPRM proposed an alternative method so that covered entities with sufficient statistical experience and expertise could remove or encrypt a combination of information different from the enumerated list, using commonly accepted scientific and statistical standards for disclosure avoidance. Such covered entities would have been able to include information from the enumerated list of 19 items if they (1) believed that the probability of re-identification was very low, and (2) removed additional information if they had a reasonable basis to believe that the resulting information could be used to re-identify someone.

We proposed that covered entities and their business partners be permitted to use protected health information to create de-identified health information using either of these two methods. Covered entities would have been permitted to further use and disclose such de-identified information in any way, provided that they did not disclose the key or other mechanism that would have enabled the information to be re-identified, and provided that they reasonably believed that such use or disclosure of de-identified information would not have resulted in the use or ***82543** disclosure of protected health information.

A number of examples were provided of how valuable such de-identified information would be for various purposes. We expressed the hope that covered entities, their business partners, and others would make greater use of de-identified health information than they do today, when it is sufficient for the purpose, and that such practice would reduce the burden and the confidentiality concerns that result from the use of individually identifiable health information for some of these purposes.

In §§ 164.514(a)-(c) of this final rule, we make several modifications to the provisions for de-identification. First, we explicitly adopt the statutory standard as the basic regulatory standard for whether health information is individually identifiable health information under this rule. Information is not individually identifiable under this rule if it does not identify the individual, or if the covered entity has no reasonable basis to believe it can be used to identify the individual. Second, in the implementation specifications we reformulate the two ways in which a covered entity can demonstrate that it has met the standard.

One way a covered entity may demonstrate that it has met the standard is if a person with appropriate knowledge and experience applying generally accepted statistical and scientific principles and methods for rendering information not individually identifiable makes a determination that the risk is very small that the information could be used, either by itself or in combination with other available information, by anticipated recipients to identify a subject of the information. The covered entity must also document the analysis and results that justify the determination. We provide guidance regarding this standard in our responses to the comments we received on this provision.

We also include an alternate, safe harbor, method by which covered entities can demonstrate compliance with the standard. Under the safe harbor, a covered entity is considered to have met the standard if it has removed all of a list of enumerated identifiers, and if the covered entity has no actual knowledge that the information could be used alone or in combination to identify a subject of the information. We note that in the NPRM, we had proposed that to meet the safe harbor, a covered entity must have “no reason to believe” that the information remained identifiable after the enumerated identifiers were removed. In the final rule, we have changed the standard to one of actual knowledge in order to provide greater certainty to covered entities using the safe harbor approach.

In the safe harbor, we explicitly allow age and some geographic location information to be included in the de-identified information, but all dates directly related to the subject of the information must be removed or limited to the year, and zip codes must be removed or aggregated (in the form of most 3-digit zip codes) to include at least 20,000 people. Extreme ages of 90 and over must be aggregated to a category of 90+ to avoid identification of very old individuals. Other demographic information, such as gender, race, ethnicity, and marital status are not included in the list of identifiers that must be removed.

The intent of the safe harbor is to provide a means to produce some de-identified information that could be used for many purposes with a very small risk of privacy violation. The safe harbor is intended to involve a minimum of burden and convey a maximum of certainty that the rules have been met by interpreting the statutory “reasonable basis to believe that the information can be used to identify the individual” to produce an easily followed, cook book approach.

Covered entities may use codes and similar means of marking records so that they may be linked or later re-identified, if the code does not contain information about the subject of the information (for example, the code may not be a derivative of the individual's social security number), and if the covered entity does not use or disclose the code for any other purpose. The covered entity is also prohibited from disclosing the mechanism for re-identification, such as tables, algorithms, or other tools that could be used to link the code with the subject of the information.

Language to clarify that covered entities may contract with business associates to perform the de-identification has been added to the section on business associates.

Section 164.514(d)—Minimum Necessary

The proposed rule required a covered entity to make all reasonable efforts not to use or disclose more than the minimum amount of protected health information necessary to accomplish the intended purpose of the use or disclosure (proposed § 164.506(b)).

The proposed minimum necessary standard did not apply to uses or disclosures that were made by covered entities at the request of the individual, either to allow the individual access to protected health information about him or her or pursuant to an authorization initiated by the individual. The requirement also did not apply to uses and disclosures made: pursuant to the compliance and enforcement provisions of the rule; as required by law and permitted by the regulation without individual authorization; by a covered health care provider to a health plan, when the information was requested for audit and related purposes. Finally, the standard did not apply to the HIPAA administrative simplification transactions.

The proposed implementation specifications would have required a covered entity to have procedures to: (i) Identify appropriate persons within the entity to determine what information should be used or disclosed consistent with the minimum necessary standard; (ii) ensure that those persons make the minimum necessary determinations, when required; and (iii) within the limits of the entity's technological capabilities, provide for the making of such determinations individually. The proposal allowed a covered entity, when making disclosures to public officials that were permitted without individual authorization but not required by other law, to reasonably rely on the representations of such officials that the information requested was the minimum necessary for the stated purpose(s).

The preamble provided further guidance. The preamble explained that covered entities could not have general policies of approving all requests (or all requests of a particular type) without carefully considering certain criteria (see “Criteria,” below) as well as other information specific to the request. The minimum necessary determination would have needed to be consistent with and directly related to the purpose of the use or disclosure. Where there was ambiguity regarding the information to be used or disclosed, the preamble directed covered entities to interpret the “minimum necessary” standard to “require” the covered entity to make some effort to limit the amount of protected health information used/disclosed.

The proposal would have required the minimum necessary determination to take into consideration the ability of a covered entity to delimit the amount of information used or disclosed. The preamble noted that these determinations would have to be made under a reasonableness standard: covered entities would be required to make reasonable efforts and to incur reasonable expense to limit the use or ***82544** disclosure. The “reasonableness” of limiting particular uses or disclosures was to be determined based on the following factors (which were not included in the regulatory text):

a. The extent to which the use or disclosure would extend the number of persons with access to the protected health information.

b. The likelihood that further uses or disclosures of the protected health information could occur.

c. The amount of protected health information that would be used or disclosed.

d. The importance of the use or disclosure.

e. The potential to achieve substantially the same purpose with de-identified information. For disclosures, each covered entity would have been required to have policies for determining when protected health information must be stripped of identifiers.

f. The technology available to limit the amount of protected health information used/disclosed.

g. The cost of limiting the use/disclosure.

h. Any other factors that the covered entity believed were relevant to the determination.

The proposal shifted the "minimum necessary" burden off of covered providers when they were being audited by a health plan. The preamble explained that the duty would have been shifted to the payor to request the minimum necessary information for the audit purpose, although the regulatory text did not include such a requirement. Outside of the audit context, the preamble stated that a health plan would be required, when requesting a disclosure, to limit its requests to the information required to achieve the purpose of the request; the regulation text did not include this requirement.

The preamble stated that disclosure of an entire medical record, in response to a request for something other than the entire medical record, would presumptively violate the minimum necessary standard.

This final rule significantly modifies the proposed requirements for implementing the minimum necessary standard. For all uses and many disclosures and requests for disclosures from other covered entities, we require covered entities to implement policies and procedures for "minimum necessary" uses and disclosures. Implementation of such policies and procedures is required in lieu of making the "minimum necessary" determination for each separate use or disclosure as discussed in the proposal. Disclosures to or requests by a health care provider for treatment purposes are not subject to the standard (see § 164.502).

Specifically (and as further described below), the proposed requirement for individual review of all uses of protected health information is replaced with a requirement for covered entities to implement policies and procedures that restrict access and uses based on the specific roles of members of the covered entity's workforce. Routine disclosures also are not subject to individual review; instead, covered entities must implement policies and procedures to limit the protected health information in routine disclosures to the minimum necessary to achieve the purpose of that type of disclosure. The proposed exclusion of disclosures to health plans for audit purposes is deleted and replaced with a general requirement that covered entities must limit requests to other covered entities for individually identifiable health information to what is reasonably necessary for the use or disclosure intended. The other exclusions from the standard are unchanged from the proposed rule (e.g., for individuals' access to information about themselves, pursuant to an authorization initiated by the individual, for enforcement of this rule, as required by law).

The language of the basic "standard" itself is largely unchanged; covered entities must make reasonable efforts to use or disclose or to request from another covered entity, only the minimum amount of protected health information required to achieve the purpose of a particular use or disclosure. We delete the word "all" from the "reasonable efforts" that covered entities must take in making a "minimum necessary" determination. The implementation specifications are significantly modified, and differ based on whether the activity is a use or disclosure.

Similarly, a "minimum necessary" disclosure for oversight purposes in accordance with § 164.512(d) could include large numbers of records to allow oversight agencies to perform statistical analyses to identify deviations in payment or billing patterns, and other data analyses.

Uses of Protected Health Information

A covered entity must implement policies and procedures to identify the persons or classes of persons in the entity's workforce who need access to protected health information to carry out their duties, the category or categories of protected health information to which such persons or classes need access, and the conditions, as appropriate, that would apply to such access. Covered entities must also implement policies and procedures to limit access to only the identified persons, and only to the identified protected health information. The policies and procedures must be based on reasonable determinations regarding the persons or classes of persons who require protected health information, and the nature of the health information they require, consistent with their job responsibilities.

For example, a hospital could implement a policy that permitted nurses access to all protected health information of patients in their ward while they are on duty. A health plan could permit its underwriting analysts unrestricted access to aggregate claims information for rate setting purposes, but require documented approval from its department manager to obtain specific identifiable claims records of a member for the purpose of determining the cause of unexpected claims that could influence renewal premium rate setting.

The "minimum necessary" standard is intended to reflect and be consistent with, not override, professional judgment and standards. For example, we expect that covered entities will implement policies that allow persons involved in treatment to have access to the entire record, as needed.

Disclosures of Protected Health Information

For any type of disclosure that is made on a routine, recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that permit only the disclosure of the minimum protected health information reasonably necessary to achieve the purpose of the disclosure. Individual review of each disclosure is not required. Instead, under § 164.514(d)(3), these policies and procedures must identify the types of protected health information to be disclosed, the types of persons who would receive the protected health information, and the conditions that would apply for such access. We recognize that specific disclosures within a type may vary, and require that the policies address what is the norm for the type of disclosure involved. For example, a covered entity may decide to participate in research studies and therefore establish a protocol to minimize the information released for such purposes, e.g., by requiring researchers requesting disclosure of data contained in paper-based records to review the paper records on-site and to ***82545** abstract only the information relevant to the research. Covered entities must develop policies and procedures (which may be standard protocols) to apply to disclosures to routinely hired types of business associates. For instance, a standard protocol could describe the subset of information that may be disclosed to medical transcription services.

For non-routine disclosures, a covered entity must develop reasonable criteria for determining, and limiting disclosure to, only the minimum amount of protected health information necessary to accomplish the purpose of the disclosure. They also must establish and implement procedures for reviewing such requests for disclosures on an individual basis in accordance with these criteria.

Disclosures to health care providers for treatment purposes are not subject to these requirements.

Covered entities' policies and procedures must provide that disclosure of an entire medical record will not be made except pursuant to policies which specifically justify why the entire medical record is needed. For instance, disclosure of all protected health information to an accreditation group would not necessarily violate the regulation, because the entire record may be the "minimum necessary" for its purpose; covered entities may establish policies allowing for and justifying such a disclosure. Disclosure of the entire medical record absent such documented justification is a presumptive violation of this rule.

Requests for Protected Health Information

For requests for protected health information from other covered entities made on a routine, recurring basis, the requesting covered entities' policies and procedures may establish standard protocols describing what information is reasonably necessary for the purposes and limiting their requests to only that information, in lieu of making this determination individually for each request. For all other requests, the policies and procedures must provide for review of the requests on an individualized basis. A request by a covered entity may be made in order to obtain information that will subsequently be disclosed to a third party, for example, to obtain information that will then be disclosed to a business associate for quality assessment purposes; such requests are subject to this requirement.

Covered entities' policies and procedures must provide that requests for an entire medical record will not be made except pursuant to policies which specifically justify why the entire medical record is needed. For instance, a health plan's request for

all protected health information from an applicant for insurance would not necessarily violate the regulation, because the entire record may be the "minimum necessary" for its purpose. Covered entities may establish policies allowing for and justifying such a request. A request for the entire medical record absent such documented justification is a presumptive violation of this rule.

Reasonable Reliance

A covered entity may reasonably rely on the assertion of a requesting covered entity that it is requesting the minimum protected health information necessary for the stated purpose. A covered entity may also rely on the assertions of a professional (such as attorneys and accountants) who is a member of its workforce or its business associate regarding what protected health information he or she needs in order to provide professional services to the covered entity when such person represents that the information requested is the minimum necessary. As we proposed in the NPRM, covered entities making disclosures to public officials that are permitted under § 164.512 may rely on the representation of a public official that the information requested is the minimum necessary.

Uses and Disclosures for Research

In making a minimum necessary determination regarding the use or disclosure of protected health information for research purposes, a covered entity may reasonably rely on documentation from an IRB or privacy board describing the protected health information needed for research and consistent with the requirements of § 164.512(i), "Uses and Disclosures for Research Purposes." A covered entity may also reasonably rely on a representation made by the requestor that the information is necessary to prepare a research protocol or for research on decedents. The covered entity must ensure that the representation or documentation of IRB or privacy board approval it obtains from a researcher describes with sufficient specificity the protected health information necessary for the research. Covered entities must use or disclose such protected health information in a manner that minimizes the scope of the use or disclosure.

Standards for Electronic Transactions

We clarify that under § 164.502(b)(2)(v), covered entities are not required to apply the minimum necessary standard to the required or situational data elements specified in the implementation guides for HIPAA administrative simplification standard transactions in the Transactions Rule. The standard does apply for uses or disclosures in standard transactions that are made at the option of the covered entity.

Section 164.514(e)—Marketing

In the proposed rule, we would have required covered entities to obtain the individual's authorization in order to use or disclose protected health information to market health and non-health items and services.

We have made a number of changes in the final rule that relate to marketing. In the final rule, we retain the general rule that covered entities must obtain the individual's authorization before making uses or disclosures of protected health information for marketing. However, we add a new definition of "marketing" that clarifies that certain activities, such as communications made by a covered entity for the purpose of describing the products and services it provides, are not marketing. See § 164.501 and the associated preamble regarding the definition of marketing. In the final rule we also permit covered entities to use and disclose protected health information for certain marketing activities without individual authorization, subject to conditions enumerated at § 164.514(e).

First, § 164.514(e) permits a covered entity to use or disclose protected health information without individual authorization to make a marketing communication if the communication occurs in a face-to-face encounter with the individual. This provision would permit a covered entity to discuss any services and products, including those of a third-party, without restriction during a face-to-face communication. A covered entity also could give the individual sample products or other information in this setting.

Second, we permit a covered entity to use or disclose protected health information without individual authorization to make marketing communications involving products or services of only nominal value. This provision ensures that covered entities do not violate the rule when they distribute calendars, pens and other merchandise that generally promotes the covered entity.

Third, we permit a covered entity to use or disclose protected health information without individual authorization to make marketing communications about the health- ***82546** related products or services of the covered entity or of a third party if the communication: (1) Identifies the covered entity as the party making the communication; (2) to the extent that the covered entity receives direct or indirect remuneration from a third-party for making the communication, prominently states that fact; (3) except in the case of a general communication (such as a newsletter), contains instructions describing how the individual may opt-out of receiving future communications about health-related products and services; and (4) where protected health information is used to target the communication about a product or service to individuals based on their health status or health condition, explains why the individual has been targeted and how the product or service relates to the health of the individual. The final rule also requires a covered entity to make a determination, prior to using or disclosing protected health information to target a communication to individuals based on their health status or condition, that the product or service may be beneficial to the health of the type or class of individual targeted to receive the communication.

This third provision accommodates the needs of health care entities to be able to discuss their own health-related products and services, or those of third parties, as part of their everyday business and as part of promoting the health of their patients and enrollees. The provision is restricted to uses by covered entities or disclosures to their business associates pursuant to a contract that requires confidentiality, ensuring that protected health information is not distributed to third parties. To provide individuals with a better understanding of how their protected health information is being used for marketing, the provision requires that the communication identify that the covered entity is the source of the communication; a covered entity may not send out information about the product of a third party without disclosing to the individual where the communication originated. We also require covered entities to disclose any direct or indirect remuneration from third parties. This requirement permits individuals to better understand why they are receiving a communication, and to weigh the extent to which their information is being used to promote their health or to enrich the covered entity. Covered entities also are required to include in their communication (unless it is a general newsletter or similar device) how the individual may prevent further communications about health-related products and services. This provision enhances individuals' control over how their information is being used. Finally, where a covered entity targets communications to individuals on the basis of their health status or condition, we require that the entity make a determination that the product or service being communicated may be beneficial to the health of the type of individuals targeted, and that the communication to the targeted individuals explain why they have been targeted and how the product or service relates to their health. This final provision balances the advantages that accrue from health care entities informing their patients and enrollees of new or valuable health products with individuals' expectations that their protected health information will be used to promote their health.

Section 164.514(f)—Fundraising

We proposed in the NPRM to require covered entities to obtain authorization from an individual in order to use the individual's protected health information for fundraising activities.

As noted in § 164.501, in the final rule we define fundraising on behalf of a covered entity to be a health care operation. In § 164.514, we permit a covered entity to use protected health information without individual authorization for fundraising on behalf of itself, provided that it limits the information that it uses to demographic information about the individual and the dates that it has provided service to the individual (see the § 164.501 discussion of “health care operations”). In addition, we require fundraising materials to explain how the individual may opt out of any further fundraising communications, and covered entities are required to honor such requests. We permit a covered entity to disclose the limited protected health information to a business associate for fundraising on its own behalf. We also permit a covered entity to disclose the information to an institutionally related foundation.

By "institutionally related foundation," we mean a foundation that qualifies as a nonprofit charitable foundation under section 501(c)(3) of the Internal Revenue Code and that has in its charter statement of charitable purposes an explicit linkage to the covered entity. An institutionally related foundation may, as explicitly stated in its charter, support the covered entity as well as other covered entities or health care providers in its community. For example, a covered hospital may disclose for fundraising on its own behalf the specified protected health information to a nonprofit foundation established for the specific purpose of raising funds for the hospital or to a foundation that has as its mission the support of the members of a particular hospital chain that includes the covered hospital. The term does not include an organization with a general charitable purpose, such as to support research about or to provide treatment for certain diseases, that may give money to a covered entity, because its charitable purpose is not specific to the covered entity.

Section 164.514(g)—Underwriting

As described under the definition of "health care operations" (§ 164.501), protected health information may be used or disclosed for underwriting and other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits. This final rule includes a requirement, not included in the NPRM, that health plans receiving such information for these purposes may not use or disclose it for any other purpose, except as may be required by law, if the insurance or benefits contract is not placed with the health plan.

Section 164.514(h)—Verification of Identity and Authority of Persons Requesting Protected Health Information

Disclosure of Protected Health Information

We reorganize the provision regarding verification of identity of individuals requesting protected health information to improve clarity, but we retain the substance of requirements proposed in the NPRM in § 164.518(c), as follows.

The covered entity must establish and use written policies and procedures (which may be standard protocols) that are reasonably designed to verify the identity and authority of the requestor where the covered entity does not know the person requesting the protected health information. The knowledge of the person may take the form of a known place of business, address, phone or fax number, as well a known human being. Where documentation, statements or representations, whether oral or written, from the person requesting the protected health information is a condition of disclosure under this rule or other law, this verification must involve obtaining such documentation statement, or representation. In such a case, additional verification is only required where this regulation (or other law) ***82547** requires additional proof of authority and identity.

The NPRM proposed that covered entities would be permitted to rely on the required documentation of IRB or privacy board approval to constitute sufficient verification that the person making the request was a researcher and that the research is authorized. The final rule retains this provision.

For most disclosures, verifying the authority for the request means taking reasonable steps to verify that the request is lawful under this regulation. Additional proof is required by other provisions of this regulation where the request is made pursuant to § 164.512 for national priority purposes. Where the person requesting the protected health information is a public official, covered entities must verify the identity of the requester by examination of reasonable evidence, such as a written statement of identity on agency letterhead, an identification badge, or similar proof of official status. Similarly, covered entities are required to verify the legal authority supporting the request by examination of reasonable evidence, such as a written request provided on agency letterhead that describes the legal authority for requesting the release. Where § 164.512 explicitly requires written evidence of legal process or other authority before a disclosure may be made, a public official's proof of identity and the official's oral statement that the request is authorized by law are not sufficient to constitute the required reasonable evidence of legal authority; under these provisions, only the required written evidence will suffice.

In some circumstances, a person or entity acting on behalf of a government agency may make a request for disclosure of protected health information under these subsections. For example, public health agencies may contract with a nonprofit agency to collect

and analyze certain data. In such cases, the covered entity is required to verify the requestor's identity and authority through examination of reasonable documentation that the requestor is acting on behalf of the government agency. Reasonable evidence includes a written request provided on agency letterhead that describes the legal authority for requesting the release and states that the person or entity is acting under the agency's authority, or other documentation, including a contract, a memorandum of understanding, or purchase order that confirms that the requestor is acting on behalf of the government agency.

In some circumstances, identity or authority will be verified as part of meeting the underlying requirements for disclosure. For example, a disclosure under § 164.512(j)(1)(i) to avert an imminent threat to safety is lawful only if made in the good faith belief that the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and to a person reasonably able to prevent or lessen the threat. If these conditions are met, no further verification is needed. In such emergencies, the covered entity is not required to demand written proof that the person requesting the protected health information is legally authorized. Reasonable reliance on verbal representations are appropriate in such situations.

Similarly, disclosures permitted under § 164.510(a) for facility directories may be made to the general public; the covered entity's policies and procedures do not need to address verifying the identity and authority for these disclosures. In § 164.510(b) we do not require verification of identity for persons assisting in an individual's care or for notification purposes. For disclosures when the individual is not present, such as when a friend is picking up a prescription, we allow the covered entity to use professional judgment and experience with common practice to make reasonable inferences.

Under § 164.524, a covered entity is required to give individuals access to protected health information about them (under most circumstances). Under the general verification requirements of § 164.514(h), the covered entity is required to take reasonable steps to verify the identity of the individual making the request. We do not mandate particular identification requirements (e.g., drivers licence, photo ID), but rather leave this to the discretion of the covered entity. The covered entity must also establish and document procedures for verification of identity and authority of personal representatives, if not known to the entity. For example, a health care provider can require a copy of a power of attorney, or can ask questions to determine that an adult acting for a young child has the requisite relationship to the child.

In Subpart C of Part 160, we require disclosure to the Secretary for purposes of enforcing this regulation. When a covered entity is asked by the Secretary to disclose protected health information for compliance purposes, the covered entity must verify the same information that it is required to verify for any other law enforcement or oversight request for disclosure.

Use of Protected Health Information

The proposed rule's verification requirements applied to any person requesting protected health information, whether for a use or a disclosure. In the final regulation, the verification provisions apply only to disclosures of protected health information. The requirements in § 164.514(d), for implementation of policies and procedures for "minimum necessary" uses of protected health information, are sufficient to ensure that only appropriate persons within a covered entity will have access to protected health information.

Section 164.520—Notice of Privacy Practices for Protected Health Information

Section 164.520(a)—Right to Notice

We proposed to establish a right for individuals to receive adequate notice of how covered health care providers and health plans use and disclose protected health information, and of the individual's rights with respect to that information.

In the final regulation, we retain the general right for individuals to receive and the requirement for covered entities to produce a notice of privacy practices, with significant modifications to the content and distribution requirements.

We also modify the requirements with respect to certain covered entities. First, in § 164.500(b)(2), we clarify that a health care clearinghouse that creates or receives protected health information other than as a business associate of a covered entity must produce a notice. If a health care clearinghouse creates or receives protected health information only as a business associate of other covered entities, it is not required to produce a notice.

Second, in § 164.520(a)(2), we clarify the notice requirements with respect to group health plans. Individuals who receive health benefits under a group health plan other than through insurance are entitled to a notice from the group health plan; self-insured group health plans must maintain a notice that meets the requirements of this section and must provide the notice in accordance with the requirements of § 164.520(c). At a minimum, the self-insured group health plan's notice must describe the group health plan's privacy practices with respect to the protected health information it creates or receives through its self-insured arrangements. For example, if a group health plan maintains both fully-insured and self-insured arrangements, the group health plan must, at a minimum, maintain and provide a notice that describes its ***82548** privacy practices with respect to protected health information it creates or receives through the self-insured arrangements. This notice would be distributed to all participants in the self-insured arrangements (in accordance with § 164.520(c)(1)) and would also be available on request to other persons, including participants in the fully-insured arrangements.

Individuals who receive health benefits under a group health plan through an insurance contract (i.e., a fully-insured group health plan) are entitled to a notice from the issuer or HMO through which they receive their health benefits. The health insurance issuer or HMO must maintain and provide the notice in accordance with § 164.520(c)(1). In addition, some fully-insured group health plans are required to maintain and provide a notice of the group health plan's privacy practices. If a group health plan provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and the group health plan creates or receives protected health information in addition to summary information (as defined in § 164.504(a)) and information about individuals' enrollment in or disenrollment from a health insurance issuer or HMO offered by the group health plan, the group health plan must maintain a notice that meets the requirements of this section and must provide the notice upon request of any person. The group health plan is not required to meet the other distribution requirements of § 164.520(c)(1). Individuals enrolled in such group health plans have the right to notice of the health insurance issuer or HMO's privacy practices and, on request, to notice of the group health plan's privacy practices. If the group health plan, however, provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and the only protected health information the group health plan creates or receives is summary information (as defined in § 164.504(a)) and information about individuals' enrollment in or disenrollment from a health insurance issuer or HMO offered by the group health plan, the group health plan is not required to maintain or provide a notice under this section. In this case, the individuals enrolled in the group health plan would receive notice of the health insurance issuer or HMO's privacy practices, but would not be entitled to notice of the group health plan's privacy practices.

Third, in § 164.520(a)(3), we clarify that inmates do not have a right to notice under this section and a correctional institution that is a covered entity is not required to produce a notice. No person, including a current or former inmate, has the right to notice of such a covered entity's privacy practices.

Section 164.520(b)—Content of Notice

We proposed to require the notice to be written in plain language and contain each of the following elements: a description of the uses and disclosures expected to be made without individual authorization; statements that other uses and disclosures would be made only with the individual's authorization and that the individual could revoke such authorization; descriptions of the rights to request restrictions, inspect and copy protected health information, amend or correct protected health information, and receive an accounting of disclosures of protected health information; statements about the entity's legal requirements to protect privacy, provide notice, and adhere to the notice; a statement about how individuals would be informed of changes to the entity's policies and procedures; instructions on how to make complaints with the entity or Secretary; the name and telephone number of a contact person or office; and the date the notice was produced. We provided a model notice of information policies and procedures for covered health care providers.

In § 164.520(b), and immediately below in this preamble, we describe the notice content requirements for the final rule. As described in detail, below, we make substantial changes to the uses and disclosures of protected health information that must be described in the notice. Unlike the proposed rule, we do not include a model notice. We intend to develop further guidance on notice requirements prior to the compliance date of this rule. In this section of the final rule, we also refer to the covered entity's privacy "practices," rather than its "policies and procedures." The purpose of this change in vocabulary is to clarify that a covered entity's "policies and procedures" is a detailed documentation of all of the entity's privacy practices as required under this rule, not just those described in the notice. For example, we require covered entities to have policies and procedures implementing the requirements for "minimum necessary" uses and disclosures of protected health information, but these policies and procedures need not be reflected in the entity's notice. Similarly, we require covered entities to have policies and procedures for assuring individuals access to protected health information about them. While such policies and procedures will need to include documentation of the designated record sets subject to access, who is authorized to determine when information will be withheld from an individual, and similar details, the notice need only explain generally that individuals have the right to inspect and copy information about them, and tell individuals how to exercise that right.

A covered entity that adopts and follows the notice content and distribution requirements described below will have provided adequate notice. However, the requirements for the content of the notice are not intended to be exclusive. As with the rest of the rule, we specify minimum requirements, not best practices. Covered entities may want to include more detail. We note that all federal agencies must still comply with the Privacy Act of 1974. This means that federal agencies that are covered entities or have covered health care components must comply with the notice requirements of the Privacy Act as well as those included in this rule.

In addition, covered entities may want or be required to produce more than one notice in order to satisfy the notice content requirements under this rule. For example, a covered entity that conducts business in multiple states with different laws regarding the uses and disclosures that the covered entity is permitted to make without authorization may be required to produce a different notice for each state. A covered entity that conducts business both as part of an organized health care arrangement or affiliated covered entity and as an independent enterprise (e.g., a physician who sees patients through an on-call arrangement with a hospital and through an independent private practice) may want to adopt different privacy practices with respect to each line of business; such a covered entity would be required to produce a different notice describing the practices for each line of business. Covered entities must produce notices that accurately describe the privacy practices that are relevant to the individuals receiving the notice.

Required Elements

Plain Language

As in the proposed rule, we require the notice to be written in plain language. A covered entity can satisfy the plain language requirement if it makes a reasonable effort to: organize material to serve the needs of the reader; write short sentences in the active voice, using "you" and other pronouns; use common, everyday words in sentences; and divide material into short sections.

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We do not require particular formatting specifications, such as easy-to-read design features (e.g., lists, tables, graphics, contrasting colors, and white space), type face, and font size. However, the purpose of the notice is to inform the recipients about their rights and how protected health information collected about them may be used or disclosed. Recipients who cannot understand the covered entity's notice will miss important information about their rights under this rule and about how the covered entity is protecting health information about them. One of the goals of this rule is to create an environment of open communication and transparency with respect to the use and disclosure of protected health information. A lack of clarity in the notice could undermine this goal and create misunderstandings. Covered entities have an incentive to make their notice statements clear and concise. We believe that the more understandable the notice is, the more confidence the public will have in the covered entity's commitment to protecting the privacy of health information.

It is important that the content of the notice be communicated to all recipients and therefore we encourage the covered entity to consider alternative means of communicating with certain populations. We note that any covered entity that is a recipient of federal financial assistance is generally obligated under Title VI of the Civil Rights Act of 1964 to provide material ordinarily distributed to the public in the primary languages of persons with limited English proficiency in the recipients' service areas. Specifically, this Title VI obligation provides that, where a significant number or proportion of the population eligible to be served or likely to be directly affected by a federally assisted program needs service or information in a language other than English in order to be effectively informed of or participate in the program, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide information in languages appropriate to such persons. For covered entities not subject to Title VI, the Title VI standards provide helpful guidance for effectively communicating the content of their notices to non-English speaking populations.

We also encourage covered entities to be attentive to the needs of individuals who cannot read. For example, an employee of the covered entity could read the notice to individuals upon request or the notice could be incorporated into a video presentation that is played in the waiting area.

Header

Unlike the proposed rule, covered entities must include prominent and specific language in the notice that indicates the importance of the notice. This is the only specific language we require covered entities to include in the notice. The header must read, “THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”

Uses and Disclosures

We proposed to require covered entities to describe in plain language the uses and disclosures of protected health information, and the covered entity's policies and procedures with respect to such uses and disclosures, that the health plan or covered provider expected to make without individual authorization. The covered provider or health plan would have had to distinguish between those uses and disclosures required by law and those permitted but not required by law.

We also proposed to require covered health care providers and health plans to state in the notice that all other uses and disclosures would be made only with the individual's authorization and that such authorization could be revoked. The notice would also have been required to state that the individual could request restrictions on certain uses and disclosures and that the covered entity would not be required to agree to such a request.

We significantly modify these requirements in the final rule. Covered entities must describe all uses and disclosures of protected health information that they are permitted or required to make under this rule without authorization, including those uses and disclosures subject to the consent requirements under § 164.506. If other applicable law prohibits or materially limits the covered entity's ability to make any uses or disclosures that would otherwise be permitted under the rule, the covered entity must describe only the uses and disclosures permitted under the more stringent law.

Covered entities must separately describe each purpose for which they are permitted to use or disclose protected health information under this rule without authorization, and must do so in sufficient detail to place the individual on notice of those uses and disclosures. With respect to uses and disclosures to carry out treatment, payment, and health care operations, the description must include at least one example of the types of uses and disclosures that the covered entity is permitted to make. This requirement is intended to inform individuals of all the uses and disclosures that the covered entity is legally required or permitted to make under applicable law, even if the covered entity does not anticipate actually making such uses and disclosures. We do not require covered entities to distinguish in their notices between those uses and disclosures required by law and those permitted but not required by law.

Unlike the proposed rule, we additionally require covered entities that wish to contact individuals for any of the following activities to list these activities in the notice: providing appointment reminders, describing or recommending treatment alternatives, providing information about health-related benefits and services that may be of interest to the individual, or soliciting funds to benefit the covered entity. If the covered entity does not include these statements in its notice, it is prohibited from using or disclosing protected health information for these activities without authorization. See § 164.502(i).

In addition, if a group health plan, or a health insurance issuer or HMO with respect to a group health plan, wants the option to disclose protected health information to a group health plan sponsor without authorization as permitted under § 164.504(f), the group health plan, health insurance issuer or HMO must describe that practice in its notice.

As in the proposed rule, the notice must state that all other uses and disclosures will be made only with the individual's authorization and that the individual has the right to revoke such authorization.

We anticipate this requirement will lead to significant standardization of the notice. This language could be the same for every covered entity of a particular type within a state, territory, or other locale. We encourage states, state professional associations, and other organizations to develop model language to assist covered entities in preparing their notices.

Individual Rights

As in the proposed rule, covered entities must describe individuals' rights under the rule and how individuals may exercise those rights with respect to the covered entity. Covered entities must describe each of the following rights, as provided under the rule: the right to request restrictions ***82550** on certain uses and disclosures, including a statement that the covered entity is not required to agree to a requested restriction (§ 164.522(a)); the right to receive confidential communications of protected health information (§ 164.522(b)); the right to inspect and copy protected health information (§ 164.524); the right to amend protected health information (§ 164.526); and the right to an accounting of disclosures of protected health information (§ 164.528). We additionally require the notice to describe the right of an individual, including an individual that has agreed to receive the notice electronically, to obtain a paper copy of the notice upon request.

Covered Entity's Duties

As in the proposed rule, covered entities must state in the notice that they are required by law to maintain the privacy of protected health information, to provide a notice of their legal duties and privacy practices, and to abide by the terms of the notice currently in effect. In the final rule, we additionally require the covered entity, if it wishes to reserve the right to change its privacy practices and apply the revised practices to protected health information previously created or received, to make a statement to that effect and describe how it will provide individuals with a revised notice. (See below for a more detailed discussion of a covered entity's responsibilities when it changes its privacy practices.)

Complaints

As in the proposed rule, a covered entity's notice must inform individuals about how they can lodge complaints with the covered entity if they believe their privacy rights have been violated. See § 164.530(d) and the corresponding preamble discussion for the requirements on covered entities for receiving complaints. The notice must also state that individuals may file complaints with the Secretary. In the final rule, we additionally require the notice to include a statement that the individual will not suffer retaliation for filing a complaint.

Contact

As in the proposed rule, the notice must identify a point of contact where the individual can obtain additional information about any of the matters identified in the notice.

Effective Date

The notice must include the date the notice went into effect, rather than the proposed requirement to include the date the notice was produced. The effective date cannot be earlier than the date on which the notice was first printed or otherwise published. Covered entities may wish to highlight or otherwise emphasize any material modifications that it has made, in order to help the individual recognize such changes.

Optional Elements

As described above, we proposed to require covered entities to describe the uses and disclosures of protected health information that the covered entity in fact expected to make without the individual's authorization. We did not specify any optional elements.

While the final rule requires covered entities to describe all of the types of uses and disclosures permitted or required by law (not just those that the covered entity intends to make), we also permit and encourage covered entities to include optional elements that describe the actual, more limited, uses and disclosures they intend to make without authorization. We anticipate that some covered entities will want to distinguish themselves on the basis of their more stringent privacy practices. For example, covered health care providers who routinely treat patients with particularly sensitive conditions may wish to assure their patients that, even though the law permits them to disclose information for a wide array of purposes, the covered health care provider will only disclose information in very specific circumstances, as required by law, and to avert a serious and imminent threat to health or safety. A covered entity may not include statements in the notice that purport to limit the entity's ability to make uses or disclosures that are required by law or necessary to avert a serious and imminent threat to health or safety.

As described above, if the covered entity wishes to reserve the right to change its privacy practices with respect to the more limited uses and disclosures and apply the revised practices to protected health information previously created or received, it must make a statement to that effect and describe how it will provide individuals with a revised notice. (See below for a more detailed discussion of a covered entity's responsibilities when it changes its privacy practices.)

Revisions to the Notice

We proposed to require a covered entity to adhere to the terms of its notice, and would have permitted it to change its information policies and procedures at any time. We would have required covered health care providers and health plans to update the notice to reflect material changes to the information policies and procedures described in the notice. Changes to the notice would have applied to all protected health information held by the covered entity, including information collected under prior notices. That is, we would not have require covered entities to segregate their records according to the notice in effect at the time the record was created. We proposed to prohibit covered entities from implementing a change to an information policy or procedure described in the notice until the notice was updated to reflect the change, unless a compelling reason existed to make a use or disclosure or take other action that the notice would not have permitted. In these situations, we proposed to require covered entities to document the compelling reason and, within 30 days of the use, disclosure, or other action, change its notice to permit the action.

As in the proposed rule, covered entities are required to adhere to the terms of the notice currently in effect. See § 164.502(i). When a covered entity materially changes any of the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices described in its notice, it must promptly revise its notice accordingly. See § 164.520(b)(3). (Pursuant to § 164.530(i), it must also revise its policies and procedures.) Except when required by law, a material change to any term in the notice may not be implemented prior to the effective date of the notice in which such material change is reflected. In the final rule, however, we revise the circumstances under and extent to which the covered entity may revise the practices stated in the notice and apply the new practices to protected health information it created or received under prior notice.

Under § 164.530(i), a covered entity that wishes to change its practices over time without segregating its records according to the notice in effect at the time the records were created must reserve the right to do so in its notice. For example, a covered

hospital that states in its notice that it will only make public health disclosures required by law, and that does not reserve the right to change this practice, is prohibited from making any discretionary public health disclosures of protected health information created or received during the effective period of that notice. If the covered hospital wishes at some point in the future to make discretionary disclosures for public health purposes, it must revise its notice to so state, and ***82551** must segregate its records so that protected health information created or received under the prior notice is not disclosed for discretionary public health purposes. This hospital may then make discretionary public health disclosures of protected health information created or received after the effective date of the revised notice.

If a second covered hospital states in its notice that it will only make public health disclosures required by law, but does reserve the right to change its practices, it is prohibited from making any discretionary public health disclosures of protected health information created or received during the effective period of that notice. If this hospital wishes at some point in the future to make discretionary disclosures for public health purposes, it must revise its notice to so state, but need not segregate its records. As of the effective date of the revised notice, it may disclose any protected health information, including information created or received under the prior notice, for discretionary public health purposes.

Section 164.530(i) and the corresponding discussion in this preamble describes requirements for revision of a covered entity's privacy policies and procedures, including the privacy practices reflected in its notice.

Section 164.520(c)—Provision of Notice

As in the proposed rule, all covered entities that are required to produce a notice must provide the notice upon request of any person. The requestor does not have to be a current patient or enrollee. We intend the notice to be a public document that people can use in choosing between covered entities.

For health plans, we proposed to require health plans to distribute the notice to individuals covered by the health plan as of the compliance date; after the compliance date, at enrollment in the health plan; after enrollment, within 60 days of a material revision to the content of the notice; and no less frequently than once every three years.

As in the proposed rule, under the final rule health plans must provide the notice to all health plan enrollees as of the compliance date. After the compliance date, health plans must provide the notice to all new enrollees at the time of enrollment and to all enrollees within 60 days of a material revision to the notice. Of course, the term “enrollees” includes participants and beneficiaries in group health plans.

Unlike the proposed rule, we do not require health plans to distribute the notice every three years. Instead, health plans must notify enrollees no less than once every three years about the availability of the notice and how to obtain a copy.

We also clarify that, in each of these circumstances, if a named insured and one or more dependents are covered by the same policy, the health plan can satisfy the distribution requirement with respect to the dependents by sending a single copy of the notice to the named insured. For example, if an employee of a firm and her three dependents are all covered under a single health plan policy, that health plan can satisfy the initial distribution requirement by sending a single copy of the notice to the employee rather than sending four copies, each addressed to a different member of the family.

We further clarify that if a health plan has more than one notice, it satisfies its distribution requirement by providing the notice that is relevant to the individual or other person requesting the notice. For example, a health insurance issuer may have contracts with two different group health plans. One contract specifies that the issuer may use and disclose protected health information about the participants in the group health plan for research purposes without authorization (subject to the requirements of this rule) and one contract specifies that the issuer must always obtain authorizations for these uses and disclosures. The issuer accordingly develops two notices reflecting these different practices and satisfies its distribution requirements by providing the relevant notice to the relevant group health plan participants.

We proposed to require covered health care providers with face-to-face contact with individuals to provide the notice to all such individuals at the first service delivery to the individual during the one year period after the compliance date. After this one year period, covered providers with face-to-face contact with individuals would have been required to distribute the notice to all new patients at the first service delivery. Covered providers without face-to-face contact with individuals would have been required to provide the notice in a reasonable period of time following first service delivery.

We proposed to require all covered providers to post the notice in a clear and prominent location where it would be reasonable to expect individuals seeking services from the covered provider to be able to read the notice. We would have required revisions to be posted promptly.

In the final rule, we vary the distribution requirements according to whether the covered health care provider has a direct treatment relationship with an individual, rather than whether the covered health care provider has face-to-face contact with an individual. See § 164.501 and the corresponding discussion in this preamble regarding the definition of indirect treatment relationship.

Covered health care providers that have direct treatment relationships with individuals must provide the notice to such individuals as of the first service delivery after the compliance date. This requirement applies whether the first service is delivered electronically or in person. Covered providers may satisfy this requirement by sending the notice to all of their patients at once, by giving the notice to each patient as he or she comes into the provider's office or facility or contacts the provider electronically, or by some combination of these approaches. Covered providers that maintain a physical service delivery site must prominently post the notice where it is reasonable to expect individuals seeking service from the provider to be able to read the notice. The notice must also be available on site for individuals to take on request. In the event of a revision to the notice, the covered provider must promptly post the revision and make it available on site.

Covered health care providers that have indirect treatment relationships with individuals are only required to produce the notice upon request, as described above.

The proposed rule was silent regarding electronic distribution of the notice. Under the final rule, a covered entity that maintains a web site describing the services and benefits it offers must make its privacy notice prominently available through the site.

A covered entity may satisfy the applicable distribution requirements described above by providing the notice to the individual electronically, if the individual agrees to receiving materials from the covered entity electronically and the individual has not withdrawn his or her agreement. If the covered entity knows that the electronic transmission has failed, the covered entity must provide a paper copy of the notice to the individual.

If an individual's first service delivery from a covered provider occurs electronically, the covered provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. For example, the first time an individual requests to fill a prescription through a covered internet pharmacy, the pharmacy must automatically and contemporaneously provide the individual with the ***82552** pharmacy's notice of privacy practices. An individual that receives a covered entity's notice electronically retains the right to request a paper copy of the notice as described above. This right must be described in the notice.

We note that the Electronic Signatures in Global and National Commerce Act (Pub. L. 106-229) may apply to documents required under this rule to be provided in writing. We do not intend to affect the application of that law to documents required under this rule.

Section 164.520(d)—Joint Notice by Separate Covered Entities

The proposed rule was silent regarding the ability of legally separate covered entities to produce a single notice.

In the final rule, we allow covered entities that participate in an organized health care arrangement to comply with this section by producing a single notice that describes their combined privacy practices. See § 164.501 and the corresponding preamble discussion regarding the definition of organized health care arrangement. (We note that, under § 164.504(d), covered entities that are under common ownership or control may designate themselves as a single affiliated covered entity. Joint notice requirements do not apply to such entities. Single affiliated covered entities must produce a single notice, consistent with the requirements described above for any other covered entity. Covered entities under common ownership or control that elect not to designate themselves as a single affiliated covered entity, however, may elect to produce a joint notice if they meet the definition of an organized health care arrangement.)

The joint notice must meet all of the requirements described above. The covered entities must agree to abide by the terms of the notice with respect to protected health information created or received by the covered entities as part of their participation in the organized health care arrangement. In addition, the joint notice must reasonably identify the covered entities, or class of covered entities, to which the joint notice applies and the service delivery sites, or classes of service delivery sites, to which the joint notice applies. If the covered entities participating in the organized health care arrangement will share protected health information with each other as necessary to carry out treatment, payment, or health care operations relating to the arrangement, that fact must be stated in the notice.

Typical examples where this policy may be useful are health care facilities where physicians and other providers who have offices elsewhere also provide services at the facility (e.g. hospital staff privileges, physicians visiting their patients at a residential facility). In these cases, a single notice may cover both the physician and the facility, if the above conditions are met. The physician is required to have a separate notice covering the privacy practices at the physician's office if those practices are different than the practices described in the joint notice.

If any one of the covered entities included in the joint notice distributes the notice to an individual, as required above, the distribution requirement is met for all of the covered entities included in the joint notice.

Section 164.520(e)—Documentation

As in the proposed rule, we establish documentation requirements for covered entities subject to this provision. In the final rule, we specify that covered entities must retain copies of the notice(s) they issue in accordance with § 164.530(j). See § 164.530(j) and the corresponding preamble discussion for further description of the documentation requirements.

Section 164.522—Rights To Request Privacy Protection for Protected Health Information

Section 164.522(a)—Right of An Individual To Request Restriction of Uses and Disclosures

We proposed that individuals have the right to request that a covered health care provider restrict the use or disclosure of protected health information for treatment, payment, or health care operations. Providers would not have been required to agree to requested restrictions. However, a covered provider that agreed to a restriction could not use or disclose protected health information inconsistent with the restriction. The requirement would not have applied to permissible uses or disclosures under proposed § 164.510, including uses and disclosures in emergency circumstances under proposed § 164.510(k); when the health care services provided were emergency services; or to required disclosures to the Secretary under proposed § 164.522. We would have required covered providers to have procedures for individuals to request restrictions, for agreed-upon restrictions to be documented, for the provider to honor such restrictions, and for notification of the existence of a restriction to others to whom such protected health information is disclosed.

In the final rule, we retain the general right of an individual to request that uses and disclosures of protected health information be restricted and the requirement for covered entities to adhere to restrictions to which they have agreed. However, we include some significant changes and clarifications.

Under the final rule, we extend the right to request restrictions to health plans and to health care clearinghouses that create or receive protected health information other than as a business associate of another covered entity. All covered entities must permit individuals to request that uses and disclosures of protected health information to carry out treatment, payment, and health care operations be restricted and must adhere to restrictions to which they have agreed. A covered entity is not required to agree to a restriction. We note that restrictions between an individual and a covered entity for these or other purposes may be otherwise enforceable under other law.

Under § 164.522(a)(1)(i)(B), the right to request restrictions applies to disclosures to persons assisting in the individual's care under § 164.510(b). An individual may request that a covered entity agree not to disclose protected health information to persons assisting with the individual's care, even if such disclosure is permissible in accordance with § 164.510(b). For example, if an individual requests that a covered entity never disclose protected health information to a particular family member, and the covered entity agrees to that restriction, the covered entity is prohibited from disclosing protected health information to that family member, even if the disclosure would otherwise be permissible under § 164.510(b). We note that individuals additionally have the opportunity to agree or object to disclosures to persons assisting in the individual's care under § 164.510(b)(2). The individual retains the right to agree or object to such disclosures under § 164.510(b)(2), in accordance with the standards of that provision, regardless of whether the individual has requested a restriction under § 164.522(a). See § 164.510(b) and the corresponding preamble discussion regarding the individual's right to agree or object to disclosures to persons assisting in the individual's care.

In §§ 164.522(a)(1)(iii) and (iv) we clarify the requirements with respect to emergency treatment situations. In emergency treatment situations, a covered entity that has agreed to a restriction may use, or disclose to a health care provider, restricted protected health information that is ***82553** necessary to provide the emergency treatment. If the covered entity discloses restricted protected health information to a health care provider for emergency treatment purposes, it must request that the provider not further use or disclose the information. We expect covered entities to consider the need for access to protected health information for treatment purposes when considering a request for a restriction, to discuss this need with the individual making the request for restriction, and to agree to restrictions that will not foreseeably impede the individual's treatment. Therefore, we expect covered entities will rarely need to use or disclose restricted protected health information in emergency treatment situations. We do not intend, however, to adversely impact the delivery of health care. We therefore provide a means for the use and disclosure of restricted protected health information in emergency treatment situations, where an unexpected need for the information could arise and there is insufficient time to secure the individual's permission to use or disclose the restricted information.

In § 164.522(a)(1)(v) we clarify that restrictions are not effective under this rule to prevent uses and disclosures required by § 164.502(a)(2)(ii) or permitted under § 164.510(a) (regarding facility directories) or § 164.512 (regarding uses and disclosures for which consent, individual authorization, or opportunity to agree or object is not required). Covered entities are permitted to agree to such restrictions, but if they do so, the restrictions are not enforceable under this rule. For example, a provider who makes a disclosure under § 164.512(j)(1)(i) relating to serious and imminent threats will not be in violation of this rule even if the disclosure is contrary to a restriction agreed to under this paragraph.

In § 164.522(a)(2) we clarify a covered entity's ability to terminate a restriction to which it has agreed. A covered entity may terminate a restriction with the individual's written or oral agreement. If the individual's agreement is obtained orally, the covered entity must document that agreement. A note in the medical record or similar notation is sufficient documentation. If the individual agrees to terminate the restriction, the covered entity may use and disclose protected health information as otherwise permitted under the rule. If the covered entity wants to terminate the restriction without the individual's agreement, it may only terminate the restriction with respect to protected health information it creates or receives after it informs the individual of the termination. The restriction continues to apply to protected health information created or received prior to informing the individual of the termination. That is, any protected health information that had been collected before the termination may not be used or disclosed in a way that is inconsistent with the restriction, but any information that is collected after informing the individual of the termination of the restriction may be used or disclosed as otherwise permitted under the rule.

In § 164.522(a)(3), we clarify that a covered entity must document a restriction to which it has agreed. We do not require a specific form of documentation; a note in the medical record or similar notation is sufficient. The documentation must be retained for six years from the date it was created or the date it was last in effect, whichever is later, in accordance with § 164.530(j).

We eliminate the requirement from the NPRM for covered entities to inform persons to whom they disclose protected health information of the existence of any restriction on that information. A restriction is only binding on the covered entity that agreed to the restriction. We encourage covered entities to inform others of the existence of a restriction when it is appropriate to do so. We note, however, that disclosure of the existence of a restriction often amounts to a de facto disclosure of the restricted information itself. If a restriction does not permit a covered entity to disclose protected health information to a particular person, the covered entity must carefully consider whether disclosing the existence of the restriction to that person would also violate the restriction.

Section 164.522(b)—Confidential Communications Requirements

In the NPRM, we did not directly address the issue of whether an individual could request that a covered entity restrict the manner in which it communicated with the individual. As described above, the NPRM would have provided individuals with the right to request that health care providers restrict uses and disclosures of protected health information for treatment, payment and health care operations, but would not have required providers to agree to such a restriction.

In the final rule, we require covered entities to permit individuals to request that the covered entity provide confidential communications of protected health information about the individual. The requirement applies to communications from the covered entity to the individual, and also communications from the covered entity that would otherwise be sent to the named insured of an insurance policy that covers the individual as a dependent of the named insured. Individuals may request that the covered entity send such communications by alternative means or at alternative locations. For example, an individual who does not want his or her family members to know about a certain treatment may request that the provider communicate with the individual about that treatment at the individual's place of employment, by mail to a designated address, or by phone to a designated phone number. Similarly, an individual may request that the provider send communications in a closed envelope rather than a post card, as an "alternative means." Covered health care providers must accommodate all reasonable requests. Health plans must accommodate all reasonable requests, if the individual clearly states that the disclosure of all or part of the protected health information could endanger the individual. For example, if an individual requests that a health plan send explanations of benefits about particular services to the individual's work rather than home address because the individual is concerned that a member of the individual's household (e.g., the named insured) might read the explanation of benefits and become abusive towards the individual, the health plan must accommodate the request.

The reasonableness of a request made under this paragraph must be determined by a covered entity solely on the basis of the administrative difficulty of complying with the request and as otherwise provided in this section. A covered health care provider or health plan cannot refuse to accommodate a request based on its perception of the merits of the individual's reason for making the request. A covered health care provider may not require the individual to provide a reason for the request as a condition of accommodating the request. As discussed above, a health plan is not required to accommodate a request unless the individual indicates that the disclosure could endanger the individual. If the individual indicates such endangerment, however, the covered entity cannot further consider the individual's reason for making the request in determining whether it must accommodate the request.

A covered health care provider or health plan may refuse to accommodate a request, however, if the individual has ***82554** not provided information as to how payment, if applicable, will be handled, or if the individual has not specified an alternative address or method of contact.

Section 164.524—Access of Individuals to Protected Health Information

Section 164.524(a)—Right of Access

In the NPRM, we proposed to establish a right for individuals to access (i.e., inspect and obtain a copy of) protected health information about them maintained by a covered provider or health plan, or its business partners, in a designated record set.

As in the proposed rule, in the final rule we provide that individuals have a right of access to protected health information that is maintained in a designated record set. This right applies to health plans, covered health care providers, and health care clearinghouses that create or receive protected health information other than as a business associate of another covered entity (see § 164.500(b)). In the final rule, however, we modify the definition of designated record set. For a discussion of the significant changes made to the definition of designated record set, see § 164.501 and the corresponding preamble.

Under the revised definition, individuals have a right of access to any protected health information that is used, in whole or in part, to make decisions about individuals. This information includes, for example, information used to make health care decisions or information used to determine whether an insurance claim will be paid. Covered entities often incorporate the same protected health information into a variety of different data systems, not all of which will be utilized to make decisions about individuals. For example, information systems that are used for quality control or peer review analyses may not be used to make decisions about individuals. In that case, the information systems would not fall within the definition of designated record set. We do not require entities to grant an individual access to protected health information maintained in these types of information systems.

Duration of the Right of Access

As in the proposed rule, covered entities must provide access to individuals for as long as the protected health information is maintained in a designated record set.

Exceptions to the Right of Access

In the NPRM, we proposed to establish a right for individuals to access any protected health information maintained in a designated record set. Though we proposed to permit covered entities to deny access in certain situations relating to the particular individual requesting access, we did not specifically exclude any protected health information from the right of access.

In the final rule, we specify three types of information to which individuals do not have a right of access, even if the information is maintained in a designated record set. They are psychotherapy notes, information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding, and certain protected health information maintained by a covered entity that is subject to or exempted from the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Covered entities may, but are not required to, provide access to this information.

First, unlike the proposed rule, we specify that individuals do not have a right of access to psychotherapy notes.

Second, individuals do not have a right of access to information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. In the NPRM, we would have permitted covered entities to deny a request for access to protected health information complied in reasonable anticipation of, or for use in, a legal proceeding. We change the language in the final rule to clarify that a legal proceeding includes civil, criminal, and administrative actions and proceedings. In the final rule, we clarify that an individual does not have a right to this information by including it in the list of exceptions rather than stating that a covered entity may deny access to this information. Under this exception, the covered entity may deny access to any information that relates specifically to legal preparations but may not deny access to the individual's underlying health information. We do not intend to require covered entities to provide access to documents protected by attorney work-product privilege nor do we intend to alter rules of discovery.

Third, unlike the proposed rule, individuals do not have a right of access to protected health information held by clinical laboratories if CLIA prohibits such access. CLIA states that clinical laboratories may provide clinical laboratory test records and reports only to "authorized persons," as defined primarily by state law. The individual who is the subject of the information is not always included in this set of authorized persons. When an individual is not an authorized person, this restriction effectively prohibits the clinical laboratory from providing an individual access to this information. We do not intend to preempt CLIA and, therefore, do not require covered clinical laboratories to provide an individual access to this information if CLIA prohibits them from doing so. We note, however, that individuals have the right of access to this information if it is maintained by a covered health care provider, clearinghouse, or health plan that is not subject to CLIA.

Finally, unlike the proposed rule, individuals do not have access to protected health information held by certain research laboratories that are exempt from the CLIA regulations. The CLIA regulations specifically exempt the components or functions of "research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients." 42 CFR 493.3(a)(2). If subject to the access requirements, these laboratories, or the applicable components of them, would be forced to comply with the CLIA regulations once they provided an individual with the access under this privacy rule. Therefore, to alleviate this additional regulatory burden, we have exempted these laboratories, or the relevant components of them, from the access requirements of this regulation.

Grounds for Denial of Access

In the NPRM we proposed to permit covered health care providers and health plans to deny an individual access to inspect and copy protected health information about them for five reasons: (1) a licensed health care professional determined the inspection and copying was reasonably likely to endanger the life or physical safety of the individual or another person; (2) the information was about another person (other than a health care provider) and a licensed health care professional determined the inspection and copying was reasonably likely to cause substantial harm to that other person; (3) the information was obtained under a promise of confidentiality from someone other than a health care provider and the inspection and copying was likely to reveal the source of the information; (4) the information was obtained by a covered provider in the course of a clinical trial, the individual agreed to the denial of access in consenting to participate in the trial, and the trial was in progress; and (5) the information was compiled in reasonable anticipation of, or for use in, a legal ***82555** proceeding. In the NPRM, covered entities would not have been permitted to use these grounds to deny individuals access to protected health information that was also subject to the Privacy Act.

In the final rule, we retain all of these grounds for denial, with some modifications. One of the proposed grounds for denial (regarding legal proceedings) is retained as an exception to the right of access. (See discussion above.) We also include additional grounds for denial and create a right for individuals to request review of certain denials.

There are five types of denials covered entities may make without providing the individual with a right to have the denial reviewed.

First, a covered entity may deny an individual access to any information that is excepted from the right of access under § 164.524(a)(1). (See discussion above.)

Second, we add a new provision that permits a covered entity that is a correctional institution or covered health care provider acting under the direction of a correctional institution to deny an inmate's request to obtain a copy of protected health information if obtaining a copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or other inmates or the safety of any officer, employee or other person at the correctional institution or responsible for the transporting of the inmate. This ground for denial is restricted to an inmate's request to obtain a copy of protected health information. If an inmate requests inspection of protected health information, the request must be granted unless one of the other grounds for denial applies. The purpose for this exception, and the reason that the exception is limited to denying an inmate a copy and not to denying a right

to inspect, is to give correctional institutions the ability to maintain order in these facilities and among inmates without denying an inmate the right to review his or her protected health information.

Third, as in the proposed rule, a covered entity may deny an individual access to protected health information obtained by a covered provider in the course of research that includes treatment of the research participants, while such research is in progress. For this exception to apply, the individual must have agreed to the denial of access in conjunction with the individual's consent to participate in the research and the covered provider must have informed the individual that the right of access will be reinstated upon completion of the research. If either of these conditions is not met, the individual has the right to inspect and copy the information (subject to the other exceptions we provide here). In all cases, the individual has the right to inspect and copy the information after the research is complete.

As with all the grounds for denial, covered entities are not required to deny access under the research exception. We expect all researchers to maintain a high level of ethical consideration for the welfare of research participants and provide access in appropriate circumstances. For example, if a participant has a severe adverse reaction, disclosure of information during the course of the research may be necessary to give the participant adequate information for proper treatment decisions.

Fourth, we clarify the ability of a covered entity to deny individuals access to protected health information that is also subject to the Privacy Act. In the final rule, we specify that a covered entity may deny an individual access to protected health information that is contained in records that are subject to the Privacy Act if such denial is permitted under the Privacy Act. This ground for denial exists in addition to the other grounds for denial available under this rule. If an individual requests access to protected health information that is also subject to the Privacy Act, a covered entity may deny access to that information for any of the reasons permitted under the Privacy Act and for any of the reasons permitted under this rule.

Fifth, as in the proposed rule, a covered entity may deny an individual access to protected health information if the covered entity obtained the requested information from someone other than a health care provider under a promise of confidentiality and such access would be reasonably likely to reveal the source of the information. This provision is intended to preserve a covered entity's ability to maintain an implicit or explicit promise of confidentiality. A covered entity may not, however, deny access to protected health information when the information has been obtained from a health care provider. An individual is entitled to have access to all information about him or her generated by the health care system (apart from the other exceptions we provide here). Confidentiality promises to health care providers should not interfere with that access.

As in the proposed rule, a covered entity may deny access to protected health information under certain circumstances in which the access may harm the individual or others. In the final rule, we specify that a covered entity may only deny access for these reasons if the covered entity provides the individual with a right to have the denial reviewed. (See below for a discussion of the right to review.)

There are three types of denials for which covered entities must provide the individual with a right to review. A denial under these provisions requires a determination by a licensed health care professional (such as a physician, physician's assistant, or nurse) based on an assessment of the particular circumstances and current professional medical standards of harm. Therefore, when the request is made to a health plan or clearinghouse, the covered entity will need to consult with a licensed health care professional before denying access under this provision.

First, as in the proposed rule, covered entities may deny individuals access to protected health information about them if a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person. The most commonly cited example is when an individual exhibits suicidal or homicidal tendencies. If a licensed health care professional determines that an individual exhibits such tendencies and that permitting inspection or copying of some of the individual's protected health information is reasonably likely to result in the individual committing suicide, murder, or other physical violence, then the health care professional may

deny the individual access to that information. Under this reason for denial, covered entities may not deny access on the basis of the sensitivity of the health information or the potential for causing emotional or psychological harm.

Second, as in the proposed rule, covered entities may deny an individual access to protected health information if the information requested makes reference to someone other than the individual (and other than a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause serious harm to that other person. On some occasions when health information about one person is relevant to the care of another, a physician may incorporate it into the latter's record, such as information from group therapy sessions and information about illnesses with a genetic component. This provision permits a covered entity to withhold information in such cases if ***82556** the release of such information is reasonably likely to cause substantial physical, emotional, or psychological harm.

Third, we add a new provision regarding denial of access requested by personal representatives. Under § 164.502(g), a person that is a personal representative of an individual may exercise the rights of the individual, including the right to inspect and copy protected health information about the individual that is relevant to such person's representation. The provision permits covered entities to refuse to treat a personal representative as the individual, generally, if the covered entity has a reasonable belief that the individual has been or will be subjected to domestic violence, abuse or neglect by the personal representative, or that treating the personal representative as the individual may endanger the individual and, in its professional judgment, the covered entity decides that it is not in the best interest of the individual to treat such person as the personal representative.

In addition to that provision, we add a new provision at § 164.524(a)(3)(iii) to clarify that a covered entity may deny a request to inspect or copy protected health information if the information is requested by a personal representative of the individual and a licensed health care professional has determined that, in the exercise of professional judgment, such access is reasonably likely to cause substantial harm to the individual who is the subject of the information or to another person. The health care professional need not have a reasonable belief that the personal representative has abused or neglected the individuals and the harm that is likely to result need not be limited to the individual who is the subject of the requested protected health information. Therefore, a covered entity can recognize a person as a personal representative but deny such person access to protected health information as a personal representative.

We do not intend these provisions to create a legal duty for the covered entity to review all of the relevant protected health information before releasing it. Rather, we are preserving the flexibility and judgment of covered entities to deny access under appropriate circumstances. Denials are not mandatory; covered entities may always elect to provide requested health information to the individual. For each request by an individual, the covered entity may provide all of the information requested or evaluate the requested information, consider the circumstances surrounding the individual's request, and make a determination as to whether that request should be granted or denied, in whole or in part, in accordance with one of the reasons for denial under this rule. We intend to create narrow exceptions to the right of access and we expect covered entities to employ these exceptions rarely, if at all. Covered entities may only deny access for the reasons specifically provided in the rule.

Review of a Denial of Access

In the NPRM, we proposed to require covered entities, when denying an individual's request for access, to inform the individual of how to make a complaint to the covered entity and the Secretary.

We retain in the final rule the proposed approach (see below). In addition, if the covered entity denies the request on the basis of one of the reviewable grounds for denial described above, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny access. The covered entity must provide access in accordance with the reviewing official's determination. (See below for further description of the covered entity's requirements under § 164.524(d)(4) if the individual requests a review of denial of access.)

Section 164.524(b)—Requests for Access and Timely Action

In the NPRM, we proposed to require covered health care providers and health plans to provide a means for individuals to request access to protected health information about them. We proposed to require covered health care providers and health plans to take action on a request for access as soon as possible, but not later than 30 days following the request.

As in the proposed rule, the final rule requires covered entities to permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. We additionally permit covered entities to require individuals to make requests for access in writing, if the individual is informed of this requirement.

In the final rule, we eliminate the requirement for the covered entity to act on a request as soon as possible. We recognize that circumstances may arise in which an individual will request access on an expedited basis. We encourage covered entities to have procedures in place for handling such requests. The time limitation is intended to be an outside deadline, rather than an expectation.

In the final rule, covered entities must act on a request for access within 30 days of receiving the request if the information is maintained or accessible on-site. Covered entities must act on a request for access within 60 days of receiving the request if the information is not maintained or accessible on-site. If the covered entity is unable to act on a request within the applicable deadline, it may extend the deadline by no more than 30 days by providing the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request. This written statement describing the extension must be provided within the standard deadline. A covered entity may only extend the deadline once per request for access. This provision permits a covered entity to take a total of up to 60 days to act on a request for access to information maintained on-site and up to 90 days to act on a request for access to information maintained off-site.

The requirements for a covered entity to comply with or deny a request for access, in whole or in part, are described below.

Section 164.524(c)—Provision of Access

In the NPRM, we proposed to require covered health care providers and health plans, upon accepting a request for access, to notify the individual of the decision and of any steps necessary to fulfill the request; to provide the information requested in the form or format requested, if readily producible in such form or format; and to facilitate the process of inspection and copying.

We generally retain the proposed approach in the final rule. If a covered entity accepts a request, in whole or in part, it must notify the individual of the decision and provide the access requested. Individuals have the right both to inspect and to copy protected health information in a designated record set. The individual may choose whether to inspect the information, to copy the information, or to do both.

In the final rule, we clarify that if the same protected health information is maintained in more than one designated record set or at more than one location, the covered entity is required to produce the information only once per request for access. We intend this provision to reduce covered entities' burden in complying with requests without reducing individuals' access to protected health information. We note that summary information and reports ***82557** are not the same as the underlying information on which the summary or report was based. Individuals have the right to obtain access both to summaries and to the underlying information. An individual retains the right of access to the underlying information even if the individual requests access to, or production of, a summary. (See below regarding requests for summaries.)

The covered entity must provide the information requested in the form or format requested if it is readily producible in such form or format. For example, if the covered entity maintains health information electronically and the individual requests an electronic copy, the covered entity must accommodate such request, if possible. Additionally, we specify that if the information is not available in the form or format requested, the covered entity must produce a readily readable hard copy of the information or another form or format to which the individual and covered entity can agree. If the individual agrees, including agreeing to

any associated fees (see below), the covered entity may provide access to a summary of information rather than all protected health information in designated record sets. Similarly, a covered entity may provide an explanation in addition to the protected health information, if the individual agrees in advance to the explanation and any associated fees.

The covered entity must provide the access requested in a timely manner, as described above, and arrange for a mutually convenient time and place for the individual to inspect the protected health information or obtain a copy. If the individual requests that the covered entity mail a copy of the information, the covered entity must do so, and may charge certain fees for copying and mailing. For requests to inspect information that is maintained electronically, the covered entity may print a copy of the information and allow the individual to view the print-out on-site. Covered entities may discuss the request with the individual as necessary to facilitate the timely provision of access. For example, if the individual requested a copy of the information by mail, but the covered entity is able to provide the information faster by providing it electronically, the covered entity may discuss this option with the individual.

We proposed in the NPRM to permit the covered entity to charge a reasonable, cost-based fee for copying the information.

We clarify this provision in the final rule. If the individual requests a copy of protected health information, a covered entity may charge a reasonable, cost-based fee for the copying, including the labor and supply costs of copying. If hard copies are made, this would include the cost of paper. If electronic copies are made to a computer disk, this would include the cost of the computer disk. Covered entities may not charge any fees for retrieving or handling the information or for processing the request. If the individual requests the information to be mailed, the fee may include the cost of postage. Fees for copying and postage provided under state law, but not for other costs excluded under this rule, are presumed reasonable. If such per page costs include the cost of retrieving or handling the information, such costs are not acceptable under this rule.

If the individual requests an explanation or summary of the information provided, and agrees in advance to any associated fees, the covered entity may charge for preparing the explanation or summary as well.

The inclusion of a fee for copying is not intended to impede the ability of individuals to copy their records. Rather, it is intended to reduce the burden on covered entities. If the cost is excessively high, some individuals will not be able to obtain a copy. We encourage covered entities to limit the fee for copying so that it is within reach of all individuals.

We do not intend to affect the fees that covered entities charge for providing protected health information to anyone other than the individual. For example, we do not intend to affect current practices with respect to the fees one health care provider charges for forwarding records to another health care provider for treatment purposes.

Section 164.524(d)—Denial of Access

We proposed in the NPRM to require a covered health care provider or health plan that elects to deny a request for inspection or copying to make any other protected health information requested available to the individual to the extent possible, consistent with the denial.

In the final rule, we clarify the proposed approach. A covered entity that denies access, in whole or in part, must, to the extent possible, give the individual access to any other protected health information requested after excluding the protected health information to which the covered entity has a ground to deny access. We intend covered entities to redact or otherwise exclude only the information that falls within one or more of the denial criteria described above and to permit inspection and copying of all remaining information, to the extent it is possible to do so.

We also proposed to require covered providers and health plans, upon denying a request for access in whole or in part, to provide the individual with a written statement in plain language of the basis for the denial and how the individual could make a complaint to the covered entity or the Secretary.

We retain the proposed approach. A covered entity that denies access, in whole or in part, must provide the individual with a written denial in plain language that explains the basis for the denial. The written denial could include a direct reference to the section of the regulation relied upon for the denial, but the regulatory citation alone does not sufficiently explain the reason for the denial. The written denial must also describe how the individual can complain to the covered entity and the Secretary and must include the name or title and the telephone number of the covered entity's contact person or office that is responsible for receiving complaints.

In the final rule, we impose two additional requirements when the covered entity denies access, in whole or in part. First, if a covered entity denies a request on the basis of one of the reviewable grounds for denial, the written denial must describe the individual's right to a review of the denial and how the individual may exercise this right. Second, if the covered entity denies the request because it does not maintain the requested information, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

Finally, we specify a covered entity's responsibilities when an individual requests a review of a denial. If the individual requests a review of a denial made under § 164.524(a)(3), the covered entity must designate a licensed health care professional to act as the reviewing official. This reviewing official must not have been involved in the original decision to deny access. The covered entity must promptly refer a request for review to the designated reviewing official. The reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in § 164.524(a)(3). The covered entity must promptly provide the individual with written notice of the reviewing official's decision and otherwise carry out the decision in accordance with the requirements of this section. ***82558**

Section 164.524(e)—Policies, Procedures, and Documentation

As in the proposed rule, we establish documentation requirements for covered entities that are subject to this provision. In accordance with § 164.530(j), the covered entity must retain documentation of the designated record sets that are subject to access by individuals and the titles of the persons or offices responsible for receiving and processing requests for access by individuals.

Section 164.526—Amendment of Protected Health Information

Section 164.526(a)—Right to Amend

In proposed § 164.516, we proposed to establish the individual's right to request a covered health care provider or health plan to amend or correct protected health information about the individual for as long as the covered entity maintains the information.

In § 164.526 of the final rule, we retain the general proposed approach, but establish an individual's right to have the covered entity amend, rather than amend or correct, protected health information. This right applies to protected health information and records in a designated record set for as long as the information is maintained in the designated record set. In the final rule, covered health care providers, health plans, and health care clearinghouses that create or receive protected health information other than as a business associate must comply with these requirements.

Denial of Amendment

We proposed to permit a covered health care provider or health plan to deny a request for amendment if it determined that the protected health information that was the subject of the request was not created by the covered provider or health plan, would not be available for inspection and copying under proposed § 164.514, or was accurate and complete. A covered entity would have been permitted, but not required, to deny a request if any of these conditions were met.

As in the proposed rule, the final rule permits a covered entity to deny a request for amendment if the covered entity did not create the protected health information or record that is the subject of the request for amendment. We add one exception to this

provision: if the individual provides a reasonable basis to believe that the originator of the protected health information is no longer available to act on the requested amendment, the covered entity must address the request for amendment as though the covered entity had created the information.

As in the proposed rule, a covered entity also may deny a request for amendment if the protected health information that is the subject of the request for amendment is not part of a designated record set or would not otherwise be available for inspection under § 164.524. We eliminate the ability to deny a request for amendment if the information or record that is the subject of the request would not be available for copying under the rule. Under § 164.524(a)(2)(ii), an inmate may be denied a copy of protected health information about the inmate. We intend to preserve an inmate's ability to request amendments to information, even if a copy of the information would not be available to the inmate, subject to the other exceptions provided in this section.

Finally, as in the proposed rule, a covered entity may deny a request for amendment if the covered entity determines that the information in dispute is accurate and complete. We draw this concept from the Privacy Act of 1974, governing records held by federal agencies, which permits an individual to request correction or amendment of a record "which the individual believes is not accurate, relevant, timely, or complete." (5 U.S.C. 552a(d)(2)). We adopt the standards of "accuracy" and "completeness" and draw on the clarification and analysis of these terms that have emerged in administrative and judicial interpretations of the Privacy Act during the last 25 years. We note that for federal agencies that are also covered entities, this rule does not diminish their present obligations under the Privacy Act of 1974.

This right is not intended to interfere with medical practice or to modify standard business record keeping practices. Perfect records are not required. Instead, a standard of reasonable accuracy and completeness should be used. In addition, this right is not intended to provide a procedure for substantive review of decisions such as coverage determinations by payors. It is intended only to affect the content of records, not the underlying truth or correctness of materials recounted therein. Attempts under the Privacy Act of 1974 to use this mechanism as a basis for collateral attack on agency determinations have generally been rejected by the courts. The same results are intended here.

Section 164.526(b)—Requests for Amendment and Timely Action

We proposed to require covered health care providers and health plans to provide a means for individuals to request amendment of protected health information about them. Under the NPRM, we would have required covered health care providers and health plans to take action on a request for amendment or correction within 60 days of the request.

As in the proposed rule, covered entities must permit individuals to request that the covered entity amend protected health information about them. We also permit certain specifications for the form and content of the request. If a covered entity informs individuals of such requirements in advance, a covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment. If the covered entity imposes such a requirement and informs individuals of the requirement in advance, the covered entity is not required to act on an individual's request that does not meet the requirements.

We retain the requirement for covered entities to act on a request for amendment within 60 days of receipt of the request. In the final rule, we specify the nature of the action the covered entity must take within the time frame. The covered entity must inform the individual, as described below, that the request has been either accepted or denied, in whole or in part. It must also take certain actions pursuant to its decision to accept or deny the request, as described below. If the covered entity is unable to meet the deadline, the covered entity may extend the deadline by no more than 30 days. The covered entity must inform the individual in writing, within the initial 60-day period, of the reason for the delay and the date by which the covered entity will complete its action on the request. A covered entity may only extend the deadline one time per request for amendment.

Section 164.526(c)—Accepting the Amendment

If a covered health care provider or health plan accepted a request for amendment, in whole or in part, we proposed to require the covered entity to make the appropriate change. The covered entity would have had to identify the challenged entries as amended or corrected and indicate the location of the amended or corrected information. ***82559**

We also proposed to require the covered provider or health plan to make reasonable efforts to notify certain entities of the amendment: 1) entities the individual identified as needing to be notified and 2) entities the covered provider or health plan knew had received the erroneous or incomplete information and who may have relied, or could foreseeably rely, on such information to the detriment of the individual.

The covered provider or health plan would also have been required to notify the individual of the decision to amend the information.

As in the proposed rule, if a covered entity accepts an individual's request for amendment or correction, it must make the appropriate amendment. In the final rule, we clarify that, at a minimum, the covered entity must identify the records in the designated record set that are affected by the amendment and must append or otherwise provide a link to the location of the amendment. We do not require covered entities to expunge any protected health information. Covered entities may expunge information if doing so is consistent with other applicable law and the covered entity's record keeping practices.

We alter some of the required procedures for informing the individual and others of the accepted amendment. As in the proposed rule, the covered entity must inform individuals about accepted amendments. In the final rule, the covered entity must obtain the individual's agreement to have the amended information shared with certain persons. If the individual agrees, the covered entity must make reasonable efforts to provide a copy of the amendment within a reasonable time to: (1) Persons the individual identifies as having received protected health information about the individual and needing the amendment; and (2) persons, including business associates, that the covered entity knows have the unamended information and who may have relied, or could foreseeably rely, on the information to the detriment of the individual. For example, a covered entity must make reasonable efforts to inform a business associate that uses protected health information to make decisions about individuals about amendments to protected health information used for such decisions.

Section 164.526(d)—Denying the Amendment

If a covered health care provider or health plan denied a request for amendment, in whole or in part, we proposed to require the covered entity to provide the individual with a written statement in plain language of the basis for the denial, a description of how the individual could submit a written statement of disagreement with the denial, and a description of how the individual could make a complaint with the covered entity and the Secretary.

We proposed to require covered health care providers and health plans to have procedures to permit the individual to file a written statement of disagreement with the denial and to include the covered entity's statement of denial and the individual's statement of disagreement with any subsequent disclosure of the disputed information. Covered entities would have been permitted to establish a limit to the length of the individual's statement of disagreement and to summarize the statement if necessary. We also proposed to permit covered entities to provide a rebuttal to the individual's statement with future disclosures.

As in the proposed rule, if a covered entity denies a request for amendment, it must provide the individual with a statement of denial written in plain language. The written denial must include the basis for the denial, how the individual may file a written statement disagreeing with the denial, and how the individual may make a complaint to the covered entity and the Secretary.

In the final rule, we additionally require the covered entity to inform individuals of their options with respect to future disclosures of the disputed information in order to ensure that an individual is aware of his or her rights. The written denial must state that if the individual chooses not to file a statement of disagreement, the individual may request that the covered entity include the individual's request for amendment and the covered entity's denial of the request with any future disclosures of the protected health information that is the subject of the requested amendment.

As in the proposed rule, the covered entity must permit the individual to submit a written statement disagreeing with the denial and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement and may prepare a written rebuttal to the individual's statement of disagreement. If the covered entity prepares a rebuttal, it must provide a copy to the individual.

The covered entity must identify the record or protected health information that is the subject of the disputed amendment and append or otherwise link the following information to the designated record set: the individual's request for amendment, the covered entity's denial of the request, the individual's statement of disagreement (if any), and the covered entity's rebuttal (if any). If the individual submits a written statement of disagreement, all of the appended or linked information, or an accurate summary of it, must be included with any subsequent disclosure of the protected health information to which the disagreement relates. If the individual does not submit a written statement of disagreement, the covered entity must include the appended or linked information only if the individual requests that the covered entity do so.

In the final rule, we clarify that when a subsequent disclosure is a standard transaction adopted under the Transactions Rule that cannot accommodate the additional materials described above, the covered entity may separately disclose the additional material to the recipient of the transaction.

Section 164.526(e)—Actions on Notices of Amendment

We proposed to require any covered entity that received a notification of amendment to have procedures in place to make the amendment in any of its designated record sets and to notify its business associates, if appropriate, of amendments.

We retain the proposed approach in the final rule. If a covered entity receives a notification of amended protected health information from another covered entity as described above, the covered entity must make the necessary amendment to protected health information in designated record sets it maintains. In addition, covered entities must require their business associates who receive such notifications to incorporate any necessary amendments to designated record sets maintained on the covered entity's behalf. (See § 164.504 regarding business associate requirements.)

Section 164.526(f)—Policies, Procedures, and Documentation

As in the proposed rule, we establish documentation requirements for covered entities subject to this provision. In accordance with § 164.530(j), the covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendment.

§ 164.528—Accounting of Disclosures of Protected Health Information

Right to an Accounting of Disclosures

We proposed in the NPRM to grant individuals a right to receive an ***82560** accounting of all disclosures of protected health information about them by a covered entity for purposes other than treatment, payment, and health care operations. We proposed this right to exist for as long as the covered entity maintained the protected health information.

We also proposed that individuals would not have a right to an accounting of disclosures to health oversight or law enforcement agencies if the agency provided a written request for exclusion for a specified time period and the request stated that access by the individual during that time period would be reasonably likely to impede the agency's activities.

We generally retain the proposed approach in the final rule. As in the proposed rule, individuals have a right to receive an accounting of disclosures made by a covered entity, including disclosures by or to a business associate of the covered entity, for purposes other than treatment, payment, and health care operations, subject to certain exceptions as discussed below.

We revise the duration of this right under the final rule. Individuals have a right to an accounting of the applicable disclosures that have been made in the 6 year period prior to the date of a request for an accounting. We additionally clarify in § 164.528(b)(1) that an individual may request, and a covered entity may then provide, an accounting of disclosures for a period of time less than 6 years from the date of the request. For example, an individual could request an accounting only of disclosures that occurred during the year prior to the request.

In the final rule, we exclude several additional types of disclosures from the accounting requirement. Covered entities are not required to include in the accounting disclosures to the individual as provided in § 164.502; disclosures for facility directories, disclosures to persons involved in the individual's care, or other disclosures for notification purposes as provided in § 164.510; disclosures for national security or intelligence purposes as provided in § 164.512(k)(2); disclosures to correctional institutions or law enforcement officials as provided in § 164.512(k)(5); or any disclosures that were made by the covered entity prior to the compliance date of the rule for that covered entity.

We retain the time-limited exclusion for disclosures to health oversight and law enforcement agencies, but require rather than permit the exclusion for the specified time period. Covered entities must exclude disclosures to a health oversight agency or law enforcement official from the accounting for the time period specified by the applicable agency or official if the agency or official provides the covered entity with a statement that inclusion of the disclosure(s) in the accounting to the individual during that time period would be reasonably likely to impede the agency or official's activities. The agency or official's statement must specifically state how long the information must be excluded. At the expiration of that period, the covered entity is required to include the disclosure(s) in an accounting for the individual. If the agency or official's statement is made orally, the covered entity must document the identity of the agency or official who made the statement and must exclude the disclosure(s) for no longer than 30 days from the date of the oral statement, unless a written statement is provided during that time. If the agency or official provides a written statement, the covered entity must exclude the disclosure(s) for the time period specified in the written statement.

Content of the Accounting

We proposed in the NPRM to require the accounting to include all disclosures as described above, including disclosures authorized by the individual. The accounting would have been required to contain the date of each disclosure; the name and address of the organization or person who received the protected health information; a brief description of the information disclosed; and copies of all requests for disclosures. For disclosures other than those made at the request of the individual, the accounting would have also included the purpose for which the information was disclosed.

We generally retain the proposed approach in the final rule, but do not require covered entities to make copies of authorizations or other requests for disclosures available with the accounting. Instead, we require the accounting to contain a brief statement of the purpose of the disclosure. The statement must reasonably inform the individual of the basis for the disclosure. In lieu of the statement of purpose, a covered entity may include a copy of the individual's authorization under § 164.508 or a copy of a written request for disclosure, if any, under § 164.502(a)(2)(ii) or § 164.512. We also clarify that covered entities are only required to include the address of the recipient of the disclosed protected health information if the covered entity knows the address.

We add a provision allowing for a summary accounting of recurrent disclosures. For multiple disclosures to the same recipient pursuant to a single authorization under § 164.508 or for a single purpose under §§ 164.502(a)(2)(ii) or 164.512, the covered entity may provide a summary accounting addressing the series of disclosures rather than a detailed accounting of each disclosure in the series. In this circumstance, a covered entity may limit the accounting of the series of disclosures to the following information: the information otherwise required above for the first disclosure in the series during the accounting period; the frequency, periodicity, or number of disclosures made during the accounting period; and the date of the most recent disclosure in the series. For example, if under § 164.512(b), a covered entity discloses the same protected health information to a public health authority for the same purpose every month, it can account for those disclosures by including in the accounting the date of the first disclosure, the public health authority to whom the disclosures were made and the public health authority's address,

a brief description of the information disclosed, a brief description of the purpose of the disclosures, the fact that the disclosures were made every month during the accounting period, and the date of the most recent disclosure.

Provision of the Accounting

We proposed in the NPRM to require covered entities to provide individuals with an accounting of disclosures as soon as possible, but not later than 30 days following receipt of the request for the accounting.

In the final rule, we eliminate the requirement for the covered entity to act as soon as possible. We recognize that circumstances may arise in which an individual will request an accounting on an expedited basis. We encourage covered entities to implement procedures for handling such requests. The time limitation is intended to be an outside deadline, rather than an expectation. We expect covered entities always to be attentive to the circumstances surrounding each request and to respond in an appropriate time frame.

In the final rule, covered entities must provide a requested accounting no later than 60 days after receipt of the request. If the covered entity is unable to meet the deadline, the covered entity may extend the deadline by no more than 30 days. The covered entity must inform the individual in writing, within the standard 60-day deadline, of the reason for the delay and the date by which the covered entity will provide the request. ***82561** A covered entity may only extend the deadline one time per request for accounting.

The NPRM did not address whether a covered entity could charge a fee for the accounting of disclosures.

In the final rule, we provide that individuals have a right to receive one free accounting per 12 month period. For each additional request by an individual within the 12 month period, the covered entity may charge a reasonable, cost-based fee. If it imposes such a fee, the covered entity must inform the individual of the fee in advance and provide the individual with an opportunity to withdraw or modify the request in order to avoid or reduce the fee.

Procedures and Documentation

As in the proposed rule, we establish documentation requirements for covered entities subject to this provision. In accordance with § 164.530(j), for disclosures that are subject to the accounting requirement, the covered entity must retain documentation of the information required to be included in the accounting. The covered entity must also retain a copy of any accounting provided and must document the titles of the persons or offices responsible for receiving and processing requests for an accounting.

Section 164.530—Administrative Requirements

Designation of a Privacy Official and Contact Person

In § 164.518(a) of the NPRM, we proposed that covered entities be required to designate an individual as the covered entity's privacy official, responsible for the implementation and development of the entity's privacy policies and procedures. We also proposed that covered entities be required to designate a contact person to receive complaints about privacy and provide information about the matters covered by the entity's notice. We indicated that the contact person could be, but was not required to be, the person designated as the privacy official. We proposed to leave implementation details to the discretion of the covered entity. We expected implementation to vary widely depending on the size and nature of the covered entity, with small offices assigning this as an additional duty to an existing staff person, and large organizations creating a full-time privacy official. In proposed § 164.512, we also proposed to require the covered plan or provider's privacy notice to include the name of a contact person for privacy matters.

The final regulation retains the requirements for a privacy official and contact person as specified in the NPRM. These designations must be documented. The designation of privacy official and contact person positions within affiliated entities will

depend on how the covered entity chooses to designate the covered entity(ies) under § 164.504(b). If a subsidiary is defined as a covered entity under this regulation, then a separate privacy official and contact person is required for that covered entity. If several subsidiaries are designated as a single covered entity, pursuant to § 164.504(b), then together they need have only a single privacy officer and contact person. If several covered entities share a notice for services provided on the same premises, pursuant to § 164.520(d), that notice need designate only one privacy official and contact person for the information collected under that notice.

These requirements are consistent with the approach recommended by the Joint Commission on Accreditation of Healthcare Organizations, and the National Committee for Quality Assurance, in its paper "Protecting Personal Health Information; A framework for Meeting the Challenges in a Managed Care Environment." This paper notes that "accountability is enhanced by having focal points who are responsible for assessing compliance with policies and procedures * * * " (p. 29)

Training

In § 164.518(b) of the NPRM we proposed to require that covered entities provide training on the entities' policies and procedures to all members of the workforce likely to have access to protected health information. Each entity would be required to provide initial training by the date on which this rule became applicable. After that date, each covered entity would have to provide training to new members of the workforce within a reasonable time after joining the entity. In addition, we proposed that when a covered entity made material changes in its privacy policies or procedures, it would be required to retrain those members of the workforce whose duties were related to the change within a reasonable time of making the change.

The NPRM would have required that, upon completion of the training, the trainee would be required to sign a statement certifying that he or she received the privacy training and would honor all of the entity's privacy policies and procedures. Entities would determine the most effective means of achieving this training requirement for their workforce. We also proposed that, at least every three years after the initial training, covered entities would be required to have each member of the workforce sign a new statement certifying that he or she would honor all of the entity's privacy policies and procedures. The covered entity would have been required to document its policies and procedures for complying with the training requirements.

The final regulation requires covered entities to train all members of their workforce on the policies and procedures with respect to protected health information required by this rule, as necessary and appropriate for the members of the workforce to carry out their functions within the covered entity. We do not change the proposed time lines for training existing and new members of the workforce, or for training due to material changes in the covered entity's policies and procedures. We eliminate both the requirement for employees to sign a certification following training and the triennial re-certification requirement. Covered entities are responsible for implementing policies and procedures to meet these requirements and for documenting that training has been provided.

Safeguards

In § 164.518(c) of the NPRM, we proposed to require covered entities to put in place administrative, technical, and physical safeguards to protect the privacy of protected health information. We made reference in the preamble to similar requirements proposed for certain electronic information in the Notice of Proposed Rulemaking entitled the Security and Electronic Signature Standards (HCFA-0049-P). We stated that we were proposing parallel and consistent requirements for safeguarding the privacy of protected health information. In § 164.518(c)(3) of the NPRM, we required covered entities to have safeguards to ensure that information was not used in violation of the requirements of this subpart or by people who did not have proper authorization to access the information.

We do not change the basic proposed requirements that covered entities have administrative, technical and physical safeguards to protect the privacy of protected health information. We combine the proposed requirements into a single standard that requires covered entities to safeguard protected health information from accidental or intentional use or disclosure that is a violation of the requirements of this rule ***82562** and to protect against the inadvertent disclosure of protected health information to persons

other than the intended recipient. Limitations on access to protected health information by the covered entities workforce will also be covered by the policies and procedures for "minimum necessary" use of protected health information, pursuant to § 164.514(d). We expect these provisions to work in tandem.

We do not prescribe the particular measures that covered entities must take to meet this standard, because the nature of the required policies and procedures will vary with the size of the covered entity and the type of activities that the covered entity undertakes. (That is, as with other provisions of this rule, this requirement is "scalable.") Examples of appropriate safeguards include requiring that documents containing protected health information be shredded prior to disposal, and requiring that doors to medical records departments (or to file cabinets housing such records) remain locked and limiting which personnel are authorized to have the key or pass-code. We intend this to be a common sense, scalable, standard. We do not require covered entities to guarantee the safety of protected health information against all assaults. Theft of protected health information may or may not signal a violation of this rule, depending on the circumstances and whether the covered entity had reasonable policies to protect against theft. Organizations such as the Association for Testing and Materials (ASTM) and the American Health Information Management Association (AHIMA) have developed a body of recommended practices for handling of protected health information that covered entities may find useful.

We note that the proposed HIPAA Security Standards would require covered entities to safeguard the privacy and integrity of health information. For electronic information, compliance with both regulations will be required.

In § 164.518(c)(2) of the NPRM we proposed requirements for verification procedures to establish identity and authority for permitted disclosures of protected health information.

In the final rule, this material has been moved to § 164.514(h).

Use or Disclosure of Protected Health Information by Whistleblowers

In § 164.518(c)(4) of the NPRM, this provision was entitled "Implementation Specification: Disclosures by whistleblowers." It is now retitled "Disclosures by whistleblowers," with certain changes, and moved to § 164.502(j)(1).

Complaints to the Covered Entity

In § 164.518(d) of the NPRM, we proposed to require covered entities to have a mechanism for receiving complaints from individuals regarding the health plan's or provider's compliance with the requirements of this proposed rule. We did not require that the health plan or provider develop a formal appeals mechanism, nor that "due process" or any similar standard be applied. Additionally, there was no requirement to respond in any particular manner or time frame.

We proposed two basic requirements for the complaint process. First, the covered health plan or health care provider would be required to identify in the notice of information practices a contact person or office for receiving complaints. Second, the health plan or provider would be required to maintain a record of the complaints that are filed and a brief explanation of their resolution, if any.

In the final rule, we retain the requirement for an internal complaint process for compliance with this rule, including the two basic requirements of identifying a contact person and documenting complaints received and their dispositions, if any. We expand the scope of complaints that covered entities must have a means of receiving to include complaints concerning violations of the covered entity's privacy practices, not just violations of the rule. For example, a covered entity must have a mechanism for receiving a complaint that patient information is used at a nursing station in a way that it can also be viewed by visitors to the hospital, regardless of whether the practices at the nursing stations might constitute a violation of this rule.

Sanctions

In § 164.518(e) of the NPRM, we proposed to require all covered entities to develop, and apply when appropriate, sanctions against members of its workforce who failed to comply with privacy policies or procedures of the covered entity or with the requirements of the rule. Covered entities would be required to develop and impose sanctions appropriate to the nature of the violation. The preamble stated that the type of sanction applied would vary depending on factors such as the severity of the violation, whether the violation was intentional or unintentional, and whether the violation indicated a pattern or practice of improper use or disclosure of protected health information. Sanctions could range from a warning to termination. The NPRM preamble language also stated that covered entities would be required to apply sanctions against business associates that violated the proposed rule.

In the final rule, we retain the requirement for sanctions against members of a covered entity's workforce. We also require a covered entity to have written policies and procedures for the application of appropriate sanctions for violations of this subpart and to document those sanctions. These sanctions do not apply to whistleblower activities that meet the provisions of § 164.502(j) or complaints, investigations, or opposition that meet the provisions of § 164.530(g)(2). We eliminate language regarding business associates from this section. Requirements with respect to business associates are stated in § 164.504.

Duty To Mitigate

In proposed § 164.518(f), we would have required covered entities to have policies and procedures for mitigating, to the extent practicable, any deleterious effect of a use or disclosure of protected health information in violation of the requirements of this subpart. The NPRM preamble also included specific language applying this requirement to harm caused by members of the covered entity's workforce and business associates.

With respect to business associates, the NPRM preamble but not the NPRM rule text, stated that covered entities would have a duty to take reasonable steps in response to breaches of contract terms. Covered entities generally would not be required to monitor the activities of their business associates, but would be required to take steps to address problems of which they become aware, and, where the breach was serious or repeated, would also be required to monitor the business associate's performance to ensure that the wrongful behavior had been remedied. Termination of the arrangement would be required only if it became clear that a business associate could not be relied upon to maintain the privacy of protected health information provided to it.

In the final rule, we clarify this requirement by imposing a duty for covered entities to mitigate any harmful effect of a use or disclosure of protected health information that is known to the covered entity. We apply the duty to mitigate to a violation of the covered entity's policies and procedures, not just a violation of the requirements of the subpart. We resolve the ambiguities in the NPRM by imposing this duty on covered entities for harm caused by ***82563** either members of their workforce or by their business associates.

We eliminate the language regarding potential breaches of business associate contracts from this section. All other requirements with respect to business associates are stated in § 164.504.

Refraining from Intimidating or Retaliatory Acts

In § 164.522(d)(4) of the NPRM, in the Compliance and Enforcement section, we proposed that one of the responsibilities of a covered entity would be to refrain from intimidating or retaliatory acts. Specifically, the rule provided that "[a] covered entity may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the filing of a complaint under this section, for testifying, assisting, participating in any manner in an investigation, compliance review, proceeding or hearing under this Act, or opposing any act or practice made unlawful by this subpart."

In the final rule, we continue to require that entities refrain from intimidating or retaliatory acts; however, the provisions have been moved to the Administrative Requirements provisions in § 164.530. This change is not just clerical; in making this change, we apply this provision to the privacy rule alone rather than to all the HIPAA administrative simplification rules. (The compliance and enforcement provisions that were in § 164 are now in Part 160, Subpart C.)

We continue to prohibit retaliation against individuals for filing a complaint with the Secretary, but also prohibit retaliation against any other person who files such a complaint. This is the case because the term "individual" is generally limited to the person who is the subject of the information. The final rule prohibits retaliation against persons, not just individuals, for testifying, assisting, or participating in an investigation, compliance review, proceeding or hearing under Part C of Title XI. The proposed regulation referenced the "Act," which is defined in Part 160 as the Social Security Act. Because we only intend to protect activities such as participation in investigations and hearings under the Administrative Simplification provisions of HIPAA, the final rule references Part C of Title XI of the Social Security Act.

The proposed rule would have prohibited retaliatory actions against individuals for opposing any act or practice made unlawful by this subpart. The final rule retains this provision, but applies it to any person, only if the person "has a good faith belief that the practice opposed is unlawful, the manner of the opposition is reasonable and does not involve a disclosure of protected health information in violation of this subpart." The final rule provides additional protections, which had been included in the preamble to the proposed rule. Specifically, we prohibit retaliatory actions against individuals who exercise any right, or participate in any process established by the privacy rule (Part 164 Subpart E), and include as an example the filing of a complaint with the covered entity.

Waiver of Rights

In the final regulation, but not in the proposed regulation, we provide that a covered entity may not require individuals to waive their rights to file a complaint with the Secretary or their other rights under this rule as a condition of the provision of treatment, payment, enrollment in a health plan or eligibility for benefits. This provision ensures that covered entities do not take away the rights that individuals have been provided in Parts 160 and 164.

Requirements for Policies and Procedures, and Documentation Requirements

In § 164.520 of the NPRM, we proposed to require covered entities to develop and document their policies and procedures for implementing the requirements of the rule. In the final regulation we retain this approach, but specify which standards must be documented in each of the relevant sections. In this section, we state the general administrative requirements applicable to all policies and procedures required throughout the regulation.

In § 164.530(i), (j), and (k) of the final rule, we amend the NPRM language in several respects. In § 164.530(i) we require that the policies and procedures be reasonably designed to comply with the standards, implementation specifications, and other requirements of the relevant part of the regulation, taking into account the size of the covered entity and the nature of the activities undertaken by the covered entity that relate to protected health information. However, we clarify that the requirements that policies and procedures be reasonably designed may not be interpreted to permit or excuse any action that violates the privacy regulation. Where the covered entity has stated in its notice that it reserves the right to change information practices, we allow the new practice to apply to information created or collected prior to the effective date of the new practice and establish requirements for making this change. We also establish the conditions for making changes if the covered entity has not reserved the right to change its practices.

We require covered entities to modify in a prompt manner their policies and procedures to comply with changes in relevant law and, where the change also affects the practices stated in the notice, to change the notice. We make clear that nothing in our requirements regarding changes to policies and procedures or changes to the notice may be used by a covered entity to excuse a failure to comply with applicable law.

In § 164.530(j), we require that the policies and procedures required throughout the regulation be maintained in writing, and that any other communication, action, activity, or designation that must be documented under this regulation be documented in writing. We note that "writing" includes electronic storage; paper records are not required. We also note that, if a covered entity is required to document the title of a person, we mean the job title or similar description of the relevant position or office.

We require covered entities to retain any documentation required under this rule for at least six years (the statute of limitations period for the civil penalties) from the date of the creation of the documentation, or the date when the document was last in effect, which ever is later. This generalizes the NPRM provision to cover all documentation required under the rule. The language on "last was in effect" is a change from the NPRM which was worded "unless a longer period applies under this subpart."

This approach is consistent with the approach recommended by the Joint Commission on Accreditation of Healthcare Organizations, and the National Committee for Quality Assurance, in its paper "Protecting Personal Health Information; A framework for Meeting the Challenges in a Managed Care Environment." This paper notes that "MCOs [Managed Care Organizations] should have clearly defined policies and procedures for dealing with confidentiality issues." (p. 29).

Standards for Certain Group Health Plans

We add a new provision (§ 164.530(k)) to clarify the administrative responsibilities of group health plans that offer benefits through issuers and HMOs. Specifically, a group health plan that provides benefits solely through an issuer or HMO, and that does not create, receive or maintain protected health ***82564** information other than summary health information or information regarding enrollment and disenrollment, is not subject to the requirements of this section regarding designation of a privacy official and contact person, workforce training, safeguards, complaints, mitigation, or policies and procedures. Such a group health plan is only subject to the requirements of this section regarding documentation with respect to its plan documents. Issuers and HMOs are covered entities under this rule, and thus have independent obligations to comply with this section with respect to the protected health information they maintain about the enrollees in such group health plans. The group health plans subject to this provision will have only limited protected health information. Therefore, imposing these requirements on the group health plan would impose burdens not outweighed by a corresponding enhancement in privacy protections.

Section 164.532—Transition Provisions

In the NPRM, we did not address the effect of the regulation on consents and authorizations covered entities obtained prior to the compliance date of the regulation.

In the final rule, we clarify that, in certain circumstances, a covered entity may continue to rely upon consents, authorizations, or other express legal permissions obtained prior to the compliance date of this regulation to use or disclose protected health information even if these consents, authorizations, or permissions do not meet the requirements set forth in §§ 164.506 or 164.508.

We realize that a covered entity may wish to rely upon a consent, authorization, or other express legal permission obtained from an individual prior to the compliance date of this regulation which permits the use or disclosure of individually identifiable health information for activities that come within treatment, payment, or health care operations (as defined in § 164.501), but that do not meet the requirements for consents set forth in § 164.506. In the final rule, we permit a covered entity to rely upon such consent, authorization, or permission to use or disclose protected health information that it created or received before the applicable compliance date of the regulation to carry out the treatment, payment, or health care operations as long as it meets two requirements. First, the covered entity may not make any use or disclosure that is expressly excluded from the consent, authorization, or permission. Second, the covered entity must comply with all limitations expressed in the consent, authorization, or permission. Thus, we do not require a covered entity to obtain a consent that meets the requirements of § 164.506 to use or disclose this previously obtained protected health information as long as the use or disclosure is consistent with the requirements of this section. However, a covered entity will need to obtain a consent that meets the requirements of § 164.506 to the extent that it is required to obtain a consent under § 164.506 from an individual before it may use or disclose any protected health information it creates or receives after the date by which it must comply with this rule.

Similarly, we recognize that a covered entity may wish to rely upon a consent, authorization, or other express legal permission obtained from an individual prior to the applicable compliance date of this regulation that specifically permits the covered

entity to use or disclose individually identifiable health information for activities other than to carry out treatment, payment, or health care operations. In the final rule, we permit a covered entity to rely upon such a consent, authorization, or permission to use or disclose protected health information that it created or received before the applicable compliance date of the regulation for the specific activities described in the consent, authorization, or permission as long as the covered entity complies with two requirements. First, the covered entity may not make any use or disclosure that is expressly excluded from the consent, authorization, or permission. Second, the covered entity must comply with all limitations expressed in the consent, authorization, or permission. Thus, we do not required a covered entity to obtain an authorization that meets the requirements of § 164.508 to use or disclose this previously obtained protected health information so long as the use or disclosure is consistent with the requirements of this section. However, a covered entity will need to obtain an authorization that meets the requirements of § 164.508, to the extent that it is required to obtain an authorization under this rule, from an individual before it may use or disclose any protected health information it creates or receives after the date by which it must comply with this rule.

Additionally, the final rule acknowledges that covered entities may wish to rely upon consents, authorizations, or other express legal permission obtained from an individual prior to the applicable compliance date for a specific research project that includes the treatment of individuals, such as clinical trials. These consents, authorizations, or permissions may specifically permit a use or disclosure of individually identifiable health information for purposes of the project. Alternatively, they may be general consents to participate in the project. A covered entity may use or disclose protected health information it created or received before or after to the applicable compliance date of this rule for purposes of the project provided that the covered entity complies with all limitations expressed in the consent, authorization, or permission.

If, pursuant to this section, a covered entity relies upon a previously obtained consent, authorization, or other express legal permission and agrees to a request for a restriction by an individual under § 164.522(a), any subsequent use or disclosure under that consent, authorization, or permission must comply with the agreed upon restriction as well.

We believe it is necessary to grandfather in previously obtained consents, authorizations, or other express legal permissions in these circumstances to ensure that important functions of the health care system are not impeded. We link the effectiveness of such consents, authorizations, or permissions in these circumstances to the applicable compliance date to give covered entities sufficient notice of the requirements set forth in §§ 164.506 and 164.508.

The rule does not change the past effectiveness of consents, authorizations, or other express legal permissions that do not come within this section. This means that uses or disclosures of individually identifiable health information made prior to the compliance date of this regulation are not subject to sanctions, even if they were made pursuant to documents or permissions that do not meet the requirements of this rule or were made without permission. This rule alters only the future effectiveness of the previously obtained consents, authorizations, or permissions. Covered entities are not required to rely upon these consents, authorizations, or permissions and may obtain new consents or authorizations that meet the applicable requirements of §§ 164.506 and 164.508.

When reaching this decision, we considered requiring all covered entities to obtain new consents or authorizations consistent with the requirements of §§ 164.506 and 164.508 before they would be able to use or disclose protected health information obtained ***82565** after the compliance date of these rules. We rejected this option because we recognize that covered entities may not always be able to obtain new consents or authorizations consistent with the requirements of §§ 164.506 and 164.508 from all individuals upon whose information they rely. We also refrained from impeding the rights of covered entities to exercise their interests in the records they have created. We do not require covered entities with existing records or databases to destroy or remove the protected health information for which they do not have valid consents or authorizations that meet the requirements of §§ 164.506 and 164.508. Covered entities may rely upon the consents, authorizations, or permissions they obtained from individuals prior to the applicable compliance date of this regulation consistent with the constraints of those documents and the requirements discussed above.

We note that if a covered entity obtains before the applicable compliance date of this regulation a consent that meets the requirements of § 164.506, an authorization that meets the requirements of § 164.508, or an IRB or privacy board waiver of authorization that meets the requirements of § 164.512(i), the consent, authorization, or waiver is effective for uses or disclosures that occur after the compliance date and that are consistent with the terms of the consent, authorization, or waiver.

Section 164.534—Compliance Dates for Initial Implementation of the Privacy Standards

In the NPRM, we provided that a covered entity must be in compliance with this subpart not later than 24 months following the effective date of this rule, except that a covered entity that is a small health plan must be in compliance with this subpart not later than 36 months following the effective date of the rule.

The final rule did not make any substantive changes. The format is changed so as to more clearly present the various compliance dates. The final rule lists the types of covered entities and then the various dates that would apply to each of these entities.

III. Section-by-Section Discussion of Comments

The following describes the provisions in the final regulation, and the changes we make to the proposed provisions section-by-section. Following each section are our responses to the comments to that section. This section of the preamble is organized to follow the corresponding section of the final rule, not the NPRM.

General Comments

We received many comments on the rule overall, not to a particular provision. We respond to those comments here. Similar comments, but directed to a specific provision in the proposed rule, are answered below in the corresponding section of this preamble.

Comments on the Need for Privacy Standards, and Effects of this Regulation on Current Protections

Comment: Many commenters expressed the opinion that federal legislation is necessary to protect the privacy of individuals' health information. One comment advocated Congressional efforts to provide a comprehensive federal health privacy law that would integrate the substance abuse regulations with the privacy regulation.

Response: We agree that comprehensive privacy legislation is urgently needed. This administration has urged the Congress to pass such legislation. While this regulation will improve the privacy of individuals' health information, only legislation can provide the full array of privacy protection that individuals need and deserve.

Comment: Many commenters noted that they do not go to a physician, or do not completely share health information with their physician, because they are concerned about who will have access to that information. Many physicians commented on their patients' reluctance to share information because of fear that their information will later be used against them.

Response: We agree that strong federal privacy protections are necessary to enhance patients' trust in the health care system.

Comment: Many commenters expressed concerns that this regulation will allow access to health information by those who today do not have such access, or would allow their physician to disclose information which may not lawfully be disclosed today. Many of these commenters stated that today, they consent to every disclosure of health information about them, and that absent their consent the privacy of their health information is “absolute.” Others stated that, today, health information is disclosed only pursuant to a judicial order. Several commenters were concerned that this regulation would override stronger state privacy protection.

Response: This regulation does not, and cannot, reduce current privacy protections. The statutory language of the HIPAA specifically mandates that this regulation does not preempt state laws that are more protective of privacy.

As discussed in more detail in later this preamble, while many people believe that they must be asked permission prior to any release of health information about them, current laws generally do not impose such a requirement. Similarly, as discussed in more detail later in this preamble, judicial review is required today only for a small proportion of releases of health information.

Comment: Many commenters asserted that today, medical records “belong” to patients. Others asserted that patients own their medical information and health care providers and insurance companies who maintain health records should be viewed as custodians of the patients' property.

Response: We do not intend to change current law regarding ownership of or responsibility for medical records. In developing this rule we reviewed current law on this and related issues, and built on that foundation.

Under state laws, medical records are often the property of the health care provider or medical facility that created them. Some state laws also provide patients with access to medical records or an ownership interest in the health information in medical records. However, these laws do not divest the health care provider or the medical facility of its ownership interest in medical records. These statutes typically provide a patient the right to inspect or copy health information from the medical record, but not the right to take the provider's original copy of an item in the medical record. If a particular state law provides greater ownership rights, this regulation leaves such rights in place.

Comment: Some commenters argued that the use and disclosure of sensitive personal information must be strictly regulated, and violation of such regulations should subject an entity to significant penalties and sanctions.

Response: We agree, and share the commenters' concern that the penalties in the HIPAA statute are not sufficient to fully protect individuals' privacy interests. The need for stronger penalties is among the reasons we believe Congress should pass comprehensive privacy legislation.

Comment: Many commenters expressed the opinion that the proposed ruled should provide stricter privacy protections. ***82566**

Response: We received nearly 52,000 comments on the proposed regulation, and make substantial changes to the proposal in response to those comments. Many of these changes will strengthen the protections that were proposed in the NPRM.

Comment: Many comments express concerns that their health information will be given to their employers.

Response: We agree that employer access to health information is a particular concern. In this final regulation, we make significant changes to the NPRM that clarify and provide additional safeguards governing when and how the health plans covered by this regulation may disclose health information to employers.

Comment: Several commenters argued that individuals should be able to sue for breach of privacy.

Response: We agree, but do not have the legislative authority to grant a private right of action to sue under this statute. Only Congress can grant that right.

Objections to Government Access to Protected Health Information

Comment: Many commenters urged the Department not to create a government database of health information, or a tracking system that would enable the government to track individuals health information.

Response: This regulation does not create such a database or tracking system, nor does it enable future creation of such a database. This regulation describes the ways in which health plans, health care clearinghouses, and certain health care providers may use and disclose identifiable health information with and without the individual's consent.

Comment: Many commenters objected to government access to or control over their health information, which they believe the proposed regulation would provide.

Response: This regulation does not increase current government access to health information. This rule sets minimum privacy standards. It does not require disclosure of health information, other than to the subject of the records or for enforcement of this rule. Health plans and health care providers are free to use their own professional ethics and judgement to adopt stricter policies for disclosing health information.

Comment: Some commenters viewed the NPRM as creating fewer hurdles for government access to protected health information than for access to protected health information by private organizations. Some health care providers commented that the NPRM would impose substantial new restrictions on private sector use and disclosure of protected health information, but would make government access to protected health information easy. One consumer advocacy group made the same observation.

Response: We acknowledge that many of the national priority purposes for which we allow disclosure of protected health information without consent or authorization are for government functions, and that many of the governmental recipients of such information are not governed by this rule. It is the role of government to undertake functions in the broader public interest, such as public health activities, law enforcement, identification of deceased individuals through coroners' offices, and military activities. It is these public purposes which can sometimes outweigh an individual's privacy interest. In this rule, we specify the circumstances in which that balance is tipped toward the public interest with respect to health information. We discuss the rationale behind each of these permitted disclosures in the relevant preamble sections below.

Miscellaneous Comments

Comment: Many commenters objected to the establishment of a unique identifier for health care or other purposes.

Response: This regulation does not create an identifier. We assume these comments refer to the unique health identifier that Congress directed the Secretary to promulgate under section1173(b) of the Social Security Act, added by section 262 of the HIPAA. Because of the public concerns about such an identifier, in the summer of 1998 Vice President Gore announced that the Administration would not promulgate such a regulation until comprehensive medical privacy protections were in place. In the fall of that year, Congress prohibited the Department from promulgating such an identifier, and that prohibition remains in place. The Department has no plans to promulgate a unique health identifier.

Comment: Many commenters asked that we withdraw the proposed regulation and not publish a final rule.

Response: Under section 264 of the HIPAA, the Secretary is required by Congress to promulgate a regulation establishing standards for health information privacy. Further, for the reasons explained throughout this preamble above, we believe that the need to protect health information privacy is urgent and that this regulation is in the public's interest.

Comment: Many commenters express the opinion that their consent should be required for all disclosure of their health information.

Response: We agree that consent should be required prior to release of health information for many purposes, and impose such a requirement in this regulation. Requiring consent prior to all release of health information, however, would unduly jeopardize public safety and make many operations of the health care system impossible. For example, requiring consent prior to release of health information to a public health official who is attempting to track the source of an outbreak or epidemic could endanger thousands of lives. Similarly, requiring consent before an oversight official could audit a health plan would make detection of

health care fraud all but impossible; it could take health plans months or years to locate and obtain the consent of all current and past enrollees, and the health plan would not have a strong incentive to do so. These uses of medical information are clearly in the public interest.

In this regulation, we must balance individuals' privacy interests against the legitimate public interests in certain uses of health information. Where there is an important public interest, this regulation imposes procedural safeguards that must be met prior to release of health information, in lieu of a requirement for consent. In some instances the procedural safeguards consist of limits on the circumstances in which information may be disclosed, in others the safeguards consist of limits on what information may be disclosed, and in other cases we require some form of legal process (e.g., a warrant or subpoena) prior to release of health information. We also allow disclosure of health information without consent where other law mandates the disclosures. Where such other law exists, another public entity has made the determination that the public interests outweigh the individual's privacy interests, and we do not upset that determination in this regulation. In short, we tailor the safeguards to match the specific nature of the public purpose. The specific safeguards are explained in each section of this regulation below.

Comment: Many comments address matters not relevant to this regulation, such as alternative fuels, hospital reimbursement, and gulf war syndrome.

Response: These and similar matters are not relevant to this regulation and will not be addressed further. ***82567**

Comment: A few commenters questioned why this level of detail is needed in response to the HIPAA Congressional mandate.

Response: This level of detail is necessary to ensure that individuals' rights with respect to their health information are clear, while also ensuring that information necessary for important public functions, such as protecting public health, promoting biomedical research, fighting health care fraud, and notifying family members in disaster situations, will not be impaired by this regulation. We designed this rule to reflect current practices and change some of them. The comments and our fact finding revealed the complexity of current health information practices, and we believe that the complexity entailed in reflecting those practices is better public policy than a perhaps simpler rule that disturbed important information flows.

Comment: A few comments stated that the goal of administrative simplification should never override the privacy of individuals.

Response: We believe that privacy is a necessary component of administrative simplification, not a competing interest.

Comment: At least one commenter said that the goal of administrative simplification is not well served by the proposed rule.

Response: Congress recognized that privacy is a necessary component of administrative simplification. The standardization of electronic health information mandated by the HIPAA that make it easier to share that information for legitimate purposes also make the inappropriate sharing of that information easier. For this reason, Congress included a mandate for privacy standards in this section of the HIPAA. Without appropriate privacy protections, public fear and instances of abuse would make it impossible for us to take full advantage of the administrative and costs benefits inherent in the administrative simplification standards.

Comment: At least one commenter asked us to require psychotherapists to assert any applicable legal privilege on patients' behalf when protected health information is requested.

Response: Whether and when to assert a claim of privilege on a patient's behalf is a matter for other law and for the ethics of the individual health care provider. This is not a decision that can or should be made by the federal government.

Comment: One commenter called for HHS to consider the privacy regulation in conjunction with the other HIPAA standards. In particular, this comment focused on the belief that the Security Standards should be compatible with the existing and emerging health care and information technology industry standards.

Response: We agree that both this regulation and the final Security Regulation should be compatible with existing and emerging technology industry standards. This regulation is "technology neutral." We do not mandate the use of any particular technologies, but rather set standards which can be met through a variety of means.

Comment: Several commenters claimed that the statutory authority given under HIPAA cannot provide meaningful privacy protections because many entities with access to protected health information, such as employers, worker's compensation carriers, and life insurance companies, are not covered entities. These commenters expressed support for comprehensive legislation to close many of the existing loopholes.

Response: We agree with the commenters that comprehensive legislation is necessary to provide full privacy protection and have called for members of Congress to pass such legislation to prevent unauthorized and potentially harmful uses and disclosures of information.

Part 160—Subpart A—General Provisions

Section 160.103—Definitions

Business Associate

The response to comments on the definition of "business partner," renamed in this rule as "business associate," is included in the response to comments on the requirements for business associates in the preamble discussion of § 164.504.

Covered Entity

Comment: A number of commenters urged the Department to expand or clarify the definition of "covered entity" to include certain entities other than health care clearinghouses, health plans, and health care providers who conduct standard transactions. For example, several commenters asked that the Department generally expand the scope of the rule to cover all entities that receive or maintain individually identifiable health information; others specifically urged the Department to cover employers, marketing firms, and legal entities that have access to individually identifiable health information. Some commenters asked that life insurance and casualty insurance carriers be considered covered entities for purposes of this rule. One commenter recommended that Pharmacy Benefit Management (PBM) companies be considered covered entities so that they may use and disclose protected health information without authorization.

In addition, a few commenters asked the Department to clarify that the definition includes providers who do not directly conduct electronic transactions if another entity, such as a billing service or hospital, does so on their behalf.

Response: We understand that many entities may use and disclose individually identifiable health information. However, our jurisdiction under the statute is limited to health plans, health care clearinghouses, and health care providers who transmit any health information electronically in connection with any of the standard financial or administrative transactions in section 1173(a) of the Act. These are the entities referred to in section 1173(a)(1) of the Act and thus listed in § 160.103 of the final rule. Consequently, once protected health information leaves the purview of one of these covered entities, their business associates, or other related entities (such as plan sponsors), the information is no longer afforded protection under this rule. We again highlight the need for comprehensive federal legislation to eliminate such gaps in privacy protection.

We also provide the following clarifications with regard to specific entities.

We clarify that employers and marketing firms are not covered entities. However, employers may be plan sponsors of a group health plan that is a covered entity under the rule. In such a case, specific requirements apply to the group health plan. See the preamble on § 164.504 for a discussion of specific "firewall" and other organizational requirements for group health plans and

their employer sponsors. The final rule also contains provisions addressing when an insurance issuer providing benefits under a group health plan may disclose summary health information to a plan sponsor.

With regard to life and casualty insurers, we understand that such benefit providers may use and disclose individually identifiable health information. However, Congress did not include life insurers and casualty insurance carriers as "health plans" for the purposes of this rule and therefore they are not covered entities. See the discussion regarding the definition of "health plan" and excepted benefits. ***82568**

In addition, we clarify that a PBM is a covered entity only to the extent that it meets the definition of one or more of the entities listed in § 160.102. When providing services to patients through managed care networks, it is likely that a PBM is acting as a business associate of a health plan, and may thus use and disclose protected health information pursuant to the relevant provisions of this rule. PBMs may also be business associates of health care providers. See the preamble sections on §§ 164.502, 164.504, and 164.506 for discussions of the specific requirements related to business associates and consent.

Lastly, we clarify that health care providers who do not submit HIPAA transactions in standard form become covered by this rule when other entities, such as a billing service or a hospital, transmit standard electronic transactions on their behalf. The provider could not circumvent these requirements by assigning the task to a contractor.

Comment: Many commenters urged the Department to restrict or clarify the definition of "covered entity" to exclude certain entities, such as department-operated hospitals (public hospitals); state Crime Victim Compensation Programs; employers; and certain lines of insurers, such as workers' compensation insurers, property and casualty insurers, reinsurers, and stop-loss insurers. One commenter expressed concern that clergy, religious practitioners, and other faith-based service providers would have to abide by the rule and asked that the Department exempt prayer healing and non-medical health care.

Response: The Secretary provides the following clarifications in response to these comments. To the extent that a "department-operated hospital" meets the definition of a "health care provider" and conducts any of the standard transactions, it is a covered entity for the purposes of this rule. We agree that a state Crime Victim Compensation Program is not a covered entity if it is not a health care provider that conducts standard transactions, health plan, or health care clearinghouse. Further, as described above, employers are not covered entities.

In addition, we agree that workers' compensation insurers, property and casualty insurers, reinsurers, and stop-loss insurers are not covered entities, as they do not meet the statutory definition of "health plan." See further discussion in the preamble on § 160.103 regarding the definition of "health plan." However, activities related to ceding, securing, or placing a contract for reinsurance, including stop-loss insurance, are health care operations in the final rule. As such, reinsurers and stop-loss insurers may obtain protected health information from covered entities.

Also, in response to the comment regarding religious practitioners, the Department clarifies that "health care" as defined under the rule does not include methods of healing that are solely spiritual. Therefore, clergy or other religious practitioners that provide solely religious healing services are not health care providers within the meaning of this rule, and consequently not covered entities for the purposes of this rule.

Comment: A few commenters expressed general uncertainty and requested clarification as to whether certain entities were covered entities for the purposes of this rule. One commenter was uncertain as to whether the rule applies to certain social service entities, in addition to clinical social workers that the commenter believes are providers. Other commenters asked whether researchers or non-governmental entities that collect and analyze patient data to monitor and evaluate quality of care are covered entities. Another commenter requested clarification regarding the definition's application to public health agencies that also are health care providers as well as how the rule affects public health agencies in their data collection from covered entities.

Response: Whether the professionals described in these comments are covered by this rule depends on the activities they undertake, not on their profession or degree. The definitions in this rule are based on activities and functions, not titles. For example, a social service worker whose activities meet this rule's definition of health care will be a health care provider. If that social service worker also transmits information in a standard HIPAA transaction, he or she will be a covered health entity under this rule. Another social service worker may provide services that do not meet the rule's definition of health care, or may not transmit information in a standard transaction. Such a social service worker is not a covered entity under this rule. Similarly, researchers in and of themselves are not covered entities. However, researchers may also be health care providers if they provide health care. In such cases, the persons, or entities in their role as health care providers may be covered entities if they conduct standard transactions.

With regard to public health agencies that are also health care providers, the health care provider "component" of the agency is the covered entity if that component conducts standard transactions. See discussion of "health care components" below. As to the data collection activities of a public health agency, the final rule in § 164.512(b) permits a covered entity to disclose protected health information to public health authorities under specified circumstances, and permits public health agencies that are also covered entities to use protected health information for these purposes. See § 164.512(b) for further details.

Comment: A few commenters requested that the Department clarify that device manufacturers are not covered entities. They stated that the proposal did not provide enough guidance in cases where the "manufacturer supplier" has only one part of its business that acts as the "supplier," and additional detail is needed about the relationship of the "supplier component" of the company to the rest of the business. Similarly, another commenter asserted that drug, biologics, and device manufacturers should not be covered entities simply by virtue of their manufacturing activities.

Response: We clarify that if a supplier manufacturer is a Medicare supplier, then it is a health care provider, and it is a covered entity if it conducts standard transactions. Further, we clarify that a manufacturer of supplies related to the health of a particular individual, e.g., prosthetic devices, is a health care provider because the manufacturer is providing "health care" as defined in the rule. However, that manufacturer is a covered entity only if it conducts standard transactions. We do not intend that a manufacturer of supplies that are generic and not customized or otherwise specifically designed for particular individuals, e.g., ace bandages for a hospital, is a health care provider. Such a manufacturer is not providing "health care" as defined in the rule and is therefore not a covered entity. We note that, even if such a manufacturer is a covered entity, it may be an "indirect treatment provider" under this rule, and thus not subject to all of the rule's requirements.

With regard to a "supplier component," the final rule addresses the status of the unit or unit(s) of a larger entity that constitute a "health care component." See further discussion under § 164.504 of this preamble.

Finally, we clarify that drug, biologics, and device manufacturers are not health care providers simply by virtue of their manufacturing activities. The manufacturer must be providing health care consistent with the final ***82569** rule's definition in order to be considered a health care provider.

Comment: A few commenters asked that the Department clarify that pharmaceutical manufacturers are not covered entities. It was explained that pharmaceutical manufacturers provide support and guidance to doctors and patients with respect to the proper use of their products, provide free products for doctors to distribute to patients, and operate charitable programs that provide pharmaceutical drugs to patients who cannot afford to buy the drugs they need.

Response: A pharmaceutical manufacturer is only a covered entity if the manufacturer provides "health care" according to the rule's definition and conducts standard transactions. In the above case, a pharmaceutical manufacturer that provides support and guidance to doctors and patients regarding the proper use of their products is providing "health care" for the purposes of this rule, and therefore, is a health care provider to the extent that it provides such services. The pharmaceutical manufacturer that is a health care provider is only a covered entity, however, if it conducts standard transactions. We note that this rule permits a covered entity to disclose protected health information to any person for treatment purposes, without specific authorization from

the individual. Therefore, a covered health care provider is permitted to disclose protected health information to a pharmaceutical manufacturer for treatment purposes. Providing free samples to a health care provider does not in itself constitute health care. For further analysis of pharmacy assistance programs, see response to comment on § 164.501, definition of "payment."

Comment: Several commenters asked about the definition of "covered entity" and its application to health care entities within larger organizations.

Response: A detailed discussion of the final rule's organizational requirements and firewall restrictions for "health care components" of larger entities, as well as for affiliated, and other entities is found at the discussion of § 164.504 of this preamble. The following responses to comments provide additional information with respect to particular "component entity" circumstances.

Comment: Several commenters asked that we clarify the definition of covered entity to state that with respect to persons or organizations that provide health care or have created health plans but are primarily engaged in other unrelated businesses, the term "covered entity" encompasses only the health care components of the entity. Similarly, others recommended that only the component of a government agency that is a provider, health plan, or clearinghouse should be considered a covered entity.

Other commenters requested that we revise proposed § 160.102 to apply only to the component of an entity that engages in the transactions specified in the rule. Commenters stated that companies should remain free to employ licensed health care providers and to enter into corporate relationships with provider institutions without fear of being considered to be a covered entity. Another commenter suggested that the regulation not apply to the provider-employee or employer when neither the provider nor the company are a covered entity.

Some commenters specifically argued that the definition of "covered entity" did not contemplate an integrated health care system and one commenter stated that the proposal would disrupt the multi-disciplinary, collaborative approach that many take to health care today by treating all components as separate entities. Commenters, therefore, recommended that the rule treat the integrated entity, not its constituent parts, as the covered entity.

A few commenters asked that the Department further clarify the definition with respect to the unique organizational models and relationships of academic medical centers and their parent universities and the rules that govern information exchange within the institution. One commenter asked whether faculty physicians who are paid by a medical school or faculty practice plan and who are on the medical staff of, but not paid directly by, a hospital are included within the covered entity. Another commenter stated that it appears that only the health center at an academic institution is the covered entity. Uncertainty was also expressed as to whether other components of the institution that might create protected health information only incidentally through the conduct of research would also be covered.

Response: The Department understands that in today's health care industry, the relationships among health care entities and non-health care organizations are highly complex and varied. Accordingly, the final rule gives covered entities some flexibility to segregate or aggregate its operations for purposes of the application of this rule. The new component entity provision can be found at §§ 164.504(b)-(c). In response to the request for clarification on whether the rule would apply to a research component of the covered entity, we point out that if the research activities fall outside of the health care component they would not be subject to the rule. One organization may have one or several "health care component(s)" that each perform one or more of the health care functions of a covered entity, i.e., health care provider, health plan, health care clearinghouse. In addition, the final rule permits covered entities that are affiliated, i.e., share common ownership or control, to designate themselves, or their health care components, together to be a single covered entity for purposes of the rule.

It appears from the comments that there is not a common understanding of the meaning of "integrated delivery system." Arrangements that apply this label to themselves operate and share information many different ways, and may or may not be financially or clinically integrated. In some cases, multiple entities hold themselves out as one enterprise and engage together

in clinical or financial activities. In others, separate entities share information but do not provide treatment together or share financial risk. Many health care providers participate in more than one such arrangement.

Therefore, we do not include a separate category of "covered entity" under this rule for "integrated delivery systems" but instead accommodate the operations of these varied arrangements through the functional provisions of the rule. For example, covered entities that operate as "organized health care arrangements" as defined in this rule may share protected health information for the operation of such arrangement without becoming business associates of one another. Similarly, the regulation does not require a business associate arrangement when protected health information is shared for purposes of providing treatment. The application of this rule to any particular "integrated system" will depend on the nature of the common activities the participants in the system perform. When the participants in such an arrangement are "affiliated" as defined in this rule, they may consider themselves a single covered entity (see § 164. 504).

The arrangements between academic health centers, faculty practice plans, universities, and hospitals are similarly diverse. We cannot describe a blanket rule that covers all such arrangements. The application of this rule will depend on the purposes for which the participants in such arrangements share protected health information, whether some or all participants are under common ownership or control, and similar matters. We note that physicians who have staff privileges at a covered ***82570** hospital do not become part of that hospital covered entity by virtue of having such privileges.

We reject the recommendation to apply the rule only to components of an entity that engage in the transactions. This would omit as covered entities, for example, the health plan components that do not directly engage in the transactions, including components that engage in important health plan functions such as coverage determinations and quality review. Indeed, we do not believe that the statute permits this result with respect to health plans or health care clearinghouses as a matter of negative implication from section 1172(a)(3). We clarify that only a health care provider must conduct transactions to be a covered entity for purposes of this rule.

We also clarify that health care providers (such as doctors or nurses) who work for a larger organization and do not conduct transactions on their own behalf are workforce members of the covered entity, not covered entities themselves.

Comment: A few commenters asked the Department to clarify the definition to provide that a multi-line insurer that sells insurance coverages, some of which do and others which do not meet the definition of "health plan," is not a covered entity with respect to actions taken in connection with coverages that are not "health plans."

Response: The final rule clarifies that the requirements below apply only to the organizational unit or units of the organization that are the "health care component" of a covered entity, where the "covered functions" are not the primary functions of the entity. Therefore, for a multi-line insurer, the "health care component" is the insurance line(s) that conduct, or support the conduct of, the health care function of the covered entity. Also, it should be noted that excepted benefits, such as life insurance, are not included in the definition of "health plan." (See preamble discussion of § 164.504).

Comment: A commenter questioned whether the Health Care Financing Administration (HCFA) is a covered entity and how HCFA will share data with Medicare managed care organizations. The commenter also questioned why the regulation must apply to Medicaid since the existing Medicaid statute requires that states have privacy standards in place. It was also requested that the Department provide a definition of "health plan" to clarify that state Medicaid Programs are considered as such.

Response: HCFA is a covered entity because it administers Medicare and Medicaid, which are both listed in the statute as health plans. Medicare managed care organizations are also covered entities under this regulation. As noted elsewhere in this preamble, covered entities that jointly administer a health plan, such as Medicare + Choice, are both covered entities, and are not business associates of each other by virtue of such joint administration.

We do not exclude state Medicaid programs. Congress explicitly included the Medicaid program as a covered health plan in the HIPAA statute.

Comment: A commenter asked the Department to provide detailed guidance as to when providers, plans, and clearinghouses become covered entities. The commenter provided the following example: if a provider submits claims only in paper form, and a coordination of benefits (COB) transaction is created due to other insurance coverage, will the original provider need to be notified that the claim is now in electronic form, and that it has become a covered entity? Another commenter voiced concern as to whether physicians who do not conduct electronic transactions would become covered entities if another entity using its records downstream transmits information in connection with a standard transaction on their behalf.

Response: We clarify that health care providers who submit the transactions in standard electronic form, health plans, and health care clearinghouses are covered entities if they meet the respective definitions. Health care providers become subject to the rule if they conduct standard transactions. In the above example, the health care provider would not be a covered entity if the coordination of benefits transaction was generated by a payor.

We also clarify that health care providers who do not submit transactions in standard form become covered by this rule when other entities, such as a billing service or a hospital, transmit standard electronic transactions on the providers' behalf. However, where the downstream transaction is not conducted on behalf of the health care provider, the provider does not become a covered entity due to the downstream transaction.

Comment: Several commenters discussed the relationship between section 1179 of the Act and the privacy regulations. One commenter suggested that HHS retain the statement that a covered entity means “the entities to which part C of title XI of the Act applies.” In particular, the commenter observed that section 1179 of the Act provides that part C of title XI of the Act does not apply to financial institutions or to entities acting on behalf of such institutions that are covered by the section 1179 exemption. Thus, under the definition of covered entity, they comment that financial institutions and other entities that come within the scope of the section 1179 exemption are appropriately not covered entities.

Other commenters maintained that section 1179 of the Act means that the Act's privacy requirements do not apply to the request for, or the use or disclosure of, information by a covered entity with respect to payment: (a) For transferring receivables; (b) for auditing; (c) in connection with—(i) a customer dispute; or (ii) an inquiry from or to a customer; (d) in a communication to a customer of the entity regarding the customer's transactions payment card, account, check, or electronic funds transfer; (e) for reporting to consumer reporting agencies; or (f) for complying with: (i) a civil or criminal subpoena; or (ii) a federal or state law regulating the entity. These companies expressed concern that the proposed rule did not include the full text of section 1179 when discussing the list of activities that were exempt from the rule's requirements. Accordingly, they recommended including in the final rule either a full listing of or a reference to section 1179's full list of exemptions. Furthermore, these firms opposed applying the proposed rule's minimum necessary standard for disclosure of protected health information to financial institutions because of section 1179.

These commenters suggest that in light of section 1179, HHS lacks the authority to impose restrictions on financial institutions and other entities when they engage in activities described in that section. One commenter expressed concern that even though proposed § 164.510(i) would have permitted covered entities to disclose certain information to financial institutions for banking and payment processes, it did not state clearly that financial institutions and other entities described in section 1179 are exempt from the rule's requirements.

Response: We interpret section 1179 of the Act to mean that entities engaged in the activities of a financial institution, and those acting on behalf of a financial institution, are not subject to this regulation when they are engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments for a financial institution. The statutory reference to 12 U.S.C. 3401 indicates that Congress chose to adopt the definition of financial institutions found ***82571** in the Right to Financial Privacy Act, which defines financial institutions as any office of a bank, savings bank, card issuer, industrial

loan company, trust company, savings association, building and loan, homestead association, cooperative bank, credit union, or consumer finance institution located in the United States or one of its Territories. Thus, when we use the term "financial institution" in this regulation, we turn to the definition with which Congress provided us. We interpret this provision to mean that when a financial institution, or its agent on behalf of the financial institution, conducts the activities described in section 1179, the privacy regulation will not govern the activity.

If, however, these activities are performed by a covered entity or by another entity, including a financial institution, on behalf of a covered entity, the activities are subject to this rule. For example, if a bank operates the accounts payable system or other "back office" functions for a covered health care provider, that activity is not described in section 1179. In such instances, because the bank would meet the rule's definition of "business associate," the provider must enter into a business associate contract with the bank before disclosing protected health information pursuant to this relationship. However, if the same provider maintains an account through which he/she cashes checks from patients, no business associate contract would be necessary because the bank's activities are not undertaken for or on behalf of the covered entity, and fall within the scope of section 1179. In part to give effect to section 1179, in this rule we do not consider a financial institution to be acting on behalf of a covered entity when it processes consumer-conducted financial transactions by debit, credit or other payment card, clears checks, initiates or processes electronic funds transfers, or conducts any other activity that directly facilitates or effects the transfer of funds for compensation for health care.

We do not agree with the comment that section 1179 of the Act means that the privacy regulation's requirements cannot apply to the activities listed in that section; rather, it means that the entities expressly mentioned, financial institutions (as defined in the Right to Financial Privacy Act), and their agents that engage in the listed activities for the financial institution are not within the scope of the regulation. Nor do we interpret section 1179 to support an exemption for disclosures to financial institutions from the minimum necessary provisions of this regulation.

Comment: One commenter recommended that HHS include a definition of "entity" in the final rule because HIPAA did not define it. The commenter explained that in a modern health care environment, the organization acting as the health plan or health care provider may involve many interrelated corporate entities and that this could lead to difficulties in determining what "entities" are actually subject to the regulation.

Response: We reject the commenter's suggestion. We believe it is clear in the final rule that the entities subject to the regulation are those listed at § 160.102. However, we acknowledge that how the rule applies to integrated or other complex health systems needs to be addressed; we have done so in § 164.504 and in other provisions, such as those addressing organized health care arrangements.

Comment: The preamble should clarify that self-insured group health and workmen's compensation plans are not covered entities or business partners.

Response: In the preamble to the proposed rule we stated that certain types of insurance entities, such as workers' compensation, would not be covered entities under the rule. We do not change this position in this final rule. The statutory definition of health plan does not include workers' compensation products, and the regulatory definition of the term specifically excludes them. However, HIPAA specifically includes most group health plans within the definition of "health plan."

Comment: A health insurance issuer asserted that health insurers and third party administrators are usually required by employers to submit reports describing the volume, amount, payee, basis for services rendered, types of claims paid and services for which payment was requested on behalf of it covered employees. They recommended that the rule permit the disclosure of protected health information for such purposes.

Response: We agree that health plans should be able to disclose protected health information to employers sponsoring health plans under certain circumstances. Section 164.504(f) explains the conditions under which protected health information may

be disclosed to plan sponsors. We believe that this provision gives sponsors access to the information they need, but protects individual's information to the extent possible under our legislative authority.

Group Health Plan

For response to comments relating to "group health plan," see the response to comments on "health plan" below and the response to comments on § 164.504.

Health Care

Comment: A number of commenters asked that we include disease management activities and other similar health improvement programs, such as preventive medicine, health education services and maintenance, health and case management, and risk assessment, in the definition of "health care." Commenters maintained that the rule should avoid limiting technological advances and new health care trends intended to improve patient "health care."

Response: Review of these and other comments, and our fact-finding, indicate that there are multiple, different, understandings of the definition of these terms. Therefore, rather than create a blanket rule that includes such terms in or excludes such terms from the definition of "health care," we define health care based on the underlying activities that constitute health care. The activities described by these commenters are considered "health care" under this rule to the extent that they meet this functional definition. Listing activities by label or title would create the risk that important activities would be left out and, given the lack of consensus on what these terms mean, could also create confusion.

Comment: Several commenters urged that the Department clarify that the activities necessary to procure and distribute eyes and eye tissue will not be hampered by the rule. Some of these commenters explicitly requested that we include "eyes and eye tissue" in the list of procurement biologicals as well as "eye procurement" in the definition of "health care." In addition, it was argued that "administration to patients" be excluded in the absence of a clear definition. Also, commenters recommended that the definition include other activities associated with the transplantation of organs, such as processing, screening, and distribution.

Response: We delete from the definition of "health care" activities related to the procurement or banking of blood, sperm, organs, or any other tissue for administration to patients. We do so because persons who make such donations are not seeking to be treated, diagnosed, or assessed or otherwise seeking health care for themselves, but are seeking to contribute to the health care of others. In addition, the nature of ***82572** these activities entails a unique kind of information sharing and tracking necessary to safeguard the nation's organ and blood supply, and those seeking to donate are aware that this information sharing will occur. Consequently, such procurement or banking activities are not considered health care and the organizations that perform such activities are not considered health care providers for purposes of this rule.

With respect to disclosure of protected health information by covered entities to facilitate cadaveric organ and tissue donation, the final rule explicitly permits a covered entity to disclose protected health information without authorization, consent, or agreement to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating donation and transplantation. See § 164.512(h). We do not include blood or sperm banking in this provision because, for those activities, there is direct contact with the donor, and thus opportunity to obtain the individual's authorization.

Comment: A large number of commenters urged that the term "assessment" be included in the list of services in the definition, as "assessment" is used to determine the baseline health status of an individual. It was explained that assessments are conducted in the initial step of diagnosis and treatment of a patient. If assessment is not included in the list of services, they pointed out that the services provided by occupational health nurses and employee health information may not be covered.

Response: We agree and have added the term "assessment" to the definition to clarify that this activity is considered "health care" for the purposes of the rule.

Comment: One commenter asked that we revise the definition to explicitly exclude plasmapheresis from paragraph (3) of the definition. It was explained that plasmapheresis centers do not have direct access to health care recipients or their health information, and that the limited health information collected about plasma donors is not used to provide health care services as indicated by the definition of health care.

Response: We address the commenters' concerns by removing the provision related to procurement and banking of human products from the definition.

Health Care Clearinghouse

Comment: The largest set of comments relating to health care clearinghouses focused on our proposal to exempt health care clearinghouses from the patient notice and access rights provisions of the regulation. In our NPRM, we proposed to exempt health care clearinghouses from certain provisions of the regulation that deal with the covered entities' notice of information practices and consumers' rights to inspect, copy, and amend their records. The rationale for this exemption was based on our belief that health care clearinghouses engage primarily in business-to-business transactions and do not initiate or maintain direct relationships with individuals. We proposed this position with the caveat that the exemptions would be void for any health care clearinghouse that had direct contact with individuals in a capacity other than that of a business partner. In addition, we indicated that, in most instances, clearinghouses also would be considered business partners under this rule and would be bound by their contracts with covered plans and providers. They also would be subject to the notice of information practices developed by the plans and providers with whom they contract.

Commenters stated that, although health care clearinghouses do not have direct contact with individuals, they do have individually identifiable health information that may be subject to misuse or inappropriate disclosure. They expressed concern that we were proposing to exempt health care clearinghouses from all or many aspects of the regulation. These commenters suggested that we either delete the exemption or make it very narrow, specific and explicit in the final regulatory text.

Clearinghouse commenters, on the other hand, were in agreement with our proposal, including the exemption provision and the provision that the exemption is voided when the entity does have direct contact with individuals. They also stated that a health care clearinghouse that has a direct contact with individuals is no longer a health care clearinghouse as defined and should be subject to all requirements of the regulation.

Response: In the final rule, where a clearinghouse creates or receives protected health information as a business associate of another covered entity, we maintain the exemption for health care clearinghouses from certain provisions of the regulation dealing with the notice of information practices and patient's direct access rights to inspect, copy and amend records (§§ 164.524 and 164.526), on the grounds that a health care clearinghouse is engaged in business-to-business operations, and is not dealing directly with individuals. Moreover, as business associates of plans and providers, health care clearinghouses are bound by the notices of information practices of the covered entities with whom they contract.

Where a health care clearinghouse creates or receives protected health information other than as a business associate, however, it must comply with all the standards, requirements, and implementation specifications of the rule. We describe and delimit the exact nature of the exemption in the regulatory text. See § 164.500(b). We will monitor developments in this sector should the basic business-to-business relationship change.

Comment: A number of comments relate to the proposed definition of health care clearinghouse. Many commenters suggested that we expand the definition. They suggested that additional types of entities be included in the definition of health care clearinghouse, specifically medical transcription services, billing services, coding services, and “intermediaries.” One commenter suggested that the definition be expanded to add entities that receive standard transactions, process them and clean them up, and then send them on, without converting them to any standard format. Another commenter suggested that the health care clearinghouse definition be expanded to include entities that do not perform translation but may receive protected

health information in a standard format and have access to that information. Another commenter stated that the list of covered entities should include any organization that receives or maintains individually identifiable health information. One organization recommended that we expand the health care clearinghouse definition to include the concept of a research data clearinghouse, which would collect individually identifiable health information from other covered entities to generate research data files for release as de-identified data or with appropriate confidentiality safeguards. One commenter stated that HHS had gone beyond Congressional intent by including billing services in the definition.

Response: We cannot expand the definition of "health care clearinghouse" to cover entities not covered by the definition of this term in the statute. In the final regulation, we ***82573** make a number of changes to address public comments relating to definition. We modify the definition of health care clearinghouse to conform to the definition published in the Transactions Rule (with the addition of a few words, as noted above). We clarify in the preamble that, while the term "health care clearinghouse" may have other meanings and connotations in other contexts, for purposes of this regulation an entity is considered a health care clearinghouse only to the extent that it actually meets the criteria in our definition. Entities performing other functions but not meeting the criteria for a health care clearinghouse are not clearinghouses, although they may be business associates. Billing services are included in the regulatory definition of "health care clearinghouse," if they perform the specified clearinghouse functions. Although we have not added or deleted any entities from our original definition, we will monitor industry practices and may add other entities in the future as changes occur in the health system.

Comment: Several commenters suggested that we clarify that an entity acting solely as a conduit through which individually identifiable health information is transmitted or through which protected health information flows but is not stored is not a covered entity, e.g., a telephone company or Internet Service Provider. Other commenters indicated that once a transaction leaves a provider or plan electronically, it may flow through several entities before reaching a clearinghouse. They asked that the regulation protect the information in that interim stage, just as the security NPRM established a chain of trust arrangement for such a network. Others noted that these "conduit" entities are likely to be business partners of the provider, clearinghouse or plan, and we should clarify that they are subject to business partner obligations as in the proposed Security Rule.

Response: We clarify that entities acting as simple and routine communications conduits and carriers of information, such as telephone companies and Internet Service Providers, are not clearinghouses as defined in the rule unless they carry out the functions outlined in our definition. Similarly, we clarify that value added networks and switches are not health care clearinghouses unless they carry out the functions outlined in the definition, and clarify that such entities may be business associates if they meet the definition in the regulation.

Comment: Several commenters, including the large clearinghouses and their trade associations, suggested that we not treat health care clearinghouses as playing a dual role as covered entity and business partner in the final rule because such a dual role causes confusion as to which rules actually apply to clearinghouses. In their view, the definition of health care clearinghouse is sufficiently clear to stand alone and identify a health care clearinghouse as a covered entity, and allows health care clearinghouses to operate under one consistent set of rules.

Response: For reasons explained in § 164.504 of this preamble, we do not create an exception to the business associate requirements when the business associate is also a covered entity. We retain the concept that a health care clearinghouse may be a covered entity and a business associate of a covered entity under the regulation. As business associates, they would be bound by their contracts with covered plans and providers.

Health Care Provider

Comment: One commenter pointed out that the preamble referred to the obligations of providers and did not use the term, "covered entity," and thus created ambiguity about the obligations of health care providers who may be employed by persons other than covered entities, e.g., pharmaceutical companies. It was suggested that a better reading of the statute and rule is that where neither the provider nor the company is a covered entity, the rule does not impose an obligation on either the provider-employee or the employer.

Response: We agree. We use the term "covered entity" whenever possible in the final rule, except for the instances where the final rule treats the entities differently, or where use of the term "health care provider" is necessary for purposes of illustrating an example.

Comment: Several commenters stated that the proposal's definition was broad, unclear, and/or confusing. Further, we received many comments requesting clarification as to whether specific entities or persons were "health care providers" for the purposes of our rule. One commenter questioned whether affiliated members of a health care group (even though separate legal entities) would be considered as one primary health care provider.

Response: We permit legally distinct covered entities that share common ownership or control to designate themselves together to be a single covered entity. Such organizations may promulgate a single shared notice of information practices and a consent form. For more detailed information, see the preamble discussion of § 164.504(d).

We understand the need for additional guidance on whether specific entities or persons are health care providers under the final rule. We provide guidance below and will provide additional guidance as the rule is implemented.

Comment: One commenter observed that sections 1171(3), 1861(s) and 1861(u) of the Act do not include pharmacists in the definition of health care provider or pharmacist services in the definition of "medical or other health services," and questioned whether pharmacists were covered by the rule.

Response: The statutory definition of "health care provider" at section 1171(3) includes "any other person or organization who furnishes, bills, or is paid for health care in the normal course of business." Pharmacists' services are clearly within this statutory definition of "health care." There is no basis for excluding pharmacists who meet these statutory criteria from this regulation.

Comment: Some commenters recommended that the scope of the definition be broadened or clarified to cover additional persons or organizations. Several commenters argued for expanding the reach of the health care provider definition to cover entities such as state and local public health agencies, maternity support services (provided by nutritionists, social workers, and public health nurses and the Special Supplemental Nutrition Program for Women, Infants and Children), and those companies that conduct cost-effectiveness reviews, risk management, and benchmarking studies. One commenter queried whether auxiliary providers such as child play therapists, and speech and language therapists are considered to be health care providers. Other commenters questioned whether "alternative" or "complementary" providers, such as naturopathic physicians and acupuncturists would be considered health care providers covered by the rule.

Response: As with other aspects of this rule, we do not define "health care provider" based on the title or label of the professional. The professional activities of these kinds of providers vary; a person is a "health care provider" if those activities are consistent with the rule's definition of "health care provider." Thus, health care providers include persons, such as those noted by the commenters, to the extent that they meet the definition. We note that health care providers are only ***82574** subject to this rule if they conduct certain transactions. See the definition of "covered entity."

However companies that conduct cost-effectiveness reviews, risk management, and benchmarking studies are not health care providers for the purposes of this rule unless they perform other functions that meet the definition. These entities would be business associates if they perform such activities on behalf of a covered entity.

Comment: Another commenter recommended that the Secretary expand the definition of health care provider to cover health care providers who transmit or "or receive" any health care information in electronic form.

Response: We do not accept this suggestion. Section 1172(a)(3) states that providers that "transmit" health information in connection with one of the HIPAA transactions are covered, but does not use the term "receive" or a similar term.

Comment: Some comments related to online companies as health care providers and covered entities. One commenter argued that there was no reason "why an Internet pharmacy should not also be covered" by the rule as a health care provider. Another commenter stated that online health care service and content companies, including online medical record companies, should be covered by the definition of health care provider. Another commenter pointed out that the definitions of covered entities cover "Internet providers who 'bill' or are 'paid' for health care services or supplies, but not those who finance those services in other ways, such as through sale of identifiable health information or advertising." It was pointed out that thousands of Internet sites use information provided by individuals who access the sites for marketing or other purposes.

Response: We agree that online companies are covered entities under the rule if they otherwise meet the definition of health care provider or health plan and satisfy the other requirements of the rule, i.e., providers must also transmit health information in electronic form in connection with a HIPAA transaction. We restate here the language in the preamble to the proposed rule that "An individual or organization that bills and/or is paid for health care services or supplies in the normal course of business, such as * * * an "online" pharmacy accessible on the Internet, is also a health care provider for purposes of this statute" (64 FR 59930).

Comment: We received many comments related to the reference to "health clinic or licensed health care professional located at a school or business in the preamble's discussion of "health care provider." It was stated that including "licensed health care professionals located at a school or business" highlights the need for these individuals to understand they have the authority to disclose information to the Social Security Administration (SSA) without authorization.

However, several commenters urged HHS to create an exception for or delete that reference in the preamble discussion to primary and secondary schools because of employer or business partner relationships. One federal agency suggested that the reference "licensed health care professionals located at a [school]" be deleted from the preamble because the definition of health care provider does not include a reference to schools. The commenter also suggested that the Secretary consider: adding language to the preamble to clarify that the rules do not apply to clinics or school health care providers that only maintain records that have been excepted from the definition of protected health information, adding an exception to the definition of covered entities for those schools, and limiting paperwork requirements for these schools. Another commenter argued for deleting references to schools because the proposed rule appeared to supersede or create ambiguity as to the Family Educational Rights and Privacy Act (FERPA), which gives parents the right to access "education" and health records of their unemancipated minor children. However, in contrast, one commenter supported the inclusion of health care professionals who provide services at schools or businesses.

Response: We realize that our discussion of schools in the NPRM may have been confusing. Therefore, we address these concerns and set forth our policy regarding protected health information in educational agencies and institutions in the "Relationship to Other Federal Laws" discussion of FERPA, above.

Comment: Many commenters urged that direct contact with the patient be necessary for an entity to be considered a health care provider. Commenters suggested that persons and organizations that are remote to the patient and have no direct contact should not be considered health care providers. Several commenters argued that the definition of health care provider covers a person that provides health care services or supplies only when the provider furnishes to or bills the patient directly. It was stated that the Secretary did not intend that manufacturers, such as pharmaceutical, biologics, and device manufacturers, health care suppliers, medical-surgical supply distributors, health care vendors that offer medical record documentation templates and that typically do not deal directly with the patient, be considered health care providers and thus covered entities. However, in contrast, one commenter argued that, as an in vitro diagnostics manufacturer, it should be covered as a health care provider.

Response: We disagree with the comments that urged that direct dealings with an individual be a prerequisite to meeting the definition of health care provider. Many providers included in the statutory definition of provider, such as clinical labs, do not have direct contact with patients. Further, the use and disclosure of protected health information by indirect treatment providers can have a significant effect on individuals' privacy. We acknowledge, however, that providers who treat patients only indirectly

need not have the full array of responsibilities as direct treatment providers, and modify the NPRM to make this distinction with respect to several provisions (see, for example § 164.506 regarding consent). We also clarify that manufacturers and health care suppliers who are considered providers by Medicare are providers under this rule.

Comment: Some commenters suggested that blood centers and plasma donor centers that collect and distribute source plasma not be considered covered health care providers because the centers do not provide "health care services" and the blood donors are not "patients" seeking health care. Similarly, commenters expressed concern that organ procurement organizations might be considered health care providers.

Response: We agree and have deleted from the definition of "health care" the term "procurement or banking of blood, sperm, organs, or any other tissue for administration to patients." See prior discussion under "health care."

Comment: Several commenters proposed to restrict coverage to only those providers who furnished and were paid for services and supplies. It was argued that a salaried employee of a covered entity, such as a hospital-based provider, should not be covered by the rule because that provider would be subject both directly to the rule as a covered entity and indirectly as an employee of a covered entity.

Response: The "dual" direct and indirect situation described in these comments can arise only when a health ***82575** care provider conducts standard HIPAA transactions both for itself and for its employer. For example, when the services of a provider such as a hospital-based physician are billed through a standard HIPAA transaction conducted for the employer, in this example the hospital, the physician does not become a covered provider. Only when the provider uses a standard transaction on its own behalf does he or she become a covered health care provider. Thus, the result is typically as suggested by this commenter. When a hospital-based provider is not paid directly, that is, when the standard HIPAA transaction is not on its behalf, it will not become a covered provider.

Comment: Other commenters argued that an employer who provides health care services to its employees for whom it neither bills the employee nor pays for the health care should not be considered health care providers covered by the proposed rule.

Response: We clarify that the employer may be a health care provider under the rule, and may be covered by the rule if it conducts standard transactions. The provisions of § 164.504 may also apply.

Comment: Some commenters were confused about the preamble statement: "in order to implement the principles in the Secretary's Recommendations, we must impose any protections on the health care providers that use and disclose the information, rather than on the researcher seeking the information," with respect to the rule's policy that a researcher who provides care to subjects in a trial will be considered a health care provider. Some commenters were also unclear about whether the individual researcher providing health care to subjects in a trial would be considered a health care provider or whether the researcher's home institution would be considered a health care provider and thus subject to the rule.

Response: We clarify that, in general, a researcher is also a health care provider if the researcher provides health care to subjects in a clinical research study and otherwise meets the definition of "health care provider" under the rule. However, a health care provider is only a covered entity and subject to the rule if that provider conducts standard transactions. With respect to the above preamble statement, we meant that our jurisdiction under the statute is limited to covered entities. Therefore, we cannot apply any restrictions or requirements on a researcher in that person's role as a researcher. However, if a researcher is also a health care provider that conducts standard transactions, that researcher/provider is subject to the rule with regard to its provider activities.

As to applicability to a researcher/provider versus the researcher's home institution, we provide the following guidance. The rule applies to the researcher as a covered entity if the researcher is a health care provider who conducts standard transactions for services on his or her own behalf, regardless of whether he or she is part of a larger organization. However, if the services

and transactions are conducted on behalf of the home institution, then the home institution is the covered entity for purposes of the rule and the researcher/provider is a workforce member, not a covered entity.

Comment: One commenter expressed confusion about those instances when a health care provider was a covered entity one day, and one who "works under a contract" for a manufacturer the next day.

Response: If persons are covered under the rule in one role, they are not necessarily covered entities when they participate in other activities in another role. For example, that person could be a covered health care provider in a hospital one day but the next day read research records for a different employer. In its role as researcher, the person is not covered, and protections do not apply to those research records.

Comment: One commenter suggested that the Secretary modify proposed § 160.102, to add the following clause at the end (after (c)) (regarding health care provider), "With respect to any entity whose primary business is not that of a health plan or health care provider licensed under the applicable laws of any state, the standards, requirements, and implementation specifications of this subchapter shall apply solely to the component of the entity that engages in the transactions specified in [§] 160.103." (Emphasis added.) Another commenter also suggested that the definition of "covered entity" be revised to mean entities that are "primarily or exclusively engaged in health care-related activities as a health plan, health care provider, or health care clearinghouse."

Response: The Secretary rejects these suggestions because they will impermissibly limit the entities covered by the rule. An entity that is a health plan, health care provider, or health care clearinghouse meets the statutory definition of covered entity regardless of how much time is devoted to carrying out health care-related functions, or regardless of what percentage of their total business applies to health care-related functions.

Comment: Several commenters sought to distinguish a health care provider from a business partner as proposed in the NPRM. For example, a number of commenters argued that disease managers that provide services "on behalf of" health plans and health care providers, and case managers (a variation of a disease management service) are business partners and not "health care providers." Another commenter argued that a disease manager should be recognized (presumably as a covered entity) because of its involvement from the physician-patient level through complex interactions with health care providers.

Response: To the extent that a disease or case manager provides services on behalf of or to a covered entity as described in the rule's definition of business associate, the disease or case manager is a business associate for purposes of this rule. However, if services provided by the disease or case manager meet the definition of treatment and the person otherwise meets the definition of "health care provider," such a person is a health care provider for purposes of this rule.

Comment: One commenter argued that pharmacy employees who assist pharmacists, such as technicians and cashiers, are not business partners.

Response: We agree. Employees of a pharmacy that is a covered entity are workforce members of that covered entity for purposes of this rule.

Comment: A number of commenters requested that we clarify the definition of health care provider ("* * * who furnishes, bills, or is paid for health care services or supplies in the normal course of business") by defining the various terms "furnish", "supply", and "in the normal course of business." For instance, it was stated that this would help employers recognize when services such as an employee assistance program constituted health care covered by the rule.

Response: Although we understand the concern expressed by the commenters, we decline to follow their suggestion to define terms at this level of specificity. These terms are in common use today, and an attempt at specific definition would risk the inadvertent creations of conflict with industry practices. There is a significant variation in the way employers structure their

employee assistance programs (EAPs) and the type of services that they provide. If the EAP provides direct treatment to individuals, it may be a health care provider. ***82576**

Health Information

The response to comments on health information is included in the response to comments on individually identifiable health information, in the preamble discussion of § 164.501.

Health Plan

Comment: One commenter suggested that to eliminate any ambiguity, the Secretary should clarify that the catch-all category under the definition of health plan includes "24-hour coverage plans" (whether insured or self-insured) that integrate traditional employee health benefits coverage and workers' compensation coverage for the treatment of on-the-job injuries and illnesses under one program. It was stated that this clarification was essential if the Secretary persisted in excluding workers' compensation from the final rule.

Response: We understand concerns that such plans may use and disclose individually identifiable health information. We therefore clarify that to the extent that 24-hour coverage plans have a health care component that meets the definition of "health plan" in the final rule, such components must abide by the provisions of the final rule. In the final rule, we have added a new provision to § 164.512 that permits covered entities to disclose information under workers' compensation and similar laws. A health plan that is a 24-hour plan is permitted to make disclosures as necessary to comply with such laws.

Comment: A number of commenters urged that certain types of insurance entities, such as workers' compensation and automobile insurance carriers, property and casualty insurance health plans, and certain forms of limited benefits coverage, be included in the definition of "health plan." It was argued that consumers deserve the same protection with respect to their health information, regardless of the entity using it, and that it would be inequitable to subject health insurance carriers to more stringent standards than other types of insurers that use individually identifiable health information.

Response: The Congress did not include these programs in the definition of a "health plan" under section 1171 of the Act. Further, HIPAA's legislative history shows that the House Report's (H. Rep. 104-496) definition of "health plan" originally included certain benefit programs, such as workers' compensation and liability insurance, but was later amended to clarify the definition and remove these programs. Thus, since the statutory definition of a health plan both on its face and through legislative history evidence Congress' intention to exclude such programs, we do not have the authority to require that these programs comply with the standards. We have added explicit language to the final rule which excludes the excepted benefit programs, as defined in section 2971(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1).

Comment: Some commenters urged HHS to include entities such as stop loss insurers and reinsurers in the definition of "health plan." It was observed that such entities have come to play important roles in managed care delivery systems. They asserted that increasingly, capitated health plans and providers contract with their reinsurers and stop loss carriers to medically manage their high cost outlier cases such as organ and bone marrow transplants, and therefore should be specifically cited as subject to the regulations.

Response: Stop-loss and reinsurers do not meet the statutory definition of health plan. They do not provide or pay for the costs of medical care, as described in the statute, but rather insure health plans and providers against unexpected losses. Therefore, we cannot include them as health plans in the regulation.

Comment: A commenter asserted that there is a significant discrepancy between the effect of the definition of "group health plan" as proposed in § 160.103, and the anticipated impact in the cost estimates of the proposed rule at 64 FR 60014. Paragraph (1) of the proposed definition of "health plan" defined a "group health plan" as an ERISA-defined employee welfare benefit plan that provides medical care and that: "(i) Has 50 or more participants, or (ii) Is administered by an entity other than the

employer that established and maintains the plan[.]" (emphasis added) According to this commenter, under this definition, the only insured or self-insured ERISA plans that would not be regulated "health plans" would be those that have less than 50 participants and are self administered.

The commenter presumed that the we had intended to exclude from the definition of "health plan" (and from coverage under the proposed rule) all ERISA plans that are small (less than 50 participants) or are administered by a third party, whether large or small, based on the statement at 64 FR 60014, note 18. That footnote stated that the Department had "not included the 3.9 million 'other' employer-health plans listed in HCFA's administrative simplification regulations because these plans are administered by a third party. The proposed regulation will not regulate the employer plans but will regulate the third party administrators of the plan." The commenter urged us not to repeat the statutory definition, and to adopt the policy implied in the footnote.

Response: We agree with the commenter's observation that footnote 18 (64 FR 60014) was inconsistent with the proposed definition. We erred in drafting that note. The definition of "group health plan" is adopted from the statutory definition at section 1171(5)(A), and excludes from the rule as "health plans" only the few insured or self-insured ERISA plans that have less than 50 participants and are self administered. We reject the commenter's proposed change to the definition as inconsistent with the statute.

Comment: A number of insurance companies asked that long term care insurance policies be excluded from the definition of "health plan." It was argued that such policies do not provide sufficiently comprehensive coverage of the cost of medical care, and are limited benefit plans that provide or pay for the cost of custodial and other related services in connection with a long term, chronic illness or disability.

These commenters asserted that HIPAA recognizes this nature of long term care insurance, observing that, with respect to HIPAA's portability requirements, Congress enacted a series of exclusions for certain defined types of health plan arrangements that do not typically provide comprehensive coverage. They maintained that Congress recognized that long term care insurance is excluded, so long as it is not a part of a group health plan. Where a long term care policy is offered separately from a group health plan it is considered an excepted benefit and is not subject to the portability and guarantee issue requirements of HIPAA. Although this exception does not appear in the Administrative Simplification provisions of HIPAA, it was asserted that it is guidance with respect to the treatment of long term care insurance as a limited benefit coverage and not as coverage that is so "sufficiently comprehensive" that it is to be treated in the same manner as a typical, comprehensive major medical health plan arrangement.

Another commenter offered a different perspective observing that there are some long-term care policies—that do not pay for medical care and therefore are not "health plans." It was noted that most long-term care policies are reimbursement policies —that is, ***82577** they reimburse the policyholder for the actual expenses that the insured incurs for long-term care services. To the extent that these constitute "medical care," this commenter presumed that these policies would be considered "health plans." Other long-term care policies, they pointed out, simply pay a fixed dollar amount when the insured becomes chronically ill, without regard to the actual cost of any long-term care services received, and thus are similar to fixed indemnity critical illness policies. The commenter suggested that while there was an important distinction between indemnity based long-term care policies and expenses based long-term care policies, it may be wise to exclude all long-term care policies from the scope of the rule to achieve consistency with HIPAA.

Response: We disagree. The statutory language regarding long-term care policies in the portability title of HIPAA is different from the statutory language regarding long-term care policies in the Administrative Simplification title of HIPAA. Section 1171(5)(G) of the Act means that issuers of long-term care policies are considered health plans for purposes of administrative simplification. We also interpret the statute as authorizing the Secretary to exclude nursing home fixed-indemnity policies, not all long-term care policies, from the definition of "health plan," if she determines that these policies do not provide "sufficiently comprehensive coverage of a benefit" to be treated as a health plan (see section 1171 of the Act). We interpret the term "comprehensive" to refer to the breadth or scope of coverage of a policy. "Comprehensive" policies are those that cover a range

of possible service options. Since nursing home fixed indemnity policies are, by their own terms, limited to payments made solely for nursing facility care, we have determined that they should not be included as health plans for the purposes of the HIPAA regulations. The Secretary, therefore, explicitly excluded nursing home fixed-indemnity policies from the definition of "health plan" in the Transactions Rule, and this exclusion is thus reflected in this final rule. Issuers of other long-term care policies are considered to be health plans under this rule and the Transactions Rule.

Comment: One commenter was concerned about the potential impact of the proposed regulations on "unfunded health plans," which the commenter described as programs used by smaller companies to provide their associates with special employee discounts or other membership incentives so that they can obtain health care, including prescription drugs, at reduced prices. The commenter asserted that if these discount and membership incentive programs were covered by the regulation, many smaller employers might discontinue offering them to their employees, rather than deal with the administrative burdens and costs of complying with the rule.

Response: Only those special employee discounts or membership incentives that are "employee welfare benefit plans" as defined in section 3(1) of the Employee Retirement Income Security Act of 1974, 29 U.S.C. 1002(1), and provide "medical care" (as defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)), are health plans for the purposes of this rule. Discount or membership incentive programs that are not group health plans are not covered by the rule.

Comment: Several commenters agreed with the proposal to exclude "excepted benefits" such as disability income insurance policies, fixed indemnity critical illness policies, and per diem long-term care policies from the definition of "health plan," but were concerned that the language of the proposed rule did not fully reflect this intent. They asserted that clarification was necessary in order to avoid confusion and costs to both consumers and insurers.

One commenter stated that, while HHS did not intend for the rule to apply to every type of insurance coverage that paid for medical care, the language of the proposed rule did not bear this out. The problem, it was asserted, is that under the proposed rule any insurance policy that pays for "medical care" would technically be a "health plan." It was argued that despite the statements in the narrative, there are no provisions that would exempt any of the "excepted benefits" from the definition of "health care." It was stated that:

Although (with the exception of long-term care insurance), the proposed rule does not include the 'excepted benefits' in its list of sixteen examples of a health plan (proposed 45 CFR 160.104), it does not explicitly exclude them either. Because these types of policies in some instances pay benefits that could be construed as payments for medical care, we are concerned by the fact that they are not explicitly excluded from the definition of 'health plan' or the requirements of the proposed rule."

Several commenters proposed that HHS adopt the same list of "excepted benefits" contained in 29 U.S.C. 1191b, suggesting that they could be adopted either as exceptions to the definition of "health plan" or as exceptions to the requirements imposed on "health plans." They asserted that this would promote consistency in the federal regulatory structure for health plans.

It was suggested that HHS clarify whether the definition of health plan, particularly the "group health plan" and "health insurance issuer" components, includes a disability plan or disability insurer. It was noted that a disability plan or disability insurer may cover only income lost from disability and, as mentioned above, some rehabilitation services, or a combination of lost income, rehabilitation services and medical care. The commenter suggested that in addressing this coverage issue, it may be useful to refer to the definitions of group health plan, health insurance issuer and medical care set forth in Part I of HIPAA, which the statutory provisions of the Administrative Simplification subtitle expressly reference. See 42 U.S.C. 1320d(5)(A) and (B).

Response: We agree that the NPRM may have been ambiguous regarding the types of plans the rule covers. To remedy this confusion, we have added language that specifically excludes from the definition any policy, plan, or program providing or paying the cost of the excepted benefits, as defined in section 2971(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1). As defined in the statute, this includes but is not limited to benefits under one or more (or any combination thereof) of the following:

coverage only for accident, or disability income insurance, or any combination thereof; liability insurance, including general liability insurance and automobile liability insurance; and workers' compensation or similar insurance.

However, the other excepted benefits as defined in section 2971(c)(2) of the PHS Act, 42 U.S.C. 300gg-91(c)(2), such as limited scope dental or vision benefits, not explicitly excepted from the regulation could be considered "health plans" under paragraph (1)(xvii) of the definition of "health plan" in the final rule if and to the extent that they meet the criteria for the definition of "health plan." Such plans, unlike the programs and plans listed at section 2971(c)(1), directly and exclusively provide health insurance, even if limited in scope.

Comment: One commenter recommended that the Secretary clarify that "health plan" does not include property and casualty benefit providers. The commenter stated that the clarifying language is needed given the "catchall" category of entities defined as "any other individual plan or group health plan, or combination thereof, that ***82578** provides or pays for the cost of medical care," and asserted that absent clarification there could be serious confusion as to whether property and casualty benefit providers are "health plans" under the rule.

Response: We agree and as described above have added language to the final rule to clarify that the "excepted benefits" as defined under 42 U.S.C. 300gg-91(c)(1), which includes liability programs such as property and casualty benefit providers, are not health plans for the purposes of this rule.

Comment: Some commenters recommended that the Secretary replace the term "medical care" with "health care." It was observed that "health care" was defined in the proposal, and that this definition was used to define what a health care provider does. However, they observed that the definition of "health plan" refers to the provision of or payment for "medical care," which is not defined. Another commenter recommended that HHS add the parenthetical phrase "as such term is defined in section 2791 of the Public Health Service Act" after the phrase "medical care."

Response: We disagree with the first recommendation. We understand that the term "medical care" can be easily confused with the term "health care." However, the two terms are not synonymous. The term "medical care" is a statutorily defined term and its use is critical in making a determination as to whether a health plan is considered a "health plan" for purposes of administrative simplification. In addition, since the term "medical care" is used in the regulation only in the context of the definition of "health plan" and we believe that its inclusion in the regulatory text may cause confusion, we did not add a definition of "medical care" in the final rule. However, consistent with the second recommendation above, the statutory cite for "medical care" was added to the definition of "health plan" in the Transactions Rule, and thus is reflected in this final rule.

Comment: A number of commenters urged that the Secretary define more narrowly what characteristics would make a government program that pays for specific health care services a "health plan." Commenters argued that there are many "payment" programs that should not be included, as discussed below, and that if no distinctions were made, "health plan" would mean the same as "purchaser" or even "payor."

Commenters asserted that there are a number of state programs that pay for "health care" (as defined in the rule) but that are not health plans. They said that examples include the WIC program (Special Supplemental Nutrition Program for Women, Infants, and Children) which pays for nutritional assessment and counseling, among other services; the AIDS Client Services Program (including AIDS prescription drug payment) under the federal Ryan White Care Act and state law; the distribution of federal family planning funds under Title X of the Public Health Services Act; and the breast and cervical health program which pays for cancer screening in targeted populations. Commenters argued that these are not insurance plans and do not fall within the "health plan" definition's list of examples, all of which are either insurance or broad-scope programs of care under a contract or statutory entitlement. However, paragraph (16) in that list opens the door to broader interpretation through the catchall phrase, "any other individual or group plan that provides or pays for the cost of medical care." Commenters assert that clarification is needed.

A few commenters stated that other state agencies often work in partnership with the state Medicaid program to implement certain Medicaid benefits, such as maternity support services and prenatal genetics screening. They concluded that while this probably makes parts of the agency the "business partner" of a covered entity, they were uncertain whether it also makes the same agency parts a "health plan" as well.

Response: We agree with the commenters that clarification is needed as to the rule's application to government programs that pay for health care services. Accordingly, in the final rule we have excepted from the definition of "health plan" a government funded program which does not have as its principal purpose the provision of, or payment for, the cost of health care or which has as its principal purpose the provision, either directly or by grant, of health care. For example, the principal purpose of the WIC program is not to provide or pay for the cost of health care, and thus, the WIC program is not a health plan for purposes of this rule. The program of health care services for individuals detained by the INS provides health care directly, and so is not a health plan. Similarly, the family planning program authorized by Title X of the Public Health Service Act pays for care exclusively through grants, and so is not a health plan under this rule. These programs (the grantees under the Title X program) may be or include health care providers and may be covered entities if they conduct standard transactions.

We further clarify that, where a public program meets the definition of "health plan," the government agency that administers the program is the covered entity. Where two agencies administer a program jointly, they are both a health plan. For example, both the Health Care Financing Administration and the insurers that offers a Medicare+Choice plan are "health plans" with respect to Medicare beneficiaries. An agency that does not administer a program but which provides services for such a program is not a covered entity by virtue of providing such services. Whether an agency providing services is a business associate of the covered entity depends on whether its functions for the covered entity meet the definition of business associate in § 164.501 and, in the example described by this comment, in particular on whether the arrangement falls into the exception in § 164.504(e)(1)(ii)(C) for government agencies that collect eligibility or enrollment information for covered government programs.

Comment: Some commenters expressed support for retaining the category in paragraph (16) of the proposal's definition: "Any other individual or group health plan, or combination thereof, that provides or pays for the cost of medical care." Others asked that the Secretary clarify this category. One commenter urged that the final rule clearly define which plans would meet the criteria for this category.

Response: As described in the proposed rule, this category implements the language at the beginning of the statutory definition of the term "health plan": "The term 'health plan' means an individual or group plan that provides, or pays the cost of, medical care * * * Such term includes the following, and any combination thereof * * *" This statutory language is general, not specific, and as such, we are leaving it general in the final rule. However, as described above, we add explicit language which excludes certain "excepted benefits" from the definition of "health plan" in an effort to clarify which plans are not health plans for the purposes of this rule. Therefore, to the extent that a certain benefits plan or program otherwise meets the definition of "health plan" and is not explicitly excepted, that program or plan is considered a "health plan" under paragraph (1)(xvii) of the final rule.

Comment: A commenter explained that HIPAA defines a group health plan by expressly cross-referencing the statutory sections in the PHS Act and the Employee Retirement Income ***82579** Security Act of 1974 (ERISA), 29 U.S.C. 1001, et seq., which define the terms "group health plan," "employee welfare benefit plan" and "participant." See 29 U.S.C. 1002(l) (definition of "employee welfare benefit plan," which is the core of the definition of group health plan under both ERISA and the PHS Act); 29 U.S.C. 100217) (definition of participant); 29 U.S.C. 1193(a) (definition of "group health plan," which is identical to that in section 2791(a) of the PHS Act).

It was pointed out that the preamble and the text of the proposed rule both limit the definition of all three terms to their current definitions. The commenter reasoned that since the ERISA definitions may change over time through statutory amendment, Department of Labor regulations or judicial interpretation, it would not be clear what point in time is to be considered current. Therefore, they suggested deleting references to "current" or "currently" in the preamble and in the regulation with respect to these three ERISA definitions.

In addition, the commenter stated that as the preamble to the NPRM correctly reflected, HIPAA expressly cross-references ERISA's definition of "participant" in section 3(7) of ERISA, 29 U.S.C. 1002(7). 42 U.S.C. 1320d(5)(A). The text of the privacy regulation, however, omits this cross-reference. It was suggested that the reference to section 3(7) of ERISA, defining "participant," be included in the regulation.

Finally, HIPAA incorporates the definition of a group health plan as set forth in section 2791(a) of the PHS Act, 42 U.S.C. 300gg-91(a)(l). That definition refers to the provision of medical care "directly or through insurance, reimbursement, or otherwise." The word "reimbursement" is omitted in both the preamble and the text of the regulation; the commenter suggested restoring it to both.

Response: We agree. These changes were made to the definition of "health plan" as promulgated in the Transactions Rule, and are reflected in this final rule.

Small Health Plan

Comment: One commenter recommended that we delete the reference to $5 million in the definition and instead define a "small health plan" as a health plan with fewer than 50 participants. It was stated that using a dollar limitation to define a "small health plan" is not meaningful for self-insured plans and some other types of health plan coverage arrangements. A commenter pointed out that the general definition of a health plan refers to "50 or more participants," and that using a dollar factor to define a "small health plan" would be inconsistent with this definition.

Response: We disagree. The Small Business Administration (SBA) promulgates size standards that indicate the maximum number of employees or annual receipts allowed for a concern (13 CFR 121.105) and its affiliates to be considered "small." The size standards themselves are expressed either in number of employees or annual receipts (13 CFR 121.201). The size standards for compliance with programs of other agencies are those for SBA programs which are most comparable to the programs of such other agencies, unless otherwise agreed by the agency and the SBA (13 CFR 121.902). With respect to the insurance industry, the SBA has specified that annual receipts of $5 million is the maximum allowed for a concern and its affiliates to be considered small (13 CFR 121.201). Consequently, we retain the proposal's definition in the final rule to be consistent with SBA requirements.

We understand there may be some confusion as to the meaning of "annual receipts" when applied to a health plan. For our purposes, therefore, we consider "pure premiums" to be equivalent to "annual receipts."

Workforce

Comment: Some commenters requested that we exclude "volunteers" from the definition of workforce. They stated that volunteers are important contributors within many covered entities, and in particular hospitals. They argued that it was unfair to ask that these people donate their time and at the same time subject them to the penalties placed upon the paid employees by these regulations, and that it would discourage people from volunteering in the health care setting.

Response: We disagree. We believe that differentiating those persons under the direct control of a covered entity who are paid from those who are not is irrelevant for the purposes of protecting the privacy of health information, and for a covered entity's management of its workforce. In either case, the person is working for the covered entity. With regard to implications for the individual, persons in a covered entity's workforce are not held personally liable for violating the standards or requirements of the final rule. Rather, the Secretary has the authority to impose civil monetary penalties and in some cases criminal penalties for such violations on only the covered entity.

Comment: One commenter asked that the rule clarify that employees administering a group health or other employee welfare benefit plan on their employers' behalf are considered part of the covered entity's workforce.

Response: As long as the employees have been identified by the group health plan in plan documents as performing functions related to the group health plan (consistent with the requirements of § 164.504(f)), those employees may have access to protected health information. However, they are not permitted to use or disclose protected health information for employment-related purposes or in connection with any other employee benefit plan or employee benefit of the plan sponsor.

Part 160—Subpart B—Preemption of State Law

We summarize and respond below to comments received in the Transactions rulemaking on the issue of preemption, as well as those received on this topic in the Privacy rulemaking. Because no process was proposed in the Transactions rulemaking for granting exceptions under section 1178(a)(2)(A), a process for making exception determinations was not adopted in the Transactions Rule. Instead, since a process for making exception determinations was proposed in the Privacy rulemaking, we decided that the comments received in the Transactions rulemaking should be considered and addressed in conjunction with the comments received on the process proposed in the Privacy rulemaking. See 65 FR 50318 for a fuller discussion. Accordingly, we discuss the preemption comments received in the Transactions rulemaking where relevant below.

Comment: The majority of comments on preemption addressed the subject in general terms. Numerous comments, particularly from plans and providers, argued that the proposed preemption provisions were burdensome, ineffective, or insufficient, and that complete federal preemption of the "patchwork" of state privacy laws is needed. They also argued that the proposed preemption provisions are likely to invite litigation. Various practical arguments in support of this position were made. Some of these comments recognized that the Secretary's authority under section 1178 of the Act is limited and acknowledged that the Secretary's proposals were within her statutory authority. One commenter suggested that the exception determination process would result in a very costly and laborious and sometimes inconsistent analysis of the occasions in which state law would ***82580** survive federal preemption, and thus suggested the final privacy regulations preempt state law with only limited exceptions, such as reporting child abuse. Many other comments, however, recommended changing the proposed preemption provisions to preempt state privacy laws on as blanket a basis as possible.

One comment argued that the assumption that more stringent privacy laws are better is not necessarily true, citing a 1999 GAO report finding evidence that the stringent state confidentiality laws of Minnesota halted the collection of comparative information on health care quality.

Several comments in this vein were also received in the Transactions rulemaking. The majority of these comments took the position that exceptions to the federal standards should either be prohibited or discouraged. It was argued that granting exceptions to the standards, particularly the transactions standards, would be inconsistent with the statute's objective of promoting administrative simplification through the use of uniform transactions.

Many other commenters, however, endorsed the "federal floor" approach of the proposed rules. (These comments were made in the context of the proposed privacy regulations.) These comments argued that this approach was preferable because it would not impair the effectiveness of state privacy laws that are more protective of privacy, while raising the protection afforded medical information in states that do not enact laws that are as protective as the rules below. Some comments argued, however, that the rules should give even more deference to state law, questioning in particular the definitions and the proposed addition to the "other purposes" criterion for exception determinations in this regard.

Response: With respect to the exception process provided for by section 1178(a)(2)(A), the contention that the HIPAA standards should uniformly control is an argument that should be addressed to the Congress, not this agency. Section 1178 of the Act expressly gives the Secretary authority to grant exceptions to the general rule that the HIPAA standards preempt contrary state law in the circumstances she determines come within the provisions at section 1178(a)(2)(A). We agree that the underlying statutory goal of standardizing financial and administrative health care transactions dictates that exceptions should be granted only on narrow grounds. Nonetheless, Congress clearly intended to accommodate some state laws in these areas, and the Department is not free to disregard this Congressional choice. As is more fully explained below, we have interpreted the

statutory criteria for exceptions under section 1178(a)(2)(A) to balance the need for relative uniformity with respect to the HIPAA standards with state needs to set certain policies in the statutorily defined areas.

The situation is different with respect to state laws relating to the privacy of protected health information. Many of the comments arguing for uniform standards were particularly concerned with discrepancies between the federal privacy standards and various state privacy requirements. Unlike the situation with respect to the transactions standards, where states have generally not entered the field, all states regulate the privacy of some medical information to a greater or lesser extent. Thus, we understand the private sector's concern at having to reconcile differing state and federal privacy requirements.

This is, however, likewise an area where the policy choice has been made by Congress. Under section 1178(a)(2)(B) of the Act and section 264(c)(2) of HIPAA, provisions of state privacy laws that are contrary to and more stringent than the corresponding federal standard, requirement, or implementation specification are not preempted. The effect of these provisions is to let the law that is most protective of privacy control (the “federal floor” approach referred to by many commenters), and this policy choice is one with which we agree. Thus, the statute makes it impossible for the Secretary to accommodate the requests to establish uniformly controlling federal privacy standards, even if doing so were viewed as desirable.

Comment: Numerous comments stated support for the proposal at proposed Subpart B to issue advisory opinions with respect to the preemption of state laws relating to the privacy of individually identifiable health information. A number of these comments appeared to assume that the Secretary's advisory opinions would be dispositive of the issue of whether or not a state law was preempted. Many of these commenters suggested what they saw as improvements to the proposed process, but supported the proposal to have the Department undertake this function.

Response: Despite the general support for the advisory opinion proposal, we decided not to provide specifically for the issuance of such opinions. The following considerations led to this decision. First, the assumption by commenters that an advisory opinion would establish what law applied in a given situation and thereby simplify the task of ascertaining what legal requirements apply to a covered entity or entities is incorrect. Any such opinion would be advisory only. Although an advisory opinion issued by the Department would indicate to covered entities how the Department would resolve the legal conflict in question and would apply the law in determining compliance, it would not bind the courts. While we assume that most courts would give such opinions deference, the outcome could not be guaranteed.

Second, the thousands of questions raised in the public comment about the interpretation, implications, and consequences of all of the proposed regulatory provisions have led us to conclude that significant advice and technical assistance about all of the regulatory requirements will have to be provided on an ongoing basis. We recognize that the preemption concerns that would have been addressed by the proposed advisory opinions were likely to be substantial. However, there is no reason to assume that they will be the most substantial or urgent of the questions that will most likely need to be addressed. It is our intent to provide as much technical advice and assistance to the regulated community as we can with the resources available. Our concern is that setting up an advisory opinion process for just one of the many types of issues that will have to be addressed will lead to a non-optimal allocation of those resources. Upon careful consideration, therefore, we have decided that we will be better able to prioritize our workload and be better able to be responsive to the most urgent and substantial questions raised to the Department, if we do not provide for a formal advisory opinion process on preemption as proposed.

Comment: A few commenters argued that the Privacy Rule should preempt state laws that would impose more stringent privacy requirements for the conduct of clinical trials. One commenter asserted that the existing federal regulations and guidelines for patient informed consent, together with the proposed rule, would adequately protect patient privacy.

Response: The Department does not have the statutory authority under HIPAA to preempt state laws that would impose more stringent privacy requirements on covered entities. HIPAA provides that the rule promulgated by the Secretary may not preempt state laws that are in conflict ***82581** with the regulatory requirements and that provide greater privacy protections.

Section 160.201—Applicability

Comment: Several commenters indicated that the guidance provided by the definitions at proposed § 160.202 would be of substantial benefit both to regulated entities and to the public. However, these commenters argued that the applicability of such definitions would be too limited as drafted, since proposed § 160.201 provided that the definitions applied only to "determinations and advisory opinions issued by the Secretary pursuant to 42 U.S.C. 1320d-7." The commenters stated that it would be far more helpful to make the definitions in proposed § 160.202 more broadly applicable, to provide general guidance on the issue of preemption.

Response: We agree with the comments on this issue, and have revised the applicability provision of subpart B below accordingly. Section 160.201 below sets out that Subpart B implements section 1178. This means, in our view, that the definitions of the statutory terms at § 160.202 are legislative rules that apply when those statutory terms are employed, whether by HHS, covered entities, or the courts.

Section 160.202—Definitions

Contrary

Comment: Some commenters asserted that term "contrary" as defined at § 160.202 was overly broad and that its application would be time-consuming and confusing for states. These commenters argued that, under the proposed definition, a state would be required to examine all of its laws relating to health information privacy in order to determine whether or not its law were contrary to the requirements proposed. It was also suggested that the definition contain examples of how it would work in practical terms.

A few commenters, however, argued that the definition of "contrary" as proposed was too narrow. One commenter argued that the Secretary erred in her assessment of the case law analyzing what is known as "conflict preemption" and which is set forth in shorthand in the tests set out at § 160.202.

Response: We believe that the definition proposed represents a policy that is as clear as is feasible and which can be applied nationally and uniformly. As was noted in the preamble to the proposed rules (at 64 FR 59997), the tests in the proposed definition of "contrary" are adopted from the jurisprudence of "conflict preemption." Since preemption is a judicially developed doctrine, it is reasonable to interpret this term as indicating that the statutory analysis should tie in to the analytical formulations employed by the courts. Also, while the court-developed tests may not be as clear as commenters would like, they represent a long-term, thoughtful consideration of the problem of defining when a state/federal conflict exists. They will also, we assume, generally be employed by the courts when conflict issues arise under the rules below. We thus see no practical alternative to the proposed definition and have retained it unchanged. With respect to various suggestions for shorthand versions of the proposed tests, such as the arguably broader term "inconsistent with," we see no operational advantages to such terms.

Comment: One comment asked that the Department clarify that if state law is not preempted, then the federal law would not also apply.

Response: This comment raises two issues, both of which deserve discussion. First, a state law may not be preempted because there is no conflict with the analogous federal requirement; in such a situation, both laws can, and must, be complied with. We thus do not accept this suggestion, to the extent that it suggests that the federal law would give way in this situation. Second, a state law may also not be preempted because it comes within section 1178(a)(2)(B), section 1178(b), or section 1178(c); in this situation, a contrary federal law would give way.

Comment: One comment urged the Department to take the position that where state law exists and no analogous federal requirement exists, the state requirement would not be "contrary to" the federal requirement and would therefore not trigger preemption.

Response: We agree with this comment.

Comment: One commenter criticized the definition as unhelpful in the multi-state transaction context. For example, it was asked whether the issue of whether a state law was "contrary to" should be determined by the law of the state where the treatment is provided, where the claim processor is located, where the payment is issued, or the data maintained, assuming all are in different states.

Response: This is a choice of law issue, and, as is discussed more fully below, is a determination that is routinely made today in connection with multi-state transactions. See discussion below under Exception Determinations (Criteria for Exception Determinations).

State Law

Comment: Comments noted that the definition of "state law" does not explicitly include common law and recommended that it be revised to do so or to clarify that the term includes evidentiary privileges recognized at state law. Guidance concerning the impact of state privileges was also requested.

Response: As requested, we clarify that the definition of "state law" includes common law by including the term "common law." In our view, this phrase encompasses evidentiary privileges recognized at state law (which may also, we note, be embodied in state statutes).

Comment: One comment criticized this definition as unwieldy, in that locating state laws pertaining to privacy is likely to be difficult. It was noted that Florida, for example, has more than 60 statutes that address health privacy.

Response: To the extent that state laws currently apply to covered entities, they have presumably determined what those laws require in order to comply with them. Thus, while determining which laws are "contrary" to the federal requirements will require additional work in terms of comparing state law with the federal requirements, entities should already have acquired the knowledge of state law needed for this task in the ordinary course of doing business.

Comment: The New York City Department of Health noted that in many cases, provisions of New York State law are inapplicable within New York City, because the state legislature has recognized that the local code is tailored to the particular needs of the City. It urged that the New York City Code be treated as state law, for preemption purposes.

Response: We agree that, to the extent a state treats local law as substituting for state law it could be considered to be "state law" for purposes of this definition. If, however, a local law is local in scope and effect, and a tier of state law exists over the same subject matter, we do not think that the local law could or should be treated as "state law" for preemption purposes. We do not have sufficient information to assess the situation raised by this comment with respect to this principle, and so express no opinion thereon.

More Stringent

Comment: Many commenters supported the policy in the proposed definition of "individual" at proposed § 164.502, which would have permitted unemancipated minors to exercise, on ***82582** their own behalf, rights granted to individuals in cases where they consented to the underlying health care. Commenters stated, however, that the proposed preemption provision would leave in place state laws authorizing or prohibiting disclosure to parents of the protected health information of their minor children and would negate the proposed policy for the treatment of minors under the rule. The comments stated that such state laws should be treated like other state laws, and preempted to the extent that they are less protective of the privacy of minors.

Other commenters supported the proposed preemption provision—not to preempt a state law to the extent it authorizes or prohibits disclosure of protected health information regarding a minor to a parent.

Response: Laws regarding access to health care for minors and confidentiality of their medical records vary widely; this regulation recognizes and respects the current diversity of state law in this area. Where states have considered the balance involved in protecting the confidentiality of minors' health information and have explicitly acted, for example, to authorize disclosure, defer the decision to disclose to the discretion of the health care provider, or prohibit disclosure of minor's protected health information to a parent, the rule defers to these decisions to the extent that they regulate such disclosures.

Comment: The proposed definition of "more stringent" was criticized as affording too much latitude to for granting exceptions for state laws that are not protective of privacy. It was suggested that the test should be "most protective of the individual's privacy."

Response: We considered adopting this test. However, for the reasons set out at 64 FR 59997, we concluded that this test would not provide sufficient guidance. The comments did not address the concerns we raised in this regard in the preamble to the proposed rules, and we continue to believe that they are valid.

Comment: A drug company expressed concern with what it saw as the expansive definition of this term, arguing that state governments may have less experience with the special needs of researchers than federal agencies and may unknowingly adopt laws that have a deleterious effect on research. A provider group expressed concern that allowing stronger state laws to prevail could result in diminished ability to get enough patients to complete high quality clinical trials.

Response: These concerns are fundamentally addressed to the "federal floor" approach of the statute, not to the definition proposed: even if the definition of "more stringent" were narrowed, these concerns would still exist. As discussed above, since the "federal floor" approach is statutory, it is not within the Secretary's authority to change the dynamics that are of concern.

Comment: One comment stated that the proposed rule seemed to indicate that the "more stringent" and "contrary to" definitions implied that these standards would apply to ERISA plans as well as to non-ERISA plans.

Response: The concern underlying this comment is that ERISA plans, which are not now subject to certain state laws because of the "field" preemption provision of ERISA but which are subject to the rules below, will become subject to state privacy laws that are "more stringent" than the federal requirements, due to the operation of section 1178(a)(2)(B), together with section 264(c)(2). We disagree that this is the case. While the courts will have the final say on these questions, it is our view that these sections simply leave in place more stringent state laws that would otherwise apply; to the extent that such state laws do not apply to ERISA plans because they are preempted by ERISA, we do not think that section 264(c)(2) overcomes the preemption effected by section 514(a) of ERISA. For more discussion of this point, see 64 FR 60001.

Comment: The Lieutenant Governor's Office of the State of Hawaii requested a blanket exemption for Hawaii from the federal rules, on the ground that its recently enacted comprehensive health privacy law is, as a whole, more stringent than the proposed federal standards. It was suggested that, for example, special weight should be given to the severity of Hawaii's penalties. It was suggested that a new definition ("comprehensive") be added, and that "more stringent" be defined in that context as whether the state act or code as a whole provides greater protection.

An advocacy group in Vermont argued that the Vermont legislature was poised to enact stronger and more comprehensive privacy laws and stated that the group would resent a federal prohibition on that.

Response: The premise of these comments appears to be that the provision-by-provision approach of Subpart B, which is expressed in the definition of the term "contrary", is wrong. As we explained in the preamble to the proposed rules (at 64 FR 59995), however, the statute dictates a provision-by-provision comparison of state and federal requirements, not the overall

comparison suggested by these comments. We also note that the approach suggested would be practically and analytically problematic, in that it would be extremely difficult, if not impossible, to determine what is a legitimate stopping point for the provisions to be weighed on either the state side or the federal side of the scale in determining which set of laws was the "more stringent." We accordingly do not accept the approach suggested by these comments.

With respect to the comment of the Vermont group, nothing in the rules below prohibits or places any limits on states enacting stronger or more comprehensive privacy laws. To the extent that states enact privacy laws that are stronger or more comprehensive than contrary federal requirements, they will presumably not be preempted under section 1178(a)(2)(B). To the extent that such state laws are not contrary to the federal requirements, they will act as an overlay on the federal requirements and will have effect.

Comment: One comment raised the issue of whether a private right of action is a greater penalty, since the proposed federal rule has no comparable remedy.

Response: We have reconsidered the proposed "penalty" provision of the proposed definition of "more stringent" and have eliminated it. The HIPAA statute provides for only two types of penalties: fines and imprisonment. Both types of penalties could be imposed in addition to the same type of penalty imposed by a state law, and should not interfere with the imposition of other types of penalties that may be available under state law. Thus, we think it is unlikely that there would be a conflict between state and federal law in this respect, so that the proposed criterion is unnecessary and confusing. In addition, the fact that a state law allows an individual to file a lawsuit to protect privacy does not conflict with the HIPAA penalty provisions.

Relates to the Privacy of Individually Identifiable Health Information

Comment: One comment criticized the definition of this term as too narrow in scope and too uncertain. The commenter argued that determining the specific purpose of a state law may be difficult and speculative, because many state laws have incomplete, inaccessible, or non-existent legislative histories. It was suggested that the definition be revised by deleting the word "specific" before the word "purpose." Another commenter argued ***82583** that the definition of this term should be narrowed to minimize reverse preemption by more stringent state laws. One commenter generally supported the proposed definition of this term.

Response: We are not accepting the first comment. The purpose of a given state enactment should be ascertainable, if not from legislative history or a purpose statement, then from the statute viewed as a whole. The same should be true of state regulations or rulings. In any event, it seems appropriate to restrict the field of state laws that may potentially trump the federal standards to those that are clearly intended to establish state public policy and operate in the same area as the federal standards. To the extent that the definition in the rules below does this, we have accommodated the second comment. We note, however, that we do not agree that the definition should be further restricted to minimize "reverse preemption," as suggested by this comment, as we believe that state laws that are more protective of privacy than contrary federal standards should remain, in order to ensure that the privacy of individuals' health information receives the maximum legal protection available.

Sections 160.203 and 160.204—Exception Determinations and Advisory Opinions

Most of the comments received on proposed Subpart B lumped together the proposed process for exception determinations under section 1178(a)(2)(A) with the proposed process for issuing advisory opinions under section 1178(a)(2)(B), either because the substance of the comment applied to both processes or because the commenters did not draw a distinction between the two processes. We address these general comments in this section.

Comment: Numerous commenters, particularly providers and provider groups, recommended that exception determinations and advisory opinions not be limited to states and advocated allowing all covered entities (including individuals, providers and insurers), or private sector organizations, to request determinations and opinions with respect to preemption of state laws. Several commenters argued that limiting requests to states would deny third party stakeholders, such as life and disability income insurers, any means of resolving complex questions as to what rule they are subject to. One commenter noted that because it

is an insurer who will be liable if it incorrectly analyzes the interplay between laws and reaches an incorrect conclusion, there would be little incentive for the states to request clarification. It would also cause large administrative burdens which, it was stated, would be costly and confusing. It was also suggested that the request for the exception be made to the applicable state's attorney general or chief legal officer, as well as the Secretary. Various changes to the language were suggested, such as adding that "a covered entity, or any other entity impacted by this rule" be allowed to submit the written request.

Response: We agree, and have changed § 164.204(a) below accordingly.

The decision to eliminate advisory opinions makes this issue moot with respect to those opinions.

Comment: Several commenters noted that it was unclear under the proposed rule which state officials would be authorized to request a determination.

Response: We agree that the proposed rule was unclear in this respect. The final rule clarifies who may make the request for a state, with respect to exception determinations. See, § 160.204(a). The language adopted should ensure that the Secretary receives an authoritative statement from the state. At the same time, this language provides states with flexibility, in that the governor or other chief elected official may choose to designate other state officials to make such requests.

Comment: Many commenters recommended that a process be established whereby HHS performs an initial state-by-state critical analysis to provide guidance on which state laws will not be preempted; most suggested that such an analysis (alternatively referred to as a database or clearinghouse) should be completed before providers would be required to come into compliance. Many of these comments argued that the Secretary should bear the cost for the analyses of state law, disagreeing with the premise stated in the preamble to the proposed rules that it is more efficient for the private market to complete the state-by-state review. Several comments also requested that HHS continue to maintain and monitor the exception determination process, and update the database over time in order to provide guidance and certainty on the interaction of the federal rules with newly enacted or amended state laws that are produced after the final rule. Some comments recommended that each state be required to certify agreement with the HHS analyses.

In contrast, one hospital association noted concerns that the Secretary would conduct a nationwide analysis of state laws. The comment stated that implementation would be difficult since much of the law is a product of common law, and such state-specific research should only be attempted by experienced health care attorneys in each jurisdiction.

Response: These comments seem to be principally concerned with potential conflicts between state privacy laws and the privacy standards, because, as is more fully explained below, preemption of contrary state laws not relating to privacy is automatic unless the Secretary affirmatively acts under section 1178(a)(2)(A) to grant an exception. We recognize that the provisions of sections 1178(b) (state public health laws), and 1178(c) (state regulation of health plans) similarly preserve state laws in those areas, but very little of the public comment appeared to be concerned with these latter statutory provisions. Accordingly, we respond below to what we see as the commenters' main concern.

The Department will not do the kind of global analysis requested by many of these comments. What these comments are in effect seeking is a global advisory opinion as to when the federal privacy standards will control and when they will not. We understand the desire for certainty underlying these comments. Nonetheless, the reasons set out above as the basis for our decision not to establish a formal advisory opinion process apply equally to these requests. We also do not agree that the task of evaluating the requirements below in light of existing state law is unduly burdensome or unreasonable. Rather, it is common for new federal requirements to necessitate an examination by the regulated entities of the interaction between existing state law and the federal requirements incident to coming into compliance.

We agree, however, that the case is different where the Secretary has affirmatively acted, either through granting an exception under section 1178(a)(2)(A) or by making a specific determination about the effect of a particular state privacy law in, for

example, the course of determining an entity's compliance with the privacy standards. As is discussed below, the Department intends to make notice of exception determinations that it makes routinely available.

We do not agree with the comments suggesting that compliance by covered entities be delayed pending completion of an analysis by the Secretary and that states be required to certify agreement with the Secretary's analysis, as we are not institutionalizing the advisory opinion/analysis process upon which these comments are predicated. ***82584** Furthermore, with respect to the suggestion regarding delaying the compliance date, Congress provided in section 1175(b) of the Act for a delay in when compliance is required to accommodate the needs of covered entities to address implementation issues such as those raised by these comments. With respect to the suggestion regarding requiring states to certify their agreement with the Secretary's analysis, we have no authority to do this.

Comment: Several commenters criticized the proposed provision for annual publication of determinations and advisory opinions in the Federal Register as inadequate. They suggested that more frequent notices should be made and the regulation be changed accordingly, to provide for publication either quarterly or within a few days of a determination. A few commenters suggested that any determinations made, or opinions issued, by the Secretary be published on the Department's website within 10 days or a few days of the determination or opinion.

Response: We agree that the proposed provision for annual publication was inadequate and have accordingly deleted it. Subpart B contains no express requirement for publication, as the Department is free to publish its determinations absent such a requirement. It is our intention to publish notice of exception determinations on a periodic basis in the Federal Register. We will also consider other avenues of making such decisions publicly available as we move into the implementation process.

Comment: A few commenters argued that the process for obtaining an exception determination or an advisory opinion from the Secretary will result in a period of time in which there is confusion as to whether state or federal law applies. The proposed regulations say that the federal provisions will remain effective until the Secretary makes a determination concerning the preemption issue. This means that, for example, a state law that was enacted and enforced for many years will be preempted by federal law for the period of time during which it takes the Secretary to make a determination. Then if the Secretary determines that the state law is not preempted, the state law will again become effective. Such situations will result in confusion and unintended violations of the law. One of the commenters suggested that requests for exceptions be required only when a challenge is brought against a particular state law, and that a presumption of validity should lie with state laws. Another commenter, however, urged that "instead of the presumption of preemption, the state laws in question would be presumed to be subject to the exception unless or until the Secretary makes a determination to the contrary."

Response: It is true that the effect of section 1178(a)(2)(A) is that the federal standards will preempt contrary state law and that such preemption will not be removed unless and until the Secretary acts to grant an exception under that section (assuming, of course, that another provision of section 1178 does not apply). We do not agree, however, that confusion should result, where the issue is whether a given state law has been preempted under section 1178(a)(2)(A). Because preemption is automatic with respect to state laws that do not come within the other provisions of section 1178 (i.e., sections 1178(a)(2)(B), 1178(b), and 1178(c)), such state laws are preempted until the Secretary affirmatively acts to preserve them from preemption by granting an exception under section 1178(a)(2)(A).

We cannot accept the suggestion that a presumption of validity attach to state laws, and that states not be required to request exceptions except in very narrow circumstances. The statutory scheme is the opposite: The statute effects preemption in the section 1178(a)(2)(A) context unless the Secretary affirmatively acts to except the contrary state law in question.

With respect to preemption under sections 1178(b) and 1178(c) (the carve-outs for state public health laws and state regulation of health plans), we do not agree that preemption is likely to be a major cause of uncertainty. We have deferred to Congressional intent by crafting the permissible releases for public health, abuse, and oversight broadly. See, §§ 164.512(b)—(d) below. Since

there must first be a conflict between a state law and a federal requirement in order for an issue of preemption to even arise, we think that, as a practical matter, few preemption questions should arise with respect to sections 1178(b) and 1178(c).

With respect to preemption of state privacy laws under section 1178(a)(2)(B), however, we agree that the situation may be more difficult to ascertain, because the Secretary does not determine the preemption status of a state law under that section, unlike the situation with respect to section 1178(a)(2)(A). We have tried to define the term "more stringent" to identify and particularize the factors to be considered by courts to those relevant to privacy interests. The more specific (than the statute) definition of this term at § 160.202 below should provide some guidance in making the determination as to which law prevails. Ambiguity in the state of the law might also be a factor to be taken into account in determining whether a penalty should be applied.

Comment: Several comments recommended that exception determinations or advisory opinions encompass a state act or code in its entirety (in lieu of a provision-specific evaluation) if it is considered more stringent as a whole than the regulation. It was argued that since the provisions of a given law are typically interconnected and related, adopting or overriding them on a provision-by-provision basis would result in distortions and/or unintended consequences or loopholes. For example, when a state law includes authorization provisions, some of which are consistent with the federal requirements and some which are not, the cleanest approach is to view the state law as inconsistent with the federal requirements and thus preempted in its entirety. Similarly, another comment suggested that state confidentiality laws written to address the specific needs of individuals served within a discreet system of care be considered as a whole in assessing whether they are as stringent or more stringent than the federal requirements. Another comment requested explicit clarification that state laws with a broader scope than the regulation will be viewed as more stringent and be allowed to stand.

Response: We have not adopted the approach suggested by these comments. As discussed above with respect to the definition of the term "more stringent," it is our view that the statute precludes the approach suggested. We also suggest that this approach ignores the fact that each separate provision of law usually represents a nuanced policy choice to, for example, permit this use or prohibit that disclosure; the aggregated approach proposed would fail to recognize and weigh such policy choices.

Comment: One comment recommended that the final rule: permit requests for exception determinations and advisory opinions as of the date of publication of the final rule, require the Secretary to notify the requestor within a specified short period of time of all additional information needed, and prohibit enforcement action until the Secretary issues a response.

Response: With respect to the first recommendation, we clarify that requests for exception determinations may be made at any time; since the process for issuing advisory opinions has not been adopted, this recommendation is moot as it pertains ***82585** to advisory opinions. With respect to the second recommendation, we will undertake to process exception requests as expeditiously as possible, but, for the reasons discussed below in connection with the comments relating to setting deadlines for those determinations, we cannot commit at this time to a "specified short period of time" within which the Secretary may request additional information. We see no reason to agree to the third recommendation. Because contrary state laws for which an exception is available only under section 1178(a)(2)(A) will be preempted by operation of law unless and until the Secretary acts to grant an exception, there will be an ascertainable compliance standard for compliance purposes, and enforcement action would be appropriate where such compliance did not occur.

Sections 160.203(a) and 160.204(a)—Exception Determinations

Section 160.203(a)—Criteria for Exception Determinations

Comment: Numerous comments criticized the proposed criteria for their substance or lack thereof. A number of commenters argued that the effectiveness language that was added to the third statutory criterion made the exception so massive that it would swallow the rule. These comments generally expressed concern that laws that were less protective of privacy would be granted exceptions under this language. Other commenters criticized the criteria generally as creating a large loophole that would let state laws that do not protect privacy trump the federal privacy standards.

Response: We agree with these comments. The scope of the statutory criteria is ambiguous, but they could be read so broadly as to largely swallow the federal protections. We do not think that this was Congress's intent. Accordingly, we have added language to most of the statutory criteria clarifying their scope. With respect to the criteria at 1178(a)(2)(A)(i), this clarifying language generally ties the criteria more specifically to the concern with protecting and making more efficient the health care delivery and payment system that underlies the Administrative Simplification provisions of HIPAA, but, with respect to the catch-all provision at section 1178(a)(2)(A)(i)(IV), also requires that privacy interests be balanced with such concerns, to the extent relevant. We require that exceptions for rules to ensure appropriate state regulation of insurance and health plans be stated in a statute or regulation, so that such exceptions will be clearly tied to statements of priorities made by publicly accountable bodies (e.g., through the public comment process for regulations, and by elected officials through statutes). With respect to the criterion at section 1178(a)(2)(A)(ii), we have further delineated what "addresses controlled substances" means. The language provided, which builds on concepts at 21 U.S.C. 821 and the Medicare regulations at 42 CFR 1001.2, delineates the area within which the government traditionally regulates controlled substances, both civilly and criminally; it is our view that HIPAA was not intended to displace such regulation.

Comment: Several commenters urged that the request for determination by the Secretary under proposed § 160.204(a) be limited to cases where an exception is absolutely necessary, and that in making such a determination, the Secretary should be required to make a determination that the benefits of granting an exception outweigh the potential harm and risk of disclosure in violation of the regulation.

Response: We have not further defined the statutory term "necessary", as requested. We believe that the determination of what is "necessary" will be fact-specific and context dependent, and should not be further circumscribed absent such specifics. The state will need to make its case that the state law in question is sufficiently "necessary" to accomplish the particular statutory ground for exception that it should trump the contrary federal standard, requirement, or implementation specification.

Comment: One commenter noted that a state should be required to explain whether it has taken any action to correct any less stringent state law for which an exception has been requested. This commenter recommended that a section be added to proposed § 160.204(a) stating that "a state must specify what, if any, action has been taken to amend the state law to comply with the federal regulations." Another comment, received in the Transactions rulemaking, took the position that exception determinations should be granted only if the state standards in question exceeded the national standards.

Response: The first and last comments appear to confuse the "more stringent" criterion that applies under section 1178(a)(2)(B) of the Act with the criteria that apply to exceptions under section 1178(a)(2)(A). We are also not adopting the language suggested by the first comment, because we do not agree that states should necessarily have to try to amend their state laws as a precondition to requesting exceptions under section 1178(a)(2)(A). Rather, the question should be whether the state has made a convincing case that the state law in question is sufficiently necessary for one of the statutory purposes that it should trump the contrary federal policy.

Comment: One commenter stated that exceptions for state laws that are contrary to the federal standards should not be preempted where the state and federal standards are found to be equal.

Response: This suggestion has not been adopted, as it is not consistent with the statute. With respect to the administrative simplification standards in general, it is clear that the intent of Congress was to preempt contrary state laws except in the limited areas specified as exceptions or carve-outs. See, section 1178. This statutory approach is consistent with the underlying goal of simplifying health care transactions through the adoption of uniform national standards. Even with respect to state laws relating to the privacy of medical information, the statute shields such state laws from preemption by the federal standards only if they are "more" stringent than the related federal standard or implementation specification.

Comment: One commenter noted that determinations would apply only to transactions that are wholly intrastate. Thus, any element of a health care transaction that would implicate more than one state's law would automatically preclude the Secretary's

evaluation as to whether the laws were more or less stringent than the federal requirement. Other commenters expressed confusion about this proposed requirement, noting that providers and plans operate now in a multi-state environment.

Response: We agree with the commenters and have dropped the proposed requirement. As noted by the commenters, health care entities now typically operate in a multi-state environment, so already make the choice of law judgements that are necessary in multi-state transactions. It is the result of that calculus that will have to be weighed against the federal standards, requirements, and implementation specifications in the preemption analysis.

Comment: One comment received in the Transactions rulemaking suggested that the Department should allow exceptions to the standard transactions to accommodate abbreviated transactions between state agencies, such as claims between a public health department and the state Medicaid ***82586** agency. Another comment requested an exception for Home and Community Based Waiver Services from the transactions standards.

Response: The concerns raised by these comments would seem to be more properly addressed through the process established for maintaining and modifying the transactions standards. If the concerns underlying these comments cannot be addressed in this manner, however, there is nothing in the rules below to preclude states from requesting exceptions in such cases. They will then have to make the case that one or more grounds for exception applies.

Section 160.204(a)—Process for Exception Determinations—Comments and Responses

Comment: Several comments received in the Transactions rulemaking stated that the process for applying for and granting exception determinations (referred to as "waivers" by some) needed to be spelled out in the final rule.

Response: We agree with these comments. As noted above, since no process was proposed in the Transactions rulemaking, a process for making exception determinations was not adopted in those final rules. Subpart B below adopts a process for making exception determinations, which responds to these comments.

Comment: Comments stated that the exception process would be burdensome, unwieldy, and time-consuming for state agencies as well as the Department. One comment took the position that states should not be required to submit exception requests to the Department under proposed § 160.203(a), but could provide documentation that the state law meets one of the conditions articulated in proposed § 160.203.

Response: We disagree that the process adopted at § 164.204 below will be burdensome, unwieldy, or time-consuming. The only thing the regulation describes is the showings that a requestor must make as part of its submission, and all are relevant to the issue to be determined by the Secretary. How much information is submitted is, generally speaking, in the requestor's control, and the regulation places no restrictions on how the requestor obtains it, whether by acting directly, by working with providers and/or plans, or by working with others. With respect to the suggestion that states not be required to submit exception requests, we disagree that this suggestion is either statutorily authorized or advisable. We read this comment as implicitly suggesting that the Secretary must proactively identify instances of conflict and evaluate them. This suggestion is, thus, at bottom the same as the many suggestions that we create a database or compendium of controlling law, and it is rejected for the same reasons.

Comment: Several comments urged that all state requests for non-preemption include a process for public participation. These comments believe that members of the public and other interested stakeholders should be allowed to submit comments on a state's request for exception, and that these comments should be reviewed and considered by the Secretary in determining whether the exception should be granted. One comment suggested that the Secretary at least give notice to the citizens of the state prior to granting an exception.

Response: The revision to § 160.204(a), to permit requests for exception determinations by any person, responds to these comments.

Comment: Many commenters noted that the lack of a clear and reasonable time line for the Secretary to issue an exception determination would not provide sufficient assurance that the questions regarding what rules apply will be resolved in a time frame that will allow business to be conducted properly, and argued that this would increase confusion and uncertainty about which statutes and regulations should be followed. Timeframes of 60 or 90 days were suggested. One group suggested that, if a state does not receive a response from HHS within 60 days, the waiver should be deemed approved.

Response: The workload prioritization and management considerations discussed above with respect to advisory opinions are also relevant here and make us reluctant to agree to a deadline for making exception determinations. This is particularly true at the outset, since we have no experience with such requests. We therefore have no basis for determining how long processing such requests will take, how many requests we will need to process, or what resources will be available for such processing. We agree that states and other requesters should receive timely responses and will make every effort to make determinations as expeditiously as possible, but we cannot commit to firm deadlines in this initial rule. Once we have experience in handling exception requests, we will consult with states and others in regard to their experiences and concerns and their suggestions for improving the Secretary's expeditious handling of such requests.

We are not accepting the suggestion that requests for exception be deemed approved if not acted upon in some defined time period. Section 1178(a)(2)(A) requires a specific determination by the Secretary. The suggested policy would not be consistent with this statutory requirement. It is also inadvisable from a policy standpoint, in that it would tend to maximize exceptions. This would be contrary to the underlying statutory policy in favor of uniform federal standards.

Comment: One commenter took exception to the requirement for states to seek a determination from the Department that a provision of state law is necessary to prevent fraud and abuse or to ensure appropriate state regulation of insurance plans, contending that this mandate could interfere with the Insurance Commissioners' ability to do their jobs. Another commenter suggested that the regulation specifically recognize the broad scope of state insurance department activities, such as market conduct examinations, enforcement investigations, and consumer complaint handling.

Response: The first comment raises an issue that lies outside our legal authority to address, as section 1178(a)(2)(A) clearly mandates that the Secretary make a determination in these areas. With respect to the second comment, to the extent these concerns pertain to health plans, we believe that the provisions at § 164.512 relating to oversight and disclosures required by law should address the concerns underlying this comment.

Section 160.204(a)(4)—Period of Effectiveness of Exception Determinations

Comment: Numerous commenters stated that the proposed three year limitation on the effectiveness of exception determinations would pose significant problems and should be limited to one year, since a one year limitation would provide more frequent review of the necessity for exceptions. The commenters expressed concern that state laws which provide less privacy protection than the federal regulation would be given exceptions by the Secretary and thus argued that the exceptions should be more limited in duration or that the Secretary should require that each request, regardless of duration, include a description of the length of time such an exception would be needed.

One state government commenter, however, argued that the 3 year limit should be eliminated entirely, on the ground that requiring a redetermination ***82587** every three years would be burdensome for the states and be a waste of time and resources for all parties. Other commenters, including two state agencies, suggested that the exemption should remain effective until either the state law or the federal regulation is changed. Another commenter suggested that the three year sunset be deleted and that the final rule provide for automatic review to determine if changes in circumstance or law would necessitate amendment or deletion of the opinion. Other recommendations included deeming the state law as continuing in effect upon the submission of a state application for an exemption rather than waiting for a determination by the Secretary that may not occur for a substantial period of time.

Response: We are persuaded that the proposed 3 year limit on exception determinations does not make sense where neither law providing the basis for the exception has changed in the interim. We also agree that where either law has changed, a previously granted exception should not continue. Section 160.205(a) below addresses these concerns.

Sections 160.203(b) and 160.204(b)—Advisory Opinions

Section 160.203(b)—Effect of Advisory Opinions

Comment: Several commenters questioned whether or not DHHS has standing to issue binding advisory opinions and recommended that the Department clarify this issue before implementation of this regulation. One respondent suggested that the Department clarify in the final rule the legal issues on which it will opine in advisory opinion requests, and state that in responding to requests for advisory opinions the Department will not opine on the preemptive force of ERISA with respect to state laws governing the privacy of individually identifiable health information, since interpretations as to the scope and extent of ERISA's preemption provisions are outside of the Department's jurisdictional authority.

One commenter asked whether a state could enforce a state law which the Secretary had indicated through an advisory opinion is preempted by federal law. This commenter also asked whether the state would be subject to penalties if it chose to continue to enforce its own laws.

Response: As discussed above, in part for reasons raised by these comments, the Department has decided not to have a formal process for issuing advisory opinions, as proposed.

Several of these concerns, however, raise issues of broader concern that need to be addressed. First, we disagree that the Secretary lacks legal authority to opine on whether or not state privacy laws are preempted. The Secretary is charged by law with determining compliance, and where state law and the federal requirements conflict, a determination of which law controls will have to be made in order to determine whether the federal standard, requirement, or implementation specification at issue has been violated. Thus, the Secretary cannot carry out her enforcement functions without making such determinations. It is further reasonable that, if the Secretary makes such determinations, she can make those determinations known, for whatever persuasive effect they may have.

The questions as to whether a state could enforce, or would be subject to penalties if it chose to continue to enforce, its own laws following a denial by the Secretary of an exception request under § 160.203 or a holding by a court of competent jurisdiction that a state privacy law had been preempted by a contrary federal privacy standard raise several issues. First, a state law is preempted under the Act only to the extent that it applies to covered entities; thus, a state is free to continue to enforce a “preempted” state law against non-covered entities to which the state law applies. If there is a question of coverage, states may wish to establish processes to ascertain which entities within their borders are covered entities within the meaning of these rules. Second, with respect to covered entities, if a state were to try to enforce a preempted state law against such entities, it would presumably be acting without legal authority in so doing. We cannot speak to what remedies might be available to covered entities to protect themselves against such wrongful state action, but we assume that covered entities could seek judicial relief, if all else failed. With respect to the issue of imposing penalties on states, we do not see this as likely. The only situation that we can envision in which penalties might be imposed on a state would be if a state agency were itself a covered entity and followed a preempted state law, thereby violating the contrary federal standard, requirement, or implementation specification.

Section 160.204(b)—Process for Advisory Opinions

Comment: Several commenters stated that it was unclear whether a state would be required to submit a request for an advisory opinion in order for the law to be considered more stringent and thus not preempted. The Department should clarify whether a state law could be non-preempted even without such an advisory opinion. Another commenter requested that the final rule explicitly state that the stricter rule always applies, whether it be state or federal, and regardless of whether there is any conflict between state and federal law.

Response: The elimination of the proposed process for advisory opinions renders moot the first question. Also, the preceding response clarifies that which law preempts in the privacy context (assuming that the state law and federal requirement are "contrary") is a matter of which one is the "more stringent." This is not a matter which the Secretary will ultimately determine; rather, this is a question about which the courts will ultimately make the final determination. With respect to the second comment, we believe that § 160.203(b) below responds to this issue, but we would note that the statute already provides for this.

Comment: Several commenters supported the decision to limit the parties who may request advisory opinions to the state. These commenters did not believe that insurers should be allowed to request an advisory opinion and open every state law up to challenge and review.

Several commenters requested that guidance on advisory opinions be provided in all circumstances, not only at the Secretary's discretion. It was suggested that proposed § 160.204(b)(2)(iv) be revised to read as follows: "A state may submit a written request to the Secretary for an advisory opinion under this paragraph. The request must include the following information: the reasons why the state law should or should not be preempted by the federal standard, requirement, or implementation specification, including how the state law meets the criteria at § 160.203(b)."

Response: The decision not to have a formal process for issuing advisory opinions renders these issues moot.

Sections 160.203(c) and 160.203(d)—Statutory Carve-Outs

Comment: Several commenters asked that the Department provide more specific examples itemizing activities traditionally regulated by the state that could constitute "carve-out" exceptions. These commenters also requested that the Department include language in the regulation stating that if a state law falls within several different exceptions, the state chooses which determination exception shall apply. ***82588**

Response: We are concerned that itemizing examples in this way could leave out important state laws or create inadvertent negative implications that laws not listed are not included. However, as explained above, we have designed the types of activities that are permissive disclosures for public health under § 164.512(b) below in part to come within the carve-out effected by section 1178(b); while the state regulatory activities covered by section 1178(c) will generally come within § 164.512(d) below. With respect to the comments asking that a state get to "choose" which exception it comes under, we have in effect provided for this with respect to exceptions under section 1178(a)(2)(A), by giving the state the right to request an exception under that section. With respect to exceptions under section 1178(a)(2)(B), those exceptions occur by operation of law, and it is not within the Secretary's power to "let" the state choose whether an exception occurs under that section.

Comment: Several commenters took the position that the Secretary should not limit the procedural requirements in proposed § 160.204(a) to only those applications under proposed § 160.203(a). They urged that the requirements of proposed § 160.204(a) should also apply to preemption under sections 1178(a)(2)(B), 1178(b) and 1178(c). It was suggested that the rules should provide for exception determinations with respect to the matters covered by these provisions of the statute; such additional provisions would provide clear procedures for states to follow and ensure that requests for exceptions are adequately documented.

A slightly different approach was taken by several commenters, who recommended that proposed § 160.204(b) be amended to clarify that the Secretary will also issue advisory opinions as to whether a state law constitutes an exception under proposed §§ 160.203(c) and 160.203(d). This change would, they argued, give states the same opportunity for guidance that they have under § 160.203(a) and (b), and as such, avoid costly lawsuits to preserve state laws.

Response: We are not taking either of the recommended courses of action. With respect to the recommendation that we expand the exception determination process to encompass exceptions under sections 1178(a)(2)(B), 1178(b), and 1178(c), we do not have the authority to grant exceptions under these sections. Under section 1178, the Secretary has authority to make exception

determinations only with respect to the matters covered by section 1178(a)(2)(A); contrary state laws coming within section 1178(a)(2)(B) are preempted if not more stringent, while if a contrary state law comes within section 1178(b) or section 1178(c), it is not preempted. These latter statutory provisions operate by their own terms. Thus, it is not within the Secretary's authority to establish the determination process which these comments seek.

With respect to the request seeking advisory opinions in the section 1178(b) and 1178(c) situations, we agree that we have the authority to issue such opinions. However, the considerations described above that have led us not to adopt a formal process for issuing advisory opinions in the privacy context apply with equal force and effect here.

Comment: One commenter argued that it would be unnecessarily burdensome for state health data agencies (whose focus is on the cost of healthcare or improving Medicare, Medicaid, or the healthcare system) to obtain a specific determination from the Department for an exception under proposed § 160.203(c). States should be required only to notify the Secretary of their own determination that such collection is necessary. It was also argued that cases where the statutory carve-outs apply should not require a Secretarial determination.

Response: We clarify that no Secretarial determination is required for activities that fall into one of the statutory carve-outs. With respect to data collections for state health data agencies, we note that provision has been made for many of these activities in several provisions of the rules below, such as the provisions relating to disclosures required by law (§ 164.512(a)), disclosures for oversight (§ 164.512(d)), and disclosures for public health (§ 164.512(b)). Some disclosures for Medicare and Medicaid purposes may also come within the definition of health care operations. A fuller discussion of this issue appears in connection with § 164.512 below.

Constitutional Comments and Responses

Comment: Several commenters suggested that as a general matter the rule is unconstitutional.

Response: We disagree that the rule is unconstitutional. The particular grounds for this conclusion are set out with respect to particular constitutional issues in the responses below. With respect to the comments that simply made this general assertion, the lack of detail of the comments makes a substantive response impossible.

Article II

Comment: One commenter contended that the Secretary improperly delegated authority to private entities by requiring covered entities to enter into contracts with, monitor, and take action for violations of the contract against their business partners. These comments assert that the selection of these entities to “enforce” the regulations violates the Executive Powers Clause and the Appointments and Take Care Clauses.

Response: We reject the assertion that the business associate provisions constitute an improper delegation of executive power to private entities. HIPAA provides HHS with authority to enforce the regulation against covered entities. The rules below regulate only the conduct of the covered entity; to the extent a covered entity chooses to conduct its funding through a business associate, those functions are still functions of the covered entity. Thus, no improper delegation has occurred because what is being regulated are the actions of the covered entity, not the actions of the business associate in its independent capacity.

We also reject the suggestion that the business associates provisions constitute an improper appointment of covered entities to enforce the regulation and violate the Take Care Clause. Because the Secretary has not delegated authority to covered entities, the inference that she has appointed covered entities to exercise such authority misses the mark.

Commerce Clause

Comment: A few commenters suggested that the privacy regulation regulates activities that are not in interstate commerce and which are, therefore, beyond the powers the U.S. Constitution gives the federal government.

Response: We disagree. Health care providers, health plans, and health care clearinghouses are engaged in economic and commercial activities, including the exchange of individually identifiable health information electronically across state lines. These activities constitute interstate commerce. Therefore, they come within the scope of Congress' power to regulate interstate commerce.

Nondelegation Doctrine

Comment: Some commenters objected to the manner by which Congress provided the Secretary authority to promulgate this regulation. These comments asserted that Congress violated the nondelegation doctrine by (1) not providing an "intelligible principle" to guide the agency, (2) not ***82589** establishing "ascertainable standards," and (3) improperly permitting the Secretary to make social policy decisions.

Response: We disagree. HIPAA clearly delineates Congress' general policy to establish strict privacy protections for individually identifiable health information to encourage electronic transactions. Congress also established boundaries limiting the Secretary's authority. Congress established these limitations in several ways, including by calling for privacy standards for "individually identifiable health information"; specifying that privacy standards must address individuals' rights regarding their individually identifiable health information, the procedures for exercising those rights, and the particular uses and disclosures to be authorized or required; restricting the direct application of the privacy standards to "covered entities," which Congress defined; requiring consultation with the National Committee on Vital and Health Statistics and the Attorney General; specifying the circumstances under which the federal requirements would supersede state laws; and specifying the civil and criminal penalties the Secretary could impose for violations of the regulation. These limitations also serve as "ascertainable standards" upon which reviewing courts can rely to determine the validity of the exercise of authority.

Although Congress could have chosen to impose expressly an exhaustive list of specifications that must be met in order to achieve the protective purposes of the HIPAA, it was entirely permissible for Congress to entrust to the Secretary the task of providing these specifications based on her experience and expertise in dealing with these complex and technical matters.

We disagree with the comments that Congress improperly delegated Congressional policy choices to her. Congress clearly decided to create federal standards protecting the privacy of "individually identifiable health information" and not to preempt state laws that are more stringent. Congress also determined over whom the Secretary would have authority, the type of information protected, and the minimum level of regulation.

Separation of Powers

Comment: Some commenters asserted that the federal government may not preempt state laws that are not as strict as the privacy regulation because to do so would violate the separation of powers in the U.S. Constitution. One comment suggested that the rules raised a substantial constitutional issue because, as proposed, they permitted the Secretary to make determinations on preemption, which is a role reserved for the judiciary.

Response: We disagree. We note that this comment only pertains to determinations under section 1178(a)(2)(A); as discussed above, the rules below provide for no Secretarial determinations with respect to state privacy laws coming within section 1178(a)(2)(B). With respect to determinations under section 1178(a)(2)(A), however, the final rules, like the proposed rules, provide that at a state's request the Secretary may make certain determinations regarding the preemptive effect of the rules on a particular state law. As usually the case with any administrative decisions, these are subject to judicial review pursuant to the Administrative Procedure Act.

First Amendment

Comment: Some comments suggested that the rules violated the First Amendment. They asserted that if the rule included Christian Science practitioners as covered entities it would violate the separation of church and state doctrine.

Response: We disagree. The First Amendment does not always prohibit the federal government from regulating secular activities of religious organizations. However, we address concerns relating to Christian Science practitioners more fully in the response to comments discussion of the definition of "covered entity" in § 160.103.

Fourth Amendment

Comment: Many comments expressed Fourth Amendment concerns about various proposed provisions. These comments fall into two categories—general concerns about warrantless searches and specific concerns about administrative searches. Several comments argued that the proposed regulations permit law enforcement and government officials access to protected health information without first requiring a judicial search warrant or an individual's consent. These comments rejected the applicability of any of the existing exceptions permitting warrantless searches in this context. Another comment argued that federal and state police should be able to obtain personal medical records only with the informed consent of an individual. Many of these comments also expressed concern that protected health information could be provided to government or private agencies for inclusion in a governmental health data system.

Response: We disagree that the provisions of these rules that permit disclosures for law enforcement purposes and governmental health data systems generally violate the Fourth Amendment. The privacy regulation does not create new access rights for law enforcement. Rather, it refrains from placing a significant barrier in front of access rights that law enforcement currently has under existing legal authority. While the regulation may permit a covered entity to make disclosures in specified instances, it does not require the covered entity make the disclosure. Thus, because we are not modifying existing law regarding disclosures to law enforcement officials, except to strengthen the requirements related to requests already authorized under law, and are not requiring any such disclosures, the privacy regulation does not infringe upon individual's Fourth Amendment rights. We discuss the rationale underlying the permissible disclosures to law enforcement officials more fully in the preamble discussion relating to § 164.512(f).

We note that the proposed provision relating to disclosures to government health data systems has been eliminated in the final rule. However, to the extent that the comments can be seen as raising concern over disclosure of protected health information to government agencies for public health, health oversight, or other purposes permitted by the final rule, the reasoning in the previous paragraph applies.

Comment: One commenter suggested that the rules violate the Fourth Amendment by requiring covered entities to provide access to the Secretary to their books, records, accounts, and facilities to ensure compliance with these rules. The commenter also suggested that the requirement that covered entities enter into agreements with their business partners to make their records available to the Secretary for inspection as well also violates the warrant requirement of the Fourth Amendment.

Response: We disagree. These requirements are consistent with U.S. Supreme Court cases holding that warrantless administrative searches of commercial property are not per se violations of the Fourth Amendment. The provisions requiring that covered entities provide access to certain material to determine compliance with the regulation come within the well-settled exception regarding closely regulated businesses and industries to the warrant requirement. From state and local licensure laws to the federal fraud and abuse statutes and regulations, the health care industry is one of the most ***82590** tightly regulated businesses in the country. Because the industry has such an extensive history of government oversight and involvement, those operating within it have no reasonable expectation of privacy from the government such that a warrant would be required to determine compliance with the rules.

In addition, the cases cited by the commenters concern unannounced searches of the premises and facilities of particular entities. Because our enforcement provisions only provide for the review of books, records, and other information and only during normal business hours with notice, except for exceptional situations, this case law does not apply.

As for business associates, they voluntarily enter into their agreements with covered entities. This agreement, therefore, functions as knowing and voluntary consents to the search (even assuming it could be understood to be a search) and obviates the need for a warrant.

Fifth Amendment

Comment: Several comments asserted that the proposed rules violated the Fifth Amendment because in the commenters' views they authorized the taking of privacy property without just compensation or due process of law.

Response: We disagree. The rules set forth below do not address the issue of who owns an individual's medical record. Instead, they address what uses and disclosures of protected health information may be made by covered entities with or without a consent or authorization. As described in response to a similar comment, medical records have been the property of the health care provider or medical facility that created them, historically. In some states, statutes directly provide these entities with ownership. These laws are limited by laws that provide patients or their representatives with access to the records or that provide the patient with an ownership interest in the information within the records. As we discuss, the final rule is consistent with current state law that provides patients access to protected health information, but not ownership of medical records. State laws that provide patients with greater access would remain in effect. Therefore, because patients do not own their records, no taking can occur. As for their interest in the information, the final rule retains their rights. As for covered entities, the final rule does not take away their ownership rights or make their ownership interest in the protected health information worthless. Therefore, no taking has occurred in these situations either.

Ninth and Tenth Amendments

Comment: Several comments asserted that the proposed rules violated the Ninth and Tenth Amendments. One commenter suggested that the Ninth Amendment prohibits long and complicated regulations. Other commenters suggested that the proposed rules authorized the compelled disclosure of individually identifiable health information in violation of State constitutional provisions, such as those in California and Florida. Similarly, a couple of commenters asserted that the privacy rules violate the Tenth Amendment.

Response: We disagree. The Ninth and Tenth Amendments address the rights retained by the people and acknowledge that the States or the people are reserved the powers not delegated to the federal government and not otherwise prohibited by the Constitution. Because HHS is regulating under a delegation of authority from Congress in an area that affects interstate commerce, we are within the powers provided to Congress in the Constitution. Nothing in the Ninth Amendment, or any other provision of the Constitution, restricts the length or complexity of any law. Additionally, we do not believe the rules below impermissibly authorize behavior that violates State constitutions. This rule requires disclosure only to the individual or to the Secretary to enforce this rule. As noted in the preamble discussion of “Preemption,” these rules do not preempt State laws, including constitutional provisions, that are contrary to and more stringent, as defined at § 160.502, than these rules. See the discussion of “Preemption” for further clarification. Therefore, if these State constitutions are contrary to the rule below and provide greater protection, they remain in full force; if they do not, they are preempted, in accordance with the Supremacy Clause of the Constitution.

Right to Privacy

Comment: Several comments suggested that the proposed regulation would violate the right to privacy guaranteed by the First, Fourth, Fifth, and Ninth Amendments because it would permit covered entities to disclose protected health information without the consent of the individual.

Response: These comments did not provide specific facts or legal basis for the claims. We are, thus, unable to provide a substantive response to these particular comments. However, we note that the rule requires disclosures only to the individual or to the Secretary to determine compliance with this rule. Other uses or disclosures under this rule are permissive, not required. Therefore, if a particular use or disclosure under this rule is viewed as interfering with a right that prohibited the use or disclosure, the rule itself is not what requires the use or disclosure.

Void for Vagueness

Comment: One comment suggested that the Secretary's use of a "reasonableness" standard is unconstitutionally vague. Specifically, this comment objected to the requirement that covered entities use "reasonable" efforts to use or disclose the minimum amount of protected health information, to ensure that business partners comply with the privacy provisions of their contracts, to notify business partners of any amendments or corrections to protected health information, and to verify the identity of individuals requesting information, as well as charge only a "reasonable" fee for inspecting and copying health information. This comment asserted that the Secretary provided "inadequate guidance" as to what qualifies as "reasonable."

Response: We disagree with the comment's suggestion that by applying a "reasonableness" standard, the regulation has failed to provide for "fair warning" or "fair enforcement." The "reasonableness" standard is well-established in law; for example, it is the foundation of the common law of torts. Courts also have consistently held as constitutional statutes that rely upon a "reasonableness" standard. Our reliance upon a "reasonableness" standard, thus, provides covered entities with constitutionally sufficient guidance.

Criminal Intent

Comment: One comment argued that the regulation's reliance upon a "reasonableness" standard criminalizes "unreasonable efforts" without requiring criminal intent or mens rea.

Response: We reject this suggestion because HIPAA clearly provides the criminal intent requirement. Specifically, HIPPA provides that a "person who knowingly and in violation of this part—(1) uses or causes to be used a unique health identifier; (2) obtains individually identifiable health information relating to an individual; or (3) discloses individually identifiable health information to another person, shall be punished as provided in subsection (b)." HIPAA section 1177 (emphasis added). Subsection (b) also relies on a knowledge standard in ***82591** outlining the three levels of criminal sanctions. Thus, Congress, not the Secretary, established the mens rea by including the term "knowingly" in the criminal penalty provisions of HIPAA.

Data Collection

Comment: One commenter suggested that the U.S. Constitution authorized the collection of data on individuals only for the purpose of the census.

Response: While it might be true that the U.S. Constitution expressly discusses the national census, it does not forbid federal agencies from collecting data for other purposes. The ability of agencies to collect non-census data has been upheld by the courts.

Relationship to Other Federal Laws

Comment: We received several comments that sought clarification of the interaction of various federal laws and the privacy regulation. Many of these comments simply listed federal laws and regulations with which the commenter currently must comply. For example, commenters noted that they must comply with regulations relating to safety, public health, and civil rights, including Medicare and Medicaid, the Americans with Disabilities Act, the Family and Medical Leave Act, the Federal Aviation Administration regulations, the Department of Transportation regulations, the Federal Highway Administration regulations, the Occupational Safety and Health Administration regulations, and the Environmental Protection Agency regulations, and alcohol

and drug free workplace rules. These commenters suggested that the regulation state clearly and unequivocally that uses or disclosures of protected health information for these purposes were permissible. Some suggested modifying the definition of health care operations to include these uses specifically. Another suggestion was to add a section that permitted the transmission of protected health information to employers when reasonably necessary to comply with federal, state, or municipal laws and regulations, or when necessary for public or employee safety and health.

Response: Although we sympathize with entities' needs to evaluate the existing laws with which they must comply in light of the requirements of the final regulation, we are unable to respond substantially to comments that do not pose specific questions. We offer, however, the following guidance: if an covered entity is required to disclose protected health information pursuant to a specific statutory or regulatory scheme, the covered entity generally will be permitted under § 164.512(a) to make these disclosures without a consent or authorization; if, however, a statute or regulation merely suggests a disclosure, the covered entity will need to determine if the disclosure comes within another category of permissible disclosure under §§ 164.510 or 164.512 or, alternatively, if the disclosure would otherwise come within § 164.502. If not, the entity will need to obtain a consent or authorization for the disclosure.

Comment: One commenter sought clarification as to when a disclosure is considered to be "required" by another law versus "permitted" by that law.

Responses: We use these terms according to their common usage. By "required by law," we mean that a covered entity has a legal obligation to disclose the information. For example, if a statute states that a covered entity must report the names of all individuals presenting with gun shot wounds to the emergency room or else be fined $500 for each violation, a covered entity would be required by law to disclose the protected health information necessary to comply with this mandate. The privacy regulation permits this type of disclosure, but does not require it. Therefore, if a covered entity chose not to comply with the reporting statute it would violate only the reporting statute and not the privacy regulation.

On the other hand, if a statute stated that a covered entity may or is permitted to report the names of all individuals presenting with gun shot wounds to the emergency room and, in turn, would receive $500 for each month it made these reports, a covered entity would not be permitted by § 164.512(a) to disclose the protected health information. Of course, if another permissible provision applied to these facts, the covered entity could make the disclosure under that provision, but it would not be considered to be a disclosure. See discussion under § 164.512(a) below.

Comment: Several commenters suggested that the proposed rule was unnecessarily duplicative of existing regulations for federal programs, such as Medicare, Medicaid, and the Federal Employee Health Benefit Program.

Response: Congress specifically subjected certain federal programs, including Medicare, Medicaid, and the Federal Employee Health Benefit Program to the privacy regulation by including them within the definition of "health plan." Therefore, covered entities subject to requirements of existing federal programs will also have to comply with the privacy regulation.

Comment: One comment asserts that the regulation would not affect current federal requirements if the current requirements are weaker than the requirements of the privacy regulation. This same commenter suggested that current federal requirements will trump both state law and the proposed regulation, even if Medicaid transactions remain wholly intrastate.

Response: We disagree. As noted in our discussion of "Relationship to Other Federal Laws," each law or regulation will need to be evaluated individually. We similarly disagree with the second assertion made by the commenter. The final rule will preempt state laws only in specific instances. For a more detailed analysis, see the preamble discussion of "Preemption."

Administrative Subpoenas

Comment: One comment stated that the final rule should not impose new standards on administrative subpoenas that would conflict with existing laws or administrative or judicial rules that establish standards for issuing subpoenas. Nor should the final

rule conflict with established standards for the conduct of administrative, civil, or criminal proceedings, including the rules regarding the discovery of evidence. Other comments sought further restrictions on access to protected health information in this context.

Response: Section 164.512(e) below addresses disclosures for judicial and administrative proceedings. The final rules generally do not interfere with these existing processes to the extent an individual served with a subpoena, court order, or other similar process is able to raise objections already available. See the discussion below under § 164.512(e) for a fuller response.

Americans with Disabilities Act

Comment: Several comments discussed the intersection between the proposed Privacy Rule and the Americans with Disabilities Act ("ADA") and sections 503 and 504 of the Rehabilitation Act of 1973. One comment suggested that the final rule explicitly allows disclosures authorized by the Americans with Disabilities Act without an individual's authorization, because this law, in the commenter's view, provides more than adequate protection for the confidentiality of medical records in the employment context. The comment noted that under these laws employers may receive information related to fitness for duty, pre-employment physicals, routine examinations, return to work examinations, examinations following other types of absences, examinations triggered by specific events, changes in ***82592** circumstances, requests for reasonable accommodations, leave requests, employee wellness programs, and medical monitoring.

Other commenters suggested that the ADA requires the disclosure of protected health information to employers so that the employee may take advantage of the protections of these laws. They suggested that the final rules clarify that employment may be conditioned on obtaining an authorization for disclosure of protected health information for lawful purposes and provide guidance concerning the interaction of the ADA with the final regulation's requirements. Several commenters wanted clarification that the privacy regulation would not permit employers to request or use protected health information in violation of the ADA.

Response: We disagree with the comment that the final rule should allow disclosures of protected health information authorized by the ADA without the individual's authorization. We learned from the comments that access to and use of protected health information by employers is of particular concern to many people. With regard to employers, we do not have statutory authority to regulate them. Therefore, it is beyond the scope of this regulation to prohibit employers from requesting or obtaining protected health information. Covered entities may disclose protected health information about individuals who are members of an employer's workforce with an authorization. Nothing in the privacy regulation prohibits employers from obtaining that authorization as a condition of employment. We note, however, that employers must comply with other laws that govern them, such as nondiscrimination laws. For example, if an employer receives a request for a reasonable accommodation, the employer may require reasonable documentation about the employee's disability and the functional limitations that require the reasonable accommodation, if the disability and the limitations are not obvious. If the individual provides insufficient documentation and does not provide the missing information in a timely manner after the employer's subsequent request, the employer may require the individual to go to an appropriate health professional of the employer's choice. In this situation, the employee does not authorize the disclosure of information to substantiate the disability and the need for reasonable accommodation, the employer need not provide the accommodation.

We agree that this rule does not permit employers to request or use protected health information in violation of the ADA or other antidiscrimination laws.

Appropriations Laws

Comment: One comment suggested that the penalty provisions of HIPAA, if extended to the privacy regulation, would require the Secretary to violate "Appropriations Laws" because the Secretary could be in the position of assessing penalties against her own and other federal agencies in their roles as covered entities. Enforcing penalties on these entities would require the transfer of agency funds to the General Fund.

Response: We disagree. Although we anticipate achieving voluntary compliance and resolving any disputes prior to the actual assessment of penalties, the Department of Justice's Office of Legal Counsel has determined in similar situations that federal agencies have authority to assess penalties against other federal agencies and that doing so is not in violation of the Anti-Deficiency Act, 31 U.S.C. 1341.

Balanced Budget Act of 1997

Comment: One comment expressed concern that the regulation would place tremendous burdens on providers already struggling with the effects of the Balanced Budget Act of 1997.

Response: We appreciate the costs covered entities face when complying with other statutory and regulatory requirements, such as the Balanced Budget Act of 1997. However, HHS cannot address the impact of the Balanced Budget Act or other statutes in the context of this regulation.

Comment: Another comment stated that the regulation is in direct conflict with the Balanced Budget Act of 1997 (“BBA”). The comment asserts that the regulation's compliance date conflicts with the BBA, as well as Generally Acceptable Accounting Principles. According to the comment, covered entities that made capital acquisitions to ensure compliance with the year 2000 (“Y2K”) problem would not be able to account for the full depreciation of these systems until 2005. Because HIPAA requires compliance before that time, the regulation would force premature obsolescence of this equipment because while it is Y2K compliant, it may be HIPAA non-compliant.

Response: This comment raises two distinct issues—(1) the investment in new equipment and (2) the compliance date. With regard to the first issue, we reject the comment's assertion that the regulation requires covered entities to purchase new information systems or information technology equipment, but realize that some covered entities may need to update their equipment. We have tried to minimize the costs, while responding appropriately to Congress' mandate for privacy rules. We have dealt with the cost issues in detail in the “Regulatory Impact Analysis” section of this Preamble. With regard to the second issue, Congress, not the Secretary, established the compliance data at section 1175(b) of the Act.

Civil Rights of Institutionalized Persons Act

Comment: A few comments expressed concern that the privacy regulation would inadvertently hinder the Department of Justice Civil Rights Divisions' investigations under the Civil Rights of Institutionalized Persons Act (“CRIPA”). These comments suggested clearly including civil rights enforcement activities as health care oversight.

Response: We agree with this comment. We do not intend for the privacy rules to hinder CRIPA investigations. Thus, the final rule includes agencies that are authorized by law to “enforce civil rights laws for which health information is relevant” in the definition of “health oversight agency” at § 164.501. Covered entities are permitted to disclose protected health information to health oversight agencies under § 164.512(d) without an authorization. Therefore, we do not believe the final rule should hinder the Department of Justice's ability to conduct investigations pursuant to its authority in CRIPA.

Clinical Laboratory Improvement Amendments

Comment: One comment expressed concern that the proposed definition of health care operations did not include activities related to the quality control clinical studies performed by laboratories to demonstrate the quality of patient test results. Because the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) requires these studies that the comment asserted require the use of protected health information, the comment suggested including this specific activity in the definition of “health care operations.”

Response: We do not intend for the privacy regulation to impede the ability of laboratories to comply with the requirements of CLIA. Quality control activities come within the definition of "health care operations" in § 164.501 because they come within the meaning of the term "quality assurance activities." To the extent they would not come within health care operations, but ***82593** are required by CLIA, the privacy regulation permits clinical laboratories that are regulated by CLIA to comply with mandatory uses and disclosures of protected health information pursuant to § 164.512(a).

Comment: One comment stated that the proposed regulation's right of access for inspection and copying provisions were contrary to CLIA in that CLIA permits laboratories to disclose lab test results only to "authorized persons." This comment suggested that the final rule include language adopting this restriction to ensure that patients not obtain laboratory test results before the appropriate health care provider has reviewed and explained those results to the patients.

A similar comment stated that the lack of preemption of state laws could create problems for clinical laboratories under CLIA. Specifically, this comment noted that CLIA permits clinical laboratories to perform tests only upon the written or electronic request of, and to provide the results to, an "authorized person." State laws define who is an "authorized person." The comment expressed concern as to whether the regulation would preempt state laws that only permit physicians to receive test results.

Response: We agree that CLIA controls in these cases. Therefore, we have amended the right of access, § 164.524(a), so that a covered entity that is subject to CLIA does not have to provide access to the individual to the extent such access would be prohibited by law. Because of this change, we believe the preemption concern is moot.

Controlled Substance Act

Comment: One comment expressed concern that the privacy regulation as proposed would restrict the Drug Enforcement Agency's ("the DEA") enforcement of the Controlled Substances Act ("CSA"). The comment suggested including enforcement activities in the definition of "health oversight agency."

Response: In our view, the privacy regulation should not impede the DEA's ability to enforce the CSA. First, to the extent the CSA requires disclosures to the DEA, these disclosures would be permissible under § 164.512(a). Second, some of the DEA's CSA activities come within the exception for health oversight agencies which permits disclosures to health oversight agencies for:

Activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections * * * civil, administrative, or criminal proceedings or actions; and other activity necessary for appropriate oversight of the health care system.

Therefore, to the extent the DEA is enforcing the CSA, disclosures to it in its capacity as a health oversight agency are permissible under § 164.512(d). Alternatively, CSA required disclosures to the DEA for law enforcement purposes are permitted under § 164.512(f). When acting as a law enforcement agency under the CSA, the DEA may obtain the information pursuant to § 164.512(f). Thus, we do not agree that the privacy regulation will impede the DEA's enforcement of the CSA. See the preamble discussion of § 164.512 for further explanation.

Comment: One commenter suggested clarifying the provisions allowing disclosures that are "required by law" to ensure that the mandatory reporting requirements the CSA imposes on covered entities, including making available reports, inventories, and records of transactions, are not preempted by the regulation.

Response: We agree that the privacy regulation does not alter covered entities' obligations under the CSA. Because the CSA requires covered entities manufacturing, distributing, and/or dispensing controlled substances to maintain and provide to the DEA specific records and reports, the privacy regulation permits these disclosures under § 164.512(a). In addition, when the DEA seeks documents to determine an entity's compliance with the CSA, such disclosures are permitted under § 164.512(d).

Comment: The same commenter expressed concern that the proposed privacy regulation inappropriately limits voluntary reporting and would prevent or deter employees of covered entities from providing the DEA with information about violations of the CSA.

Response: We agree with the general concerns expressed in this comment. We do not believe the privacy rules will limit voluntary reporting of violations of the CSA. The CSA requires certain entities to maintain several types of records that may include protected health information. Although reports that included protected health information may be restricted under these rules, reporting the fact that an entity is not maintaining proper reports is not. If it were necessary to obtain protected health information during the investigatory stages following such a voluntary report, the DEA would be able to obtain the information in other ways, such as by following the administrative procedures outlined in § 164.512(e).

We also agree that employees of covered entities who report violations of the CSA should not be subjected to retaliation by their employers. Under § 164.502(j), we specifically state that a covered entity is not considered to have violated the regulation if a workforce member or business associate in good faith reports violations of laws or professional standards by covered entities to appropriate authorities. See discussion of § 164.502(j) below.

Department of Transportation

Comment: Several commenters stated that the Secretary should recognize in the preamble that it is permissible for employers to condition employment on an individual's delivering a consent to certain medical tests and/or examinations, such as drug-free workplace programs and Department of Transportation ("DOT")-required physical examinations. These comments also suggested that employers should be able to receive certain information, such as pass/fail test and examination results, fitness-to-work assessments, and other legally required or permissible physical assessments without obtaining an authorization. To achieve this goal, these comments suggested defining "health information" to exclude information such as information about how much weight a specific employee can lift.

Response: We reject the suggestion to define "health information," which Congress defined in HIPAA, so that it excludes individually identifiable health information that may be relevant to employers for these types of examinations and programs. We do not regulate employers. Nothing in the rules prohibit employers from conditioning employment on an individual signing the appropriate consent or authorization. By the same token, however, the rules below do not relieve employers from their obligations under the ADA and other laws that restrict the disclosure of individually identifiable health information.

Comment: One commenter asserted that the proposed regulation conflicts with the DOT guidelines regarding positive alcohol and drug tests that require the employer be notified in writing of the results. This document contains protected health information. In addition, the treatment center records must be provided to the Substance Abuse Professional ("SAP") and the employer must receive a report from SAP with random drug testing recommendations.

Response: It is our understanding that DOT requires drug testing of all applicants for employment in safety-sensitive positions or individuals being transferred to such positions. ***82594** Employers, pursuant to DOT regulations, may condition an employee's employment or position upon first obtaining an authorization for the disclosure of results of these tests to the employer. Therefore, we do not believe the final rules conflict with the DOT requirements, which do not prohibit obtaining authorizations before such information is disclosed to employers.

Developmental Disabilities Act

Comment: One commenter urged HHS to ensure that the regulation would not impede access to individually identifiable health information to entities that are part of the Protection and Advocacy System to investigate abuse and neglect as authorized by the Developmental Disabilities Bill of Rights Act.

Response: The Developmental Disabilities Assistance and Bill of Rights Act of 2000 ("DD Act") mandates specific disclosures of individually identifiable health information to Protection and Advocacy systems designated by the chief elected official of the states and Territories. Therefore, covered entities may make these disclosures under § 164.512(a) without first obtaining an individual's authorization, except in those circumstances in which the DD Act requires the individual's authorization. Therefore, the rules below will not impede the functioning of the existing Protection and Advocacy System.

Employee Retirement Income Security Act of 1974

Comment: Several commenters objected to the fact that the NPRM did not clarify the scope of preemption of state laws under the Employee Retirement Income Security Act of 1974 (ERISA). These commenters asserted that the final rule must state that ERISA preempts all state laws (including those relating to the privacy of individually identifiable health information) so that multistate employers could continue to administer their group health plans using a single set of rules. In contrast, other commenters criticized the Department for its analysis of the current principles governing ERISA preemption of state law, pointing out that the Department has no authority to interpret ERISA.

Response: This Department has no authority to issue regulations under ERISA as requested by some of these commenters, so the rule below does not contain the statement requested. See the discussion of this point under "Preemption" above.

Comment: One commenter requested that the final rule clarify that section 264(c)(2) of HIPAA does not save state laws that would otherwise be preempted by the Federal Employees Health Benefits Program. The commenter noted that in the NPRM this statement was made with respect to Medicare and ERISA, but not the law governing the FEHBP.

Response: We agree with this comment. The preemption analysis set out above with respect to ERISA applies equally to the Federal Employees Health Benefit Program.

Comment: One commenter noted that the final rule should clarify the interplay between state law, the preemption standards in Subtitle A of Title I of HIPAA (Health Care Access, Portability and Renewability), and the preemption standards in the privacy requirements in Subtitle F of Title II of HIPAA (Administrative Simplification).

Response: The NPRM described only the preemption standards that apply with respect to the statutory provisions of HIPAA that were implemented by the proposed rule. We agree that the preemption standards in Subtitle A of Title I of HIPAA are different. Congress expressly provided that the preemption provisions of Title I apply only to Part 7, which addresses portability, access, and renewability requirements for Group Health Plans. To the extent state laws contain provisions regarding portability, access, or renewability, as well as privacy requirements, a covered entity will need to evaluate the privacy provisions under the Title II preemption provisions, as explained in the preemption provisions of the rules, and the other provisions under the Title I preemption requirements.

European Union Privacy Directive and U.S. Safe Harbors

Comment: Several comments stated that the privacy regulation should be consistent with the European Union's Directive on Data Protection. Others sought guidance as to how to comply with both the E.U. Directive on Data Protection and the U.S. Safe Harbor Privacy Principles.

Response: We appreciate the need for covered entities obtaining personal data from the European Union to understand how the privacy regulation intersects with the Data Protection Directive. We have provided guidance as to this interaction in the "Other Federal Laws" provisions of the preamble.

Comment: A few comments expressed concern that the proposed definition of "individual" excluded foreign military and diplomatic personnel and their dependents, as well as overseas foreign national beneficiaries. They noted that the distinctions

are based on nationality and are inconsistent with the stance of the E.U. Directive on Data Protection and the Department of Commerce's assurances to the European Commission.

Response: We agree with the general principle that privacy protections should protect every person, regardless of nationality. As noted in the discussion of the definition of "individual," the final regulation's definition does not exclude foreign military and diplomatic personnel, their dependents, or overseas foreign national beneficiaries from the definition of individual. As described in the discussion of § 164.512 below, the final rule applies to foreign diplomatic personnel and their dependents like all other individuals. Foreign military personnel receive the same treatment under the final rule as U.S. military personnel do, as discussed with regard to § 164.512 below. Overseas foreign national beneficiaries to the extent they receive care for the Department of Defense or a source acting on behalf of the Department of Defense remain generally excluded from the final rules protections. For a more detailed explanation, see § 164.500.

Fair Credit Reporting Act

Comment: A few commenters requested that we exclude information maintained, used, or disclosed pursuant to the Fair Credit Reporting Act ("FCRA") from the requirements of the privacy regulation. These commenters noted that the protection in the privacy regulation duplicate those in the FCRA.

Response: Although we realize that some overlap between FCRA and the privacy rules may exist, we have chosen not to remove information that may come within the purview of FCRA from the scope of our rules because FCRA's focus is not the same as our Congressional mandate to protect individually identifiable health information.

To the extent a covered entity seeks to engage in collection activities or other payment-related activities, it may do so pursuant to the requirements of this rule related to payment. See discussion of §§ 164.501 and 164.502 below.

We understand that some covered entities may be part of, or contain components that are, entities which meet the definition of "consumer reporting agencies." As such, these entities are subject to the FCRA. As described in the preamble to § 164.504, covered entities must designate what parts of their organizations will be treated as covered entities for the ***82595** purpose of these privacy rules. The covered entity component will need to comply with these rules, while the components that are consumer reporting agencies will need to comply with FCRA.

Comment: One comment suggested that the privacy regulation would conflict with the FCRA if the regulation's requirement applied to information disclosed to consumer reporting agencies.

Response: To the extent a covered entity is required to disclose protected health information to a consumer reporting agency, it may do so under § 164.512(a). See also discussion under the definition of "payment" below.

Fair Debt Collection and Practices Act

Comment: Several comments expressed concern that health plans and health care providers be able to continue using debt collectors in compliance with the Fair Debt Collections Practices Act and related laws.

Response: In our view, health plans and health care providers will be able to continue using debt collectors. Using the services of a debt collector to obtain payment for the provision of health care comes within the definition of "payment" and is permitted under the regulation. Thus, so long as the use of debt collectors is consistent with the regulatory requirements (such as, providers obtain the proper consents, the disclosure is of the minimum amount of information necessary to collect the debt, the provider or health plan enter into a business associate agreement with the debt collector, etc.), relying upon debt collectors to obtain reimbursement for the provision of health care would not be prohibited by the regulation.

Family Medical Leave Act

Comment: One comment suggested that the proposed regulation adversely affects the ability of an employer to determine an employee's entitlement to leave under the Family Medical Leave Act ("FMLA") by affecting the employer's right to receive medical certification of the need for leave, additional certifications, and fitness for duty certification at the end of the leave. The commenter sought clarification as to whether a provider could disclose information to an employer without first obtaining an individual's consent or authorization. Another commenter suggested that the final rule explicitly exclude from the rule disclosures authorized by the FMLA, because, in the commenter's view, it provides more than adequate protection for the confidentiality of medical records in the employment context.

Response: We disagree that the FMLA provides adequate privacy protections for individually identifiable health information. As we understand the FMLA, the need for employers to obtain protected health information under the statute is analogous to the employer's need for protected health information under the ADA. In both situations, employers may need protected health information to fulfill their obligations under these statutes, but neither statute requires covered entities to provide the information directly to the employer. Thus, covered entities in these circumstances will need an individual's authorizations before the disclosure is made to the employer.

Federal Common Law

Comment: One commenter did not want the privacy rules to interfere with the federal common law governing collective bargaining agreements permitting employers to insist on the cooperation of employees with medical fitness evaluations.

Response: We do not seek to interfere with legal medical fitness evaluations. These rules require a covered entity to have an individual's authorization before the information resulting from such evaluations is disclosed to the employer unless another provision of the rule applies. We do not prohibit employers from conditioning employment, accommodations, or other benefits, when legally permitted to do so, upon the individual/employee providing an authorization that would permit the disclosure of protected health information to employers by covered entities. See § 164.508(b)(4) below.

Federal Educational Rights and Privacy Act

Comment: A few commenters supported the exclusion of "education records" from the definition of "protected health information." However, one commenter requested that "treatment records" of students who are 18 years or older attending post-secondary education institutions be excluded from the definition of "protected health information" as well to avoid confusion.

Response: We agree with these commenters. See "Relationship to Other Federal Laws" for a description of our exclusion of FERPA "education records" and records defined at 20 U.S.C. 1232g(a)(4)(B)(iv), commonly referred to as "treatment records," from the definition of "protected health information."

Comment: One comment suggested that the regulation should not apply to any health information that is part of an "education record" in any educational agency or institution, regardless of its FERPA status.

Response: We disagree. As noted in our discussion of "Relationship of Other Federal Laws," we exclude education records from the definition of protected health information because Congress expressly provided privacy protections for these records and explained how these records should be treated in FERPA.

Comment: One commenter suggested eliminating the preamble language that describes school nurses and on-site clinics as acting as providers and subject to the privacy regulation, noting that this language is confusing and inconsistent with the statements provided in the preamble explicitly stating that HIPAA does not preempt FERPA.

Response: We agree that this language may have been confusing. We have provided a clearer expression of when schools may be required to comply with the privacy regulation in the "Relationship to Other Federal Laws" section of the preamble.

Comment: One commenter suggested adding a discussion of FERPA to the "Relationship to Other Federal Laws" section of the preamble.

Response: We agree and have added FERPA to the list of federal laws discussed in "Relationship to Other Federal Laws" section of the preamble.

Comment: One commenter stated that school clinics should not have to comply with the "ancillary" administrative requirements, such as designating a privacy official, maintaining documentation of their policies and procedures, and providing the Secretary of HHS with access.

Response: We disagree. Because we have excluded education records and records described at 20 U.S.C. 1232g(a)(4)(B)(iv) held by educational agencies and institutions subject to FERPA from the definition of protected health information, only non-FERPA schools would be subject to the administrative requirements. Most of these school clinics will also not be covered entities because they are not engaged in HIPAA transactions and these administrative requirements will not apply to them. However, to the extent a school clinic is within the definition of a health care provider, as Congress defined the term, and the school clinic is engaged in HIPAA transactions, it will be a covered entity and must comply with the rules below. ***82596**

Comment: Several commenters expressed concern that the privacy regulation would eliminate the parents' ability to have access to information in their children's school health records. Because the proposed regulation suggests that school-based clinics keep health records separate from other educational files, these comments argued that the regulation is contrary to the spirit of FERPA, which provides parents with access rights to their children's educational files.

Response: As noted in the "Relationship to Other Federal Laws" provision of the preamble, to the extent information in school-based clinics is not protected health information because it is an education record, the FERPA access requirements apply and this regulation does not. For more detail regarding the rule's application to unemancipated minors, see the preamble discussion about "Personal Representatives."

Federal Employees Compensation Act

Comment: One comment noted that the Federal Employees Compensation Act ("FECA") requires claimants to sign a release form when they file a claim. This commenter suggested that the privacy regulation should not place additional restrictions on this type of release form.

Response: We agree. In the final rule, we have added a new provision, § 164.512(l), that permits covered entities to make disclosures authorized under workers' compensation and similar laws. This provision would permit covered entities to make disclosures authorized under FECA and not require a different release form.

Federal Employees Health Benefits Program

Comment: A few comments expressed concern about the preemption effect on FEHBP and wanted clarification that the privacy regulation does not alter the existing preemptive scope of the program.

Response: We do not intend to affect the preemptive scope of the FEHBP. The Federal Employee Health Benefit Act of 1998 preempts any state law that "relates to" health insurance or plans. 5 U.S.C. 8902(m). The final rule does not attempt to alter the preemptive scope Congress has provided to the FEHBP.

Comment: One comment suggested that in the context of FEHBP HHS should place the enforcement responsibilities of the privacy regulation with Office of Personnel Management, as the agency responsible for administering the program.

Response: We disagree. Congress placed enforcement with the Secretary. See section 1176 of the Act.

Federal Rules of Civil Procedure

Comment: A few comments suggested revising proposed § 164.510(d) so that it is consistent with the existing discovery procedure under the Federal Rules of Civil Procedure or local rules.

Response: We disagree that the rules regarding disclosures and uses of protected health information for judicial and administrative procedures should provide only those protections that exist under existing discovery rules. Although the current process may be appropriate for other documents and information requested during the discovery process, the current system, as exemplified by the Federal Rules of Civil Procedure, does not provide sufficient protection for protected health information. Under current discovery rules, private attorneys, government officials, and others who develop such requests make the initial determinations as to what information or documentation should be disclosed. Independent third-party review, such as that by a court, only becomes necessary if a person of whom the request is made refuses to provide the information. If this happens, the person seeking discovery must obtain a court order or move to compel discovery. In our view this system does not provide sufficient protections to ensure that unnecessary and unwarranted disclosures of protected health information does not occur. For a related discuss, see the preamble regarding "Disclosures for Judicial and Administrative Proceedings" under § 164.512(e).

Federal Rules of Evidence

Comment: Many comments requested clarification that the privacy regulation does not conflict or interfere with the federal or state privileges. In particular, one of these comments suggested that the final regulation provide that disclosures for a purpose recognized by the regulation not constitute a waiver of federal or state privileges.

Response: We do not intend for the privacy regulation to interfere with federal or state rules of evidence that create privileges. Consistent with The Uniform Health-Care Information Act drafted by the National Conference of Commissioners on Uniform State Laws, we do not view a consent or an authorization to function as a waiver of federal or state privileges. For further discussion of the effect of consent or authorization on federal or state privileges, see preamble discussions in §§ 164.506 and 164.508.

Comment: Other comments applauded the Secretary's references to Jaffee v. Redman, 518 U.S. 1 (1996), which recognized a psychotherapist-patient privilege, and asked the Secretary to incorporate expressly this privilege into the final regulation.

Response: We agree that the psychotherapist-patient relationship is an important one that deserves protection. However, it is beyond the scope our mandate to create specific evidentiary privileges. It is also unnecessary because the United States Supreme Court has adopted this privilege.

Comment: A few comments discussed whether one remedy for violating the privacy regulation should be to exclude or suppress evidence obtained in violation of the regulation. One comment supported using this penalty, while another opposed it.

Response: We do not have the authority to mandate that courts apply or not apply the exclusionary rule to evidence obtained in violation of the regulation. This issue is in the purview of the courts.

Federal Tort Claims Act

Comment: One comment contended that the proposed regulation's requirement mandating covered entities to name the subjects of protected health information disclosed under a business partner contract as third party intended beneficiaries under the

contract would have created an impermissible right of action against the government under the Federal Tort Claims Act ("FTCA").

Response: Because we have deleted the third party beneficiary provisions from the final rules, this comment is moot.

Comment: Another comment suggested the regulation would hamper the ability of federal agencies to disclose protected health information to their attorneys, the Department of Justice, during the initial stages of the claims brought under the FTCA.

Response: We disagree. The regulation applies only to federal agencies that are covered entities. To the extent an agency is not a covered entity, it is not subject to the regulation; to the extent an agency is a covered entity, it must comply with the regulation. A covered entity that is a federal agency may disclose relevant information to its attorneys, who are business associates, for purposes of health care operations, which includes uses or disclosures for legal functions. See § 164.501 (definitions of "business associate" and "health care operations"). The final rule provides specific provisions describing how federal agencies may provide ***82597** adequate assurances for these types of disclosures of protected health information. See § 164.504(e)(3).

Food and Drug Administration

Comment: A few comments expressed concerns about the use of protected health information for reporting activities to the Food and Drug Administration ("FDA"). Their concern focused on the ability to obtain or disclose protected health information for pre-and post-marketing adverse event reports, device tracking, and post-marketing safety and efficacy evaluation.

Response: We agree with this comment and have provided that covered entities may disclose protected health information to persons subject to the jurisdiction of the FDA, to comply with the requirements of, or at the direction of, the FDA with regard to reporting adverse events (or similar reports with respect to dietary supplements), the tracking of medical devices, other post-marketing surveillance, or other similar requirements described at § 164.512(b).

Foreign Standards

Comment: One comment asked how the regulation could be enforced against foreign countries (or presumably entities in foreign countries) that solicit medical records from entities in the United States.

Response: We do not regulate solicitations of information. To the extent a covered entity wants to comply with a request for disclosure of protected health information to foreign countries or entities within foreign countries, it will need to comply with the privacy rules before making the disclosure. If the covered entity fails to comply with the rules, it will be subject to enforcement proceedings.

Freedom of Information Act

Comment: One comment asserted that the proposed privacy regulation conflicts with the Freedom of Information Act ("FOIA"). The comment argued that the proposed restriction on disclosures by agencies would not come within one of the permissible exemptions to the FOIA. In addition, the comment noted that only in exceptional circumstances would the protected health information of deceased individuals come within an exemption because, for the most part, death extinguishes an individual's right to privacy.

Response: Section 164.512(a) below permits covered entities to disclose protected health information when such disclosures are required by other laws as long as they follow the requirements of those laws. Therefore, the privacy regulation will not interfere with the ability of federal agencies to comply with FOIA, when it requires the disclosure.

We disagree, however, that most protected health information will not come within Exemption 6 of FOIA. See the discussion above under "Relationship to Other Federal Laws" for our review of FOIA. Moreover, we disagree with the comment's assertion

that the protected health information of deceased individuals does not come within Exemption 6. Courts have recognized that a deceased individual's surviving relatives may have a privacy interest that federal agencies may consider when balancing privacy interests against the public interest in disclosure of the requested information. Federal agencies will need to consider not only the privacy interests of the subject of the protected health information in the record requested, but also, when appropriate, those of a deceased individual's family consistent with judicial rulings.

If an agency receives a FOIA request for the disclosure of protected health information of a deceased individual, it will need to determine whether or not the disclosure comes within Exemption 6. This evaluation must be consistent with the court's rulings in this area. If the exemption applies, the federal agency will not have to release the information. If the federal agency determines that the exemption does not apply, may release it under § 164.512(a) of this regulation.

Comment: One commenter expressed concern that our proposal to protect the individually identifiable health information about the deceased for two years following death would impede public interest reporting and would be at odds with many state Freedom of Information laws that make death records and autopsy reports public information. The commenter suggested permitting medical information to be available upon the death of an individual or, at the very least, that an appeals process be permitted so that health information trustees would be allowed to balance the interests in privacy and in public disclosure and release or not release the information accordingly.

Response: These rules permit covered entities to make disclosures that are required by state Freedom of Information Act (FOIA) laws under § 164.512(a). Thus, if a state FOIA law designates death records and autopsy reports as public information that must be disclosed, a covered entity may disclose it without an authorization under the rule. To the extent that such information is required to be disclosed by FOIA or other law, such disclosures are permitted under the final rule. In addition, to the extent that death records and autopsy reports are obtainable from non-covered entities, such as state legal authorities, access to this information is not impeded by this rule.

If another law does not require the disclosure of death records and autopsy reports generated and maintained by a covered entity, which are protected health information, covered entities are not allowed to disclose such information except as permitted or required by the final rule, even if another entity discloses them.

Comment: One comment sought clarification of the relationship between the Freedom of Information Act, the Privacy Act, and the privacy rules.

Response: We have provided this analysis in the “Relationship to Other Federal Laws” section of the preamble in our discussion of the Freedom of Information Act.

Gramm-Leach-Bliley

Comments: One commenter noted that the Financial Services Modernization Act, also known as Gramm-Leach-Bliley (“GLB”), requires financial institutions to provide detailed privacy notices to individuals. The commenter suggested that the privacy regulation should not require financial institutions to provide additional notice.

Response: We disagree. To the extent a covered entity is required to comply with the notice requirements of GLB and those of our rules, the covered entity must comply with both. We will work with the FTC and other agencies implementing GLB to avoid unnecessary duplication. For a more detailed discussion of GLB and the privacy rules, see the “Relationship to Other Federal Laws” section of the preamble.

Comment: A few commenters asked that the Department clarify that financial institutions, such as banks, that serve as payors are covered entities. The comments explained that with the enactment of the Gramm-Leach-Bliley Act, banks are able to form holding companies that will include insurance companies (that may be covered entities). They recommended that banks be held

to the rule's requirements and be required to obtain authorization to conduct non-payment activities, such as for the marketing of health and non-health items and services or the use and disclosure to non-health related divisions of the covered entity. ***82598**

Response: These comments did not provide specific facts that would permit us to provide a substantive response. An organization will need to determine whether it comes within the definition of "covered entity." An organization may also need to consider whether or not it contains a health care component. Organizations that are uncertain about the application of the regulation to them will need to evaluate their specific facts in light of this rule.

Inspector General Act

Comment: One comment requested the Secretary to clarify in the preamble that the privacy regulation does not preempt the Inspector General Act.

Response: We agree that to the extent the Inspector General Act requires uses or disclosures of protected health information, the privacy regulation does not preempt it. The final rule provides that to the extent required under section 201(a)(5) of the Act, nothing in this subchapter should be construed to diminish the authority of any Inspector General, including the authority provided in the Inspector General Act of 1978. See discussion of § 160.102 above.

Medicare and Medicaid

Comment: One comment suggested possible inconsistencies between the regulation and Medicare/Medicaid requirements, such as those under the Quality Improvement System for Managed Care. This commenter asked that HHS expand the definition of health care operations to include health promotion activities and avoid potential conflicts.

Response: We disagree that the privacy regulation would prohibit managed care plans operating in the Medicare or Medicaid programs from fulfilling their statutory obligations. To the extent a covered entity is required by law to use or disclose protected health information in a particular manner, the covered entity may make such a use or disclosure under § 164.512(a). Additionally, quality assessment and improvement activities come within the definition of "health care operations." Therefore, the specific example provided by the commenter would seem to be a permissible use or disclosure under § 164.502, even if it were not a use or disclosure "required by law."

Comment: One commenter stated that Medicare should not be able to require the disclosure of psychotherapy notes because it would destroy a practitioner's ability to treat patients effectively.

Response: If the Title XVIII of the Social Security Act requires the disclosure of psychotherapy notes, the final rule permits, but does not require, a covered entity to make such a disclosure under § 164.512(a). If, however, the Social Security Act does not require such disclosures, Medicare does not have the discretion to require the disclosure of psychotherapy notes as a public policy matter because the final rule provides that covered entities, with limited exceptions, must obtain an individual's authorization before disclosing psychotherapy notes. See § 164.508(a)(2).

National Labor Relations Act

Comment: A few comments expressed concern that the regulation did not address the obligation of covered entities to disclose protected health information to collective bargaining representatives under the National Labor Relations Act.

Response: The final rule does not prohibit disclosures that covered entities must make pursuant to other laws. To the extent a covered entity is required by law to disclose protected health information to collective bargaining representatives under the NLRA, it may to so without an authorization. Also, the definition of "health care operations" at § 164.501 permits disclosures to employee representatives for purposes of grievance resolution.

Organ Donation

Comment: One commenter expressed concern about the potential impact of the regulation on the organ donation program under 42 CFR part 482.

Response: In the final rule, we add provisions allowing the use or disclosure of protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating donation and transplantation. See § 164.512(h).

Privacy Act Comments

Comment: One comment suggested that the final rule unambiguously permit the continued operation of the statutorily established or authorized discretionary routine uses permitted under the Privacy Act for both law enforcement and health oversight.

Response: We disagree. See the discussion of the Privacy Act in "Relationship to Other Federal Laws" above.

Public Health Services Act

Comment: One comment suggested that the Public Health Service Act places more stringent rules regarding the disclosure of information on Federally Qualified Health Centers than the proposed privacy regulation suggested. Therefore, the commenter suggested that the final rule exempt Federally Qualified Health Centers from the rules requirements

Response: We disagree. Congress expressly included Federally Qualified Health Centers, a provider of medical or other health services under the Social Security Act section 1861(s), within its definition of health care provider in section 1171 of the Act; therefore, we cannot exclude them from the regulation.

Comment: One commenter noted that no conflicts existed between the proposed rule and the Public Health Services Act.

Response: As we discuss in the "Relationship to Other Federal Laws" section of the preamble, the Public Health Service Act contains explicit confidentiality requirements that are so general as not to create problems of inconsistency. We recognized, however, that in some cases, that law or its accompanying regulations may contain greater restrictions. In those situations, a covered entity's ability to make what are permissive disclosures under this privacy regulation would be limited by those laws.

Reporting Requirement

Comment: One comment noted that federal agencies must provide information to certain entities pursuant to various federal statutes. For example, federal agencies must not withhold information from a Congressional oversight committee or the General Accounting Office. Similarly, some federal agencies must provide the Bureau of the Census and the National Archives and Records Administration with certain information. This comment expressed concern that the privacy regulation would conflict with these requirements. Additionally, the commenter asked whether the privacy notice would need to contain these uses and disclosures and recommended that a general statement that these federal agencies would disclose protected health information when required by law be considered sufficient to meet the privacy notice requirements.

Response: To the extent a federal agency acting as a covered entity is required by federal statute to disclose protected health information, the regulation permits the disclosure as required by law under § 164.512(a). The notice provisions at § 164.520(b)(1)(ii)(B) require covered entities to provide a brief description of the purposes for which the covered ***82599** entity is permitted or required by the rules to use or disclose protected health information without an individual's written authorization. If these statutes require the disclosures, covered entities subject to the requirement may make the disclosure pursuant to § 164.512(a).

Thus, their notice must include a description of the category of these disclosures. For example, a general statement such as the covered entity "will disclose your protected health information to comply with legal requirements" should suffice.

Comment: One comment stressed that the final rule should not inadvertently preempt mandatory reporting laws duly enacted by federal, state, or local legislative bodies. This commenter also suggested that the final rule not prevent the reporting of violations to law enforcement agencies.

Response: We agree. Like the proposed rule, the final rule permits covered entities to disclose protected health information when required by law under § 164.512(a). To the extent a covered entity is required by law to make a report to law enforcement agencies or is otherwise permitted to make a disclosure to a law enforcement agency as described in § 164.512(f), it may do so without an authorization. Alternatively, a covered entity may always request that individuals authorize these disclosures.

Security Standards

Comment: One comment called for HHS to consider the privacy regulation in conjunction with the other HIPAA standards. In particular, this comment focused on the belief that the security standards should be compatible with the existing and emerging health care and information technology industry standards.

Response: We agree that the security standards and the privacy rules should be compatible with one another and are working to ensure that the final rules in both areas function together. Because we are addressing comments regarding the privacy rules in this preamble, we will consider the comment about the security standard as we finalize that set of rules.

Substance Abuse Confidentiality Statute and Regulations

Comment: Several commenters noted that many health care providers are bound by the federal restrictions governing alcohol and drug abuse records. One commenter noted that the NPRM differed substantially from the substance abuse regulations and would have caused a host of practical problems for covered entities. Another commenter, however, supported the NPRM's analysis that stated that more stringent provisions of the substance abuse provisions would apply. This commenter suggested an even stronger approach of including in the text a provision that would preserve existing federal law. Yet, one comment suggested that the regulation as proposed would confuse providers by making it difficult to determine when they may disclose information to law enforcement because the privacy regulation would permit disclosures that the substance abuse regulations would not.

Response: We appreciate the need of some covered entities to evaluate the privacy rules in light of federal requirements regarding alcohol and drug abuse records. Therefore, we provide a more detailed analysis in the "Relationship to Other Federal Laws" section of the preamble.

Comment: Some of these commenters also noted that state laws contain strict confidentiality requirements. A few commenters suggested that HHS reassess the regulations to avoid inconsistencies with state privacy requirements, implying that problems exist because of conflicts between the federal and state laws regarding the confidentiality of substance abuse information.

Response: As noted in the preamble section discussing preemption, the final rules do not preempt state laws that provide more privacy protections. For a more detailed analysis of the relationship between state law and the privacy rules, see the "Preemption" provisions of the preamble.

Tribal Law

Comments: One commenter suggested that the consultation process with tribal governments described in the NPRM was inadequate under Executive Order No. 13084. In addition, the commenter expressed concern that the disclosures for research purposes as permitted by the NPRM would conflict with a number of tribal laws that offer individuals greater privacy rights with respect to research and reflects cultural appropriateness. In particular, the commenter referenced the Health Research Code

for the Navajo Nation which creates a entity with broader authority over research conducted on the Navajo Nation than the local IRB and requires informed consent by study participants. Other laws mentioned by the commenter included the Navajo Nation Privacy and Access to Information Act and a similar policy applicable to all health care providers within the Navajo Nation. The commenter expressed concern that the proposed regulation research provisions would override these tribal laws.

Response: We disagree with the comment that the consultation with tribal governments undertaken prior to the proposed regulation is inadequate under Executive Order No. 13084. As stated in the proposed regulation, the Department consulted with representatives of the National Congress of American Indians and the National Indian Health Board, as well as others, about the proposals and the application of HIPAA to the Tribes, and the potential variations based on the relationship of each Tribe with the IHS for the purpose of providing health services. In addition, Indian and tribal governments had the opportunity to, and did, submit substantive comments on the proposed rules.

Additionally, disclosures permitted by this regulation do not conflict with the policies as described by this commenter. Disclosures for research purposes under the final rule, as in the proposed regulation, are permissive disclosures only. The rule describes the outer boundaries of permissible disclosures. A covered health care provider that is subject to the tribal laws of the Navajo Nation must continue to comply with those tribal laws. If the tribal laws impose more stringent privacy standards on disclosures for research, such as requiring informed consent in all cases, nothing in the final rule would preclude compliance with those more stringent privacy standards. The final rule does not interfere with the internal governance of the Navajo Nation or otherwise adversely affect the policy choices of the tribal government with respect to the cultural appropriateness of research conducted in the Navajo Nation.

TRICARE

Comment: One comment expressed concern regarding the application of the "minimum necessary" standard to investigations of health care providers under the TRICARE (formerly the CHAMPUS) program. The comment also expressed concern that health care providers would be able to avoid providing their records to such investigators because the proposed § 164.510 exceptions were not mandatory disclosures.

Response: In our view, neither the minimum necessary standard nor the final §§ 164.510 and 164.512 permissive disclosures will impede such investigations. The regulation requires covered entities to make all reasonable efforts not to disclose more than the minimum amount of protected health ***82600** information necessary to accomplish the intended purpose of the use or disclosure. This requirement, however, does not apply to uses or disclosures that are required by law. See § 164.502(b)(2)(iv). Thus, if the disclosure to the investigators is required by law, the minimum necessary standard will not apply. Additionally, the final rule provides that covered entities rely, if such reliance is reasonable, on assertions from public officials about what information is reasonably necessary for the purpose for which it is being sought. See § 164.514(d)(3)(iii).

We disagree with the assertion that providers will be able to avoid providing their records to investigators. Nothing in this rule permits covered entities to avoid disclosures required by other laws.

Veterans Affairs

Comment: One comment sought clarification about how disclosures of protected health information would occur within the Veterans Affairs programs for veterans and their dependents.

Response: We appreciate the commenter's request for clarification as to how the rules will affect disclosures of protected health information in the specific context of Veteran's Affairs programs. Veterans health care programs under 38 U.S.C. chapter 17 are defined as "health plans." Without sufficient details as to the particular aspects of the Veterans Affairs programs that this comment views as problematic, we cannot comment substantively on this concern.

Comment: One comment suggested that the final regulation clarify that the analysis applied to the substance abuse regulations apply to laws governing Veteran's Affairs health records.

Response: Although we realize some difference may exist between the laws, we believe the discussion of federal substance abuse confidentiality regulations in the "Relationship to Other Federal Laws" preamble provides guidance that may be applied to the laws governing Veteran's Affairs ("VA") health records. In most cases, a conflict will not exist between these privacy rules and the VA programs. For example, some disclosures allowed without patient consent or authorization under the privacy regulation may not be within the VA statutory list of permissible disclosures without a written consent. In such circumstances, the covered entity would have to abide by the VA statute, and no conflict exists. If the disclosures permitted by the VA statute come within the permissible disclosures of our rules, no conflict exists. In some cases, our rules may demand additional requirements, such as obtaining the approval of a privacy board or Institutional Review Board if a covered entity seeks to disclose protected health information for research purposes without the individual's authorization. A covered entity subject to the VA statute will need to ensure that it meets the requirements of both that statute and the regulation below. If a conflict arises, the covered entity should evaluate the specific potential conflicting provisions under the implied repeal analysis set forth in the "Relationship to Other Federal Laws" discussion in the preamble.

WIC

Comment: One comment called on other federal agencies to examine their regulations and policies regarding the use and disclosure of protected health information. The comment suggested that other agencies revise their regulations and policies to avoid duplicative, contradictory, or more stringent requirements. The comment noted that the U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC") does not release WIC data. Because the commenter believed the regulation would not prohibit the disclosure of WIC data, the comment stated that the Department of Agriculture should now release such information.

Response: We support other federal agencies to whom the rules apply in their efforts to review existing regulations and policies regarding protected health information. However, we do not agree with the suggestion that other federal agencies that are not covered entities must reduce the protections or access-related rights they provide for individually identifiable health information they hold.

Part 160, Subpart C—Compliance and Enforcement

Section 160.306(a)—Who Can File Complaints With the Secretary

Comment: The proposed rule limited those who could file a complaint with the Secretary to individuals. A number of commenters suggested that other persons with knowledge of a possible violation should also be able to file complaints. Examples that were provided included a mental health care provider with first hand knowledge of a health plan improperly requiring disclosure of psychotherapy notes and an occupational health nurse with knowledge that her human resources manager is improperly reviewing medical records. A few comments raised the concern that permitting any person to file a complaint lends itself to abuse and is not necessary to ensure privacy rights and that the complainant should be a person for whom there is a duty to protect health information.

Response: As discussed below, the rule defines "individual" as the person who is the subject of the individually identifiable health information. However, the covered entity may allow other persons, such as personal representatives, to exercise the rights of the individual under certain circumstances, e.g., for a deceased individual. We agree with the commenters that any person may become aware of conduct by a covered entity that is in violation of the rule. Such persons could include the covered entity's employees, business associates, patients, or accrediting, health oversight, or advocacy agencies or organizations. Many persons, such as the covered entity's employees, may, in fact, be in a better position than the "individual" to know that a violation has occurred. Another example is a state Protection and Advocacy group that may represent persons with developmental disabilities.

We have decided to allow complaints from any person. The term "person" is not restricted here to human beings or natural persons, but also includes any type of association, group, or organization.

Allowing such persons to file complaints may be the only way the Secretary may learn of certain possible violations. Moreover, individuals who are the subject of the information may not be willing to file a complaint because of fear of embarrassment or retaliation. Based on our experience with various civil rights laws, such as Title VI of the Civil Rights Act of 1964 and Title II of the Americans with Disabilities Act, that allow any person to file a complaint with the Secretary, we do not believe that this practice will result in abuse. Finally, upholding privacy protections benefits all persons who have or may be served by the covered entity as well as the general public, and not only the subject of the information.

If a complaint is received from someone who is not the subject of protected health information, the person who is the subject of this information may be concerned with the Secretary's investigation of this complaint. While we did not receive comments on this issue, we want to protect the privacy rights of this individual. This might ***82601** involve the Secretary seeking to contact the individual to provide information as to how the Secretary will address individual's privacy concerns while resolving the complaint. Contacting all individuals may not be practicable in the case of allegations of systemic violations (e.g., where the allegation is that hundreds of medical records were wrongfully disclosed).

Requiring That a Complainant Exhaust the Covered Entity's Internal Complaint Process Prior to Filing a Complaint With the Secretary

Comment: A number of commenters, primarily health plans, suggested that individuals should not be permitted to file a complaint with the Secretary until they exhaust the covered entity's own complaint process. Commenters stated that covered entities should have a certain period of time, such as ninety days, to correct the violation. Some commenters asserted that providing for filing a complaint with the Secretary will be very expensive for both the public and private sectors of the health care industry to implement. Other commenters suggested requiring the Secretary to inform the covered entity of any complaint it has received and not initiate an investigation or "take enforcement action" before the covered entity has time to address the complaint.

Response: We have decided, for a number of reasons, to retain the approach as presented in the proposed rule. First, we are concerned that requiring that complainants first notify the covered entity would have a chilling effect on complaints. In the course of investigating individual complaints, the Secretary will often need to reveal the identity of the complainant to the covered entity. However, in the investigation of cases of systemic violations and some individual violations, individual names may not need to be identified. Under the approach suggested by these commenters, the covered entity would learn the names of all persons who file complaints with the Secretary. Some individuals might feel uncomfortable or fear embarrassment or retaliation revealing their identity to the covered entity they believe has violated the regulation. Individuals may also feel they are being forced to enter into negotiations with this entity before they can file a complaint with the Secretary.

Second, because some potential complainants would not bring complaints to the covered entity, possible violations might not become known to the Secretary and might continue. Third, the delay in the complaint coming to the attention of the Secretary because of the time allowed for the covered entity to resolve the complaint may mean that significant violations are not addressed expeditiously. Finally, the process proposed by these commenters is arguably unnecessary because an individual who believes that an agreement can be reached with the covered entity, can, through the entity's internal complaint process or other means, seek resolution before filing a complaint with the Secretary.

Our approach is consistent with other laws and regulations protecting individual rights. None of the civil rights laws enforced by the Secretary require a complainant to provide any notification to the entity that is alleged to have engaged in discrimination (e.g., Americans with Disabilities Act, section 504 of the Rehabilitation Act, Title VI of the Civil Rights Act, and the Age Discrimination Act). The concept of "exhaustion" is used in laws that require individuals to pursue administrative remedies, such as that provided by a governmental agency, before bringing a court action. Under HIPAA, individuals do not have a right to court action.

Some commenters seemed to believe that the Secretary would pursue enforcement action without notifying the covered entity. It has been the Secretary's practice in investigating cases under other laws, such as various civil rights laws, to inform entities that we have received a complaint against them and to seek early resolution if possible. In enforcing the privacy rule, the Secretary will generally inform the covered entity of the nature of any complaints it has received against the entity. (There may be situations where information is withheld to protect the privacy interests of the complainant or others or where revealing information would impede the investigation of the covered entity.) The Secretary will also generally afford the entity an opportunity to share information with the Secretary that may result in an early resolution. Our approach will be to seek informal resolution of complaints whenever possible, which includes allowing covered entities a reasonable amount of time to work with the Secretary to come into compliance before initiating action to seek civil monetary penalties.

Section 160.306(b)(3)—Requiring That Complaints Be Filed With the Secretary Within a Certain Period of Time

Comment: A number of commenters, primarily privacy and disability advocacy organizations, suggested that the regulation require that complaints be filed with the Secretary by a certain time. These commenters generally recommended that the time period for filing a complaint should commence to run from the time when the individual knew or had reason to know of the violation or omission. Another comment suggested that a requirement to file a complaint with the Secretary within 180 days of the alleged noncompliance is a problem because a patient may, because of his or her medical condition, be unable to access his or her records within that time frame.

Response: We agree with the commenters that complainants should generally be required to submit complaints in a timely fashion. Federal regulations implementing Title VI of the Civil Rights Act of 1964 provide that "[a] complaint must be filed not later than '180 days from the date of the alleged discrimination' unless the time for filing is extended by the responsible Department official or his designee." 45 CFR 80.7(b). Other civil rights laws, such as the Age Discrimination Act, section 504 of the Rehabilitation Act, and Title II of the Americans with Disabilities Act (ADA) (state and local government services), also use this approach. Under civil rights laws administered by the EEOC, individuals have 180 days of the alleged discriminatory act to file a charge with EEOC (or 300 days if there is a state or local fair employment practices agency involved).

Therefore, in the final rule we require that complaints be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred unless this time limit is waived by the Secretary for good cause shown. We believe that an investigation of a complaint is likely to be most effective if persons can be interviewed and documents reviewed as close to the time of the alleged violation as possible. Requiring that complaints generally be filed within a certain period of time increases the likelihood that the Secretary will have necessary and reliable information. Moreover, we are taking this approach in order to encourage complainants to file complaints as soon as possible. By receiving complaints in a timely fashion, we can, if such complaints prove valid, reduce the harm caused by the violation.

Section 160.308—Basis for Conducting Compliance Reviews

Comment: A number of comments expressed concern that the Secretary would conduct compliance reviews ***82602** without having received a complaint or having reason to believe there is noncompliance. A number of these commenters appeared to believe that the Secretary would engage in "routine visits." Some commenters suggested that the Secretary should only be able to conduct compliance reviews if the Secretary has initiated an investigation of a complaint regarding the covered entity in the preceding twelve months. Some commenters suggested that there should only be compliance reviews based on established criteria for reviews (e.g., finding of "reckless disregard"). Many of these commenters stated that cooperating with compliance reviews is potentially burdensome and expensive.

One commenter asked whether the Secretary will have a process for reviewing all covered entities to determine how they are complying with requirements. This commenter questioned whether covered entities will be required to submit plans and wait for Departmental approval.

Another commenter suggested that the Secretary specify a time limit for the completion of a compliance review.

Response: We disagree with the commenters that the final rule should restrict the Secretary's ability to conduct compliance reviews. The Secretary needs to maintain the flexibility to conduct whatever reviews are necessary to ensure compliance with the rule.

Section 160.310 (a) and (c)—The Secretary's Access to Information in Determining Compliance

Comment: Some commenters raised objections to provisions in the proposed rule which required that covered entities maintain records and submit compliance reports as the Secretary determines is necessary to determine compliance and required that covered entities permit access by the Secretary during normal business hours to its books, records, accounts, and other sources of information, including protected health information, and its facilities, that are pertinent to ascertaining compliance with this subpart. One commenter stated that the Secretary's access to private health information without appropriate patient consent is contrary to the intent of HIPAA. Another commenter expressed the view that, because covered entities face criminal penalties for violations, these provisions violate the Fifth Amendment protections against forced self incrimination. Other commenters stated that covered entities should be given the reason the Secretary needs to have access to its books and records. Another commenter stated that there should be a limit to the frequency or extent of intrusion by the federal government into the business practices of a covered entity and that these provisions violate the Fourth Amendment of the Constitution.

Finally, a coalition of church plans suggested that the Secretary provide church plans with additional procedural safeguards to reduce unnecessary intrusion into internal church operations. These suggested safeguards included permitting HHS to obtain records and other documents only if they are relevant and necessary to compliance and enforcement activities related to church plans, requiring a senior official to determine the appropriateness of compliance-related activities for church plans, and providing church plans with a self-correcting period similar to that Congress expressly provided in Title I of HIPAA under the tax code.

Response: The final rule retains the proposed language in these two provisions with one change. The rule adds a provision indicating that the Secretary's access to information held by the covered entity may be at any time and without notice where exigent circumstances exist, such as where time is of the essence because documents might be hidden or destroyed. Thus, covered entities will generally receive notice before the Secretary seeks to access the entity's books or records.

Other than the exigent circumstances language, the language in these two provisions is virtually the same as the language in this Department's regulation implementing Title VI of the Civil Rights Act of 1964. 45 CFR 80.6(b) and (c). The Title VI regulation is incorporated by reference in other Department regulations prohibiting discrimination of the basis of disability. 45 CFR 84.61. Similar provisions allowing this Department access to recipient information is found in the Secretary's regulation implementing the Age Discrimination Act. 45 CFR 91.34. These provisions have not proved to be burdensome to entities that are subject to these civil rights regulations (i.e., all recipients of Department funds).

We do not interpret Constitutional case law as supporting the view that a federal agency's review of information pursuant to statutory mandate violates the Fifth Amendment protections against forced self incrimination. Nor would such a review of this information raise Fourth Amendment problems. See discussion above regarding Constitutional comments and responses.

We appreciate the concern that the Secretary not involve herself unnecessarily into the internal operations of church plans. However, by providing health insurance or care to their employees, church plans are engaging in a secular activity. Under the regulation, church plans are subject to the same compliance and enforcement requirements with which other covered entities must comply. Because Congress did not carve out specific exceptions or require stricter standards for investigations related to church plans, incorporating such measures into the regulation would be inappropriate.

Additionally, there is no indication that the regulation will directly interfere with the religious practices of church plans. Also, the regulation as written appropriately limits the ability of investigators to obtain information from covered entities. The regulation provides that the Secretary may obtain access only to information that is pertinent to ascertain compliance with the regulation.

We do not anticipate asking for information that is not necessary to assess compliance with the regulation. The purpose of obtaining records and similar materials is to determine compliance, not to engage in any sort of review or evaluation of religious activities or beliefs. Therefore, we believe the regulation appropriately balances the need to access information to determine compliance with the desire of covered entities to avoid opening every record in their possession to the government.

Provision of Technical Assistance

Comment: A number of commenters inquired as to how a covered entity can request technical assistance from the Secretary to come into compliance. A number of commenters suggested that the Secretary provide interpretive guidance to assist with compliance. Others recommended that the Secretary have a contact person or privacy official, available by telephone or email, to provide guidance on the appropriateness of a disclosure or a denial of access. One commenter suggested that there be a formal process for a covered entity to submit compliance activities to the Secretary for prior approval and clarification. This commenter suggested that clarifications be published on a contemporaneous basis in the Federal Register to help correct any ambiguities and confusion in implementation. It was also suggested that the Secretary undertake an assessment of "best practices" of covered entities and document and promote the findings to serve as a convenient "road map" for other covered entities. Another commenter suggested that we work with providers to create implementation guidelines modeled after the interpretative ***82603** guidelines that HCFA creates for surveyors on the conditions of participation for Medicare and Medicaid contractors.

Response: While we have not in the final rule committed the Secretary to any specific model of providing guidance or assistance, we do state our intent, subject to budget and staffing constraints, to develop a technical assistance program that will include the provision of written material when appropriate to assist covered entities in achieving compliance. We will consider other models including HCFA's Medicare and Medicaid interpretative guidelines. Further information regarding the Secretary's technical assistance program may be provided in the Federal Register and on the HHS Office for Civil Rights (OCR) Web Site. While OCR plans to have fully trained staff available to respond to questions, its ability to provide individualized advice in regard to such matters as the appropriateness of a particular disclosure or the sufficiency of compliance activities will be based on staff resources and demands. The idea of looking at "best practices" and sharing information with all covered entities is a good one and we will explore how best to do this. We note that a covered entity is not excused from compliance with the regulation because of any failure to receive technical assistance or guidance.

Basis for Violation Findings and Enforcement

Comment: A number of commenters asked that covered entities not be liable for violations of the rule if they have acted in good faith. One commenter indicated that enforcement actions should not be pursued against covered entities that make legitimate business decisions about how to comply with the privacy standards.

Response: The commenters seemed to argue that even if a covered entity does not comply with a requirement of the rule, the covered entity should not be liable if there was an honest and sincere intention or attempt to fulfill its obligations. The final rule, however, does not take this approach but instead draws careful distinctions between what a covered entity must do unconditionally, and what a covered entity must make certain reasonable efforts to do. In addition, the final rule is clear as to the specific provisions where "good faith" is a consideration. For example, a covered entity is permitted to use and disclose protected health information without authorization based on criteria that includes a good faith belief that such use or disclosure is necessary to avert an imminent threat to health or safety (§ 164.512(j)(1)(i)). Therefore, covered entities need to pay careful attention to the specific language in each requirement. However, we note that many of these provisions can be implemented in a variety of ways; e.g, covered entities can exercise business judgement regarding how to conduct staff training.

As to enforcement, a covered entity will not necessarily suffer a penalty solely because an act or omission violates the rule. As we discuss elsewhere, the Department will exercise discretion to consider not only the harm done, but the willingness of the covered entity to achieve voluntary compliance. Further, the Administrative Simplification provisions of HIPAA provide that whether a violation was known or not is relevant in determining whether civil or criminal penalties apply. In addition, if a civil penalty applies, HIPAA allows the Secretary, where the failure to comply was due to reasonable cause and not to willful neglect,

to delay the imposition of the penalty to allow the covered entity to comply. The Department will develop and release for public comment an enforcement regulation applicable to all the administrative simplification regulations that will address these issues.

Comment: One commenter asked whether hospitals will be vicariously liable for the violations of their employees and expressed concern that hospitals and other providers will be the ones paying large fines.

Response: The enforcement regulation will address this issue. However, we note that section 1128A(1) of the Social Security Act, which applies to the imposition of civil monetary penalties under HIPAA, provides that a principal is liable for penalties for the actions of its agent acting within the scope of the agency. Therefore, a covered entity will generally be responsible for the actions of its employees such as where the employee discloses protected health information in violation of the regulation.

Comment: A commenter expressed the concern that if a covered entity acquires a non-compliant health plan, it would be liable for financial penalties. This commenter suggested that, at a minimum, the covered entity be given a grace period of at least a year, but not less than six months to bring any acquisition up to standard. The commenter stated that the Secretary should encourage, not discourage, compliant companies to acquire non-compliant ones. Another commenter expressed a general concern about resolution of enforcement if an entity faced with a HIPAA complaint acquires or merges with an entity not covered by HIPAA.

Response: As discussed above, the Secretary will encourage voluntary efforts to cure violations of the rule, and will consider that fact in determining whether to bring a compliance action. We do not agree, however, that we should limit our authority to pursue violations of the rule if the situation warrants it.

Comment: One commenter was concerned about the "undue risk" of liability on originators of information, stemming from the fact that "the number of covered entities is limited and they are unable to restrict how a recipient of information may use or re-disclose information * * *"

Response: Under this rule, we do not hold covered entities responsible for the actions of recipients of protected health information, unless the recipient is a business associate of the covered entity. We agree that it is not fair to hold covered entities responsible for the actions of persons with whom they have no on-going relationship, but believe it is fair to expect covered entities to hold their business associates to appropriate standards of behavior with respect to health information.

Other Compliance and Enforcement Comments

Comment: A number of comments raised questions regarding the Secretary's priorities for enforcement. A few commenters stated that they supported deferring enforcement until there is experience using the proposed standards. One organization asked that we clarify that the regulation does not replace or otherwise modify the self-regulatory/consumer empowerment approach to consumer privacy in the online environment.

Response: We have not made any decisions regarding enforcement priorities. It appears that some commenters believe that no enforcement action will be taken against a given covered entity until that entity has had some time to comply. Covered entities have two years to come into compliance with the regulation (three years in the case of small health plans). Some covered entities will have had experience using the standards prior to the compliance date. We do not agree that we should defer enforcement where violations of the rule occur. It would be wrong for covered entities to believe that enforcement action is based on their not having much experience in ***82604** using a particular standard or meeting another requirement.

We support a self-regulation approach in that we recognize that most compliance will be achieved by the voluntary activities of covered entities rather than by our enforcement activities. Our emphasis will be on education, technical assistance, and voluntary compliance and not on finding violations and imposing penalties. We also support a consumer empowerment approach. A knowledgeable consumer is key to the effectiveness of this rule. A consumer familiar with the requirements of this rule will be equipped to make choices regarding which covered entity will best serve their privacy interests and will know their rights under the rule and how they can seek redress for violations of this rule. Privacy-minded consumers will seek to protect the privacy

rights of others by bringing concerns to the attention of covered entities, the public, and the Secretary. However, we do not agree that we should defer enforcement where violations of the rule occur.

Comment: One commenter expressed concern that by filing a complaint an individual would be required to reveal sensitive information to the public. Another commenter suggested that complaints regarding noncompliance in regard to psychotherapy notes should be made to a panel of mental health professionals designated by the Secretary. This commenter also proposed that all patient information be maintained as privileged, not be revealed to the public, and be kept under seal after the case is reviewed and closed.

Response: We appreciate this concern and will seek to ensure that individually identifiable health information and other personal information contained in complaints will not be available to the public. The privacy regulation provides, at § 160.310(c)(3), that protected health information obtained by the Secretary in connection with an investigation or compliance review will not be disclosed except if necessary for ascertaining or enforcing compliance with the regulation or if required by law. In addition, this Department generally seeks to protect the privacy of individuals to the fullest extent possible, while permitting the exchange of records required to fulfill its administrative and program responsibilities. The Freedom of Information Act, 5 U.S.C. 552, and the HHS implementing regulation, 45 CFR part 5, provide substantial protection for records about individuals where disclosure would constitute an unwarranted invasion of their personal privacy. In implementing the privacy regulation, OCR plans to continue its current practice of protecting its complaint files from disclosure. OCR treats these files as investigatory records compiled for law enforcement purposes. Moreover, OCR maintains that disclosing protected health information in these files generally constitutes an unwarranted invasion of personal privacy.

It is not clear in regarding the use of mental health professionals, whether the commenter believes that such professionals should be involved because they would be best able to keep psychotherapy notes confidential or because such professionals can best understand the meaning or relevance of such notes. OCR anticipates that it will not have to obtain a copy or review psychotherapy notes in investigating most complaints regarding noncompliance in regard to such notes. There may be some cases where a review of the notes may be needed such as where we need to identify that the information a covered entity disclosed was in fact psychotherapy notes. If we need to obtain a copy of psychotherapy notes, we will keep these notes confidential and secure. OCR investigative staff will be trained to ensure that they fully respect the confidentiality of personal information. In addition, while the specific contents of these notes is generally not relevant to violations under this rule, if such notes are relevant, we will secure the expertise of mental health professionals if needed in reviewing psychotherapy notes.

Comment: A member of Congress and a number of privacy and consumer groups expressed concern with whether OCR has adequate funding to carry out the major responsibility of enforcing the complaint process established by this rule. The Senator stated that "[d]ue to the limited enforcement ability allowed for in this rule by HIPAA, it is essential that OCR have the capacity to enforce the regulations. Now is the time for OCR to begin building the necessary infrastructure to enforce the regulation effectively."

Response: We agree and are committed to an effective enforcement program. We are working with Congress to ensure that the Secretary has the necessary funds to secure voluntary compliance through education and technical assistance, to investigate complaints and conduct compliance reviews, to provide states with exception determinations, and to use civil and criminal penalties when necessary. We will continue to work with Congress and within the new Administration in this regard.

Coordination With Reviewing Authorities

Comment: A number of commenters referenced other entities that already consider the privacy of health information. One commenter indicated opposition to the delegation of inspections to third party organizations, such as the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). A few commenters indicated that state agencies are already authorized to investigate violations of state privacy standards and that we should rely on those agencies to investigate alleged violations of the privacy rules or delegate its complaint process to states that wish to carry out this responsibility or to those states that have a complaint process in place. Another commenter argued that individuals should be required to exhaust any state processes

before filing a complaint with the Secretary. Others referenced the fact that state medical licensing boards investigate complaints against physicians for violating patient confidentiality. One group asked that the federal government streamline all of these activities so physicians can have a single entity to whom they must be responsive. Another group suggested that OMB should be given responsibility for ensuring that FEHB Plans operate in compliance with the privacy standards and for enforcement.

A few commenters stated that the regulation might be used as a basis for violation findings and subsequent penalties under other Department authorities, such as under Medicare's Conditions of Participation related to patient privacy and right to confidentiality of medical records. One commenter wanted some assurance that this regulation will not be used as grounds for sanctions under Medicare. Another commenter indicated support for making compliance with the privacy regulation a Condition of Participation under Medicare.

Response: HIPAA does not give the Secretary the authority to delegate her responsibilities to other private or public agencies such as JCAHO or state agencies. However, we plan to explore ways that we may benefit from current activities that also serve to protect the privacy of individually identifiable health information. For example, if we conduct an investigation or review of a covered entity, that entity may want to share information regarding findings of other bodies that conducted similar reviews. We would welcome such ***82605** information. In developing its enforcement program, we may explore ways it can coordinate with other regulatory or oversight bodies so that we can efficiently and effectively pursue our joint interests in protecting privacy.

We do not accept the suggestion that individuals be required to exhaust their remedies under state law before filing a complaint with the Secretary. Our rationale is similar to that discussed above in regard to the suggestion that covered entities be required to exhaust a covered entity's internal complaint process before filing a complaint with the Secretary. Congress provided for federal privacy protection and we want to allow individuals the right to this protection without barriers or delay. Covered entities may in their privacy notice inform individuals of any rights they have under state law including any right to file privacy complaints. We do not have the authority to interfere with state processes and HIPAA explicitly provides that we cannot preempt state laws that provide greater privacy protection.

We have not yet addressed the issue as to whether this regulation might be used as a basis for violation findings or penalties under other Department authorities. We note that Medicare conditions of participation require participating providers to have procedures for ensuring the confidentiality of patient records, as well as afford patients with the right to the confidentiality of their clinical records.

Penalties

Comment: Many commenters considered the statutory penalties insufficient to protect privacy, stating that the civil penalties are too weak to have the impact needed to reduce the risk of inappropriate disclosure. Some commenters took the opposing view and stated that large fines and prison sentences for violations would discourage physicians from transmitting any sort of health care information to any other agency, regardless of the medical necessity. Another comment expressed the concern that doctors will be at risk of going to jail for protecting the privacy of individuals (by not disclosing information the government believes should be released).

Response: The enforcement regulation will address the application of the civil monetary and criminal penalties under HIPAA. The regulation will be published in the Federal Register as a proposed regulation and the public will have an opportunity to comment. We do not believe that our rule, and the penalties available under it, will discourage physicians and other providers from using or disclosing necessary information. We believe that the rule permits physicians to make the disclosures that they need to make under the health care system without exposing themselves to jeopardy under the rule. We believe that the penalties under the statute are woefully inadequate. We support legislation that would increase the amount of these penalties.

Comment: A number of commenters stated that the regulations should permit individuals to sue for damages caused by breaches of privacy under these regulations. Some of these commenters specified that damages, equitable relief, attorneys fees, and punitive damages should be available. Conversely, one comment stated that strong penalties are necessary and would preclude

the need for a private right of action. Another commenter stated that he does not believe that the statute intended to give individuals the equivalent of a right to sue, which results from making individuals third party beneficiaries to contracts between business partners.

Response: We do not have the authority to provide a private right of action by regulation. As discussed below, the final rule deletes the third party beneficiary provision that was in the proposed rule.

However, we believe that, in addition to strong civil monetary penalties, federal law should allow any individual whose rights have been violated to bring an action for actual damages and equitable relief. The Secretary's Recommendations, which were submitted to Congress on September 11, 1997, called for a private right of action to permit individuals to enforce their privacy rights.

Comment: One comment stated that, in calculating civil monetary penalties, the criteria should include aggravating or mitigating circumstances and whether the violation is a minor or first time violation. Several comments stated that penalties should be tiered so that those that commit the most egregious violations face stricter civil monetary penalties.

Response: As mentioned above, issues regarding civil fines and criminal penalties will be addressed in the enforcement regulation.

Comment: One comment stated that the regulation should clarify whether a single disclosure that involved the health information of multiple parties would constitute a single or multiple infractions, for the purpose of calculating the penalty amount.

Response: The enforcement regulation will address the calculation of penalties. However, we note that section 1176 subjects persons to civil monetary penalties of not more than $100 for each violation of a requirement or prohibition and not more than $25,000 in a calendar year for all violations of an identical requirement or prohibition. For example, if a covered entity fails to permit amendment of protected health information for 10 patients in one calendar year, the entity may be fined up to $1000 ($100 times 10 violations equals $1000).

Part 164—Subpart A—General Requirements

Part 164—Subpart B-D—Reserved

Part 164—Subpart E—Privacy

Section 164.500—Applicability

Covered Entities

The response to comments on covered entities is included in the response to comments on the definition of “covered entity” in the preamble discussion of § 160.103.

Covered Information

The response to comments on covered information is included in the response to comments on the definition of “protected health information” in the preamble discussion of § 164.501.

Section 164.501—Definitions

Designated record set

Comment: Many commenters generally supported our proposed definition of designated record set. Commenters suggested different methods for narrowing the information accessible to individuals, such as excluding information obtained without face-to-face interaction (e.g., phone consultations). Other commenters recommended broadening the information accessible to individuals, such as allowing access to "the entire medical record," not just a designated record set. Some commenters advocated for access to all information about individuals. A few commenters generally supported the provision but recommended that consultation and interpretative assistance be provided when the disclosure may cause harm or misunderstanding.

Response: We believe individuals should have a right to access any protected health information that may be used to make decisions about them and modify the final rule to accomplish this result. This approach facilitates an open and cooperative relationship between individuals and covered health care providers and health plans and allows individuals fair opportunities to know what health information may be ***82606** used to make decisions about them. We list certain records that are always part of the designated record set. For covered providers these are the medical record and billing record. For health plans these are the enrollment, payment, claims adjudication, and case or medical management records. The purpose of these specified records is management of the accounts and health care of individuals. In addition, we include in the designated record set to which individuals have access any record used, in whole or in part, by or for the covered entity to make decisions about individuals. Only protected health information that is in a designated record set is covered. Therefore, if a covered provider has a phone conversation, information obtained during that conversation is subject to access only to the extent that it is recorded in the designated record set.

We do not require a covered entity to provide access to all individually identifiable health information, because the benefits of access to information not used to make decisions about individuals is limited and is outweighed by the burdens on covered entities of locating, retrieving, and providing access to such information. Such information may be found in many types of records that include significant information not relevant to the individual as well as information about other persons. For example, a hospital's peer review files that include protected health information about many patients but are used only to improve patient care at the hospital, and not to make decisions about individuals, are not part of that hospital's designated record sets.

We encourage but do not require covered entities to provide interpretive assistance to individuals accessing their information, because such a requirement could impose administrative burdens that outweigh the benefits likely to accrue.

The importance to individuals of having the right to inspect and copy information about them is supported by a variety of industry groups and is recognized in current state and federal law. The July 1977 Report of the Privacy Protection Study Commission recommended that individuals have access to medical records and medical record information.[FN2] The Privacy Act (5 U.S.C. 552a) requires government agencies to permit individuals to review records and have a copy made in a form comprehensible to the individual. In its report "Best Principles for Health Privacy," the Health Privacy Working Group recommended that individuals should have the right to access information about them.[FN3] The National Association of Insurance Commissioners' Health Information Privacy Model Act establishes the right of an individual to examine or receive a copy of protected health information in the possession of the carrier or a person acting on behalf of the carrier.

Many states also establish a right for individuals to access health information about them. For example, Alaska law (AK Code 18.23.005) entitles patients "to inspect and copy any records developed or maintained by a health care provider or other person pertaining to the health care rendered to the patient." Hawaii law (HRS section 323C-11) requires health care providers and health plans, among others, to permit individuals to inspect and copy protected health information about them. Many other states have similar provisions.

Industry and standard-setting organizations also have developed policies to enable individual access to health information. The National Committee for Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations issued recommendations stating, "Patients' confidence in the protection of their information requires that they have the means to know what is contained in their records. The opportunity for patients to review their records will enable them to correct any errors and may provide them with a better understanding of their health status and treatment."[FN4] Standards of the American Society

for Testing and Materials state, "The patient or his or her designated personal representative has access rights to the data and information in his or her health record and other health information databases except as restricted by law. An individual should be able to inspect or see his or her health information or request a copy of all or part of the health information, or both."[FN5] We build on this well-established principle in this final rule.

Comment: Several commenters advocated for access to not only information that has already been used to make decisions, but also information that may be used to make decisions. Other commenters believed accessible information should be more limited; for example, some commenters argued that accessible information should be restricted to only information used to make health care decisions.

Response: We agree that it is desirable that individuals have access to information reasonably likely to be used to make decisions about them. On the other hand, it is desirable that the category of records covered be readily ascertainable by the covered entity. We therefore define "designated record set" to include certain categories of records (a provider's medical record and billing record, the enrollment records, and certain other records maintained by a health plan) that are normally used, and are reasonably likely to be used, to make decisions about individuals. We also add a category of other records that are, in fact, used, in whole or in part, to make decisions about individuals. This category includes records that are used to make decisions about any individuals, whether or not the records have been used to make a decision about the particular individual requesting access.

We disagree that accessible information should be restricted to information used to make health care decisions, because other decisions by covered entities can also affect individuals' interests. For example, covered entities make financial decisions about individuals, such as whether an individual's deductible has been met. Because such decisions can significantly affect individuals' interests, we believe they should have access to any protected health information included in such records.

Comment: Some commenters believed the rule should use the term "retrievable" instead of "retrieved" to describe information accessible to individuals. Other commenters suggested that the rule follow the Privacy Act's principle of allowing access only when entities retrieve records by individual identifiers. Some commenters requested clarification that covered entities are not required to maintain information by name or other patient identifier.

Response: We have modified the proposed definition of the designated record set to focus on how information is used, not how it is retrieved. Information may be retrieved or retrievable by name, but if it is never used to make decisions about any ***82607** individuals, the burdens of requiring a covered entity to find it and to redact information about other individuals outweigh any benefits to the individual of having access to the information. When the information might be used to affect the individual's interests, however, that balance changes and the benefits outweigh the burdens. We confirm that this regulation does not require covered entities to maintain any particular record set by name or identifier.

Comment: A few commenters recommended denial of access for information relating to investigations of claims, fraud, and misrepresentations. Many commenters suggested that sensitive, proprietary, and legal documents that are "typical state law privileges" be excluded from the right to access. Specific suggestions for exclusion, either from the right of access or from the definition of designated record set, include quality assurance activities, information related to medical appeals, peer review and credentialing, attorney-client information, and compliance committee activities. Some commenters suggested excluding information already supplied to individuals on previous requests and information related to health care operations. However, some commenters felt that such information was already excluded from the definition of designated record set. Other commenters requested clarification that this provision will not prevent patients from getting information related to medical malpractice.

Response: We do not agree that records in these categories are never used to affect the interests of individuals. For example, while protected health information used for peer review and quality assurance activities typically would not be used to make decisions about individuals, and, thus, typically would not be part of a designated record set, we cannot say that this is true in all cases. We design this provision to be sufficiently flexible to work with the varying practices of covered entities.

The rule addresses several of these comments by excepting from the access provisions (§ 164.524) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. Similarly, nothing in this rule requires a covered entity to divulge information covered by physician-patient or similar privilege. Under the access provisions, a covered entity may redact information in a record about other persons or information obtained under a promise of confidentiality, prior to releasing the information to the individual. We clarify that nothing in this provision would prevent access to information needed to prosecute or defend a medical malpractice action; the rules of the relevant court determine such access.

We found no persuasive evidence to support excluding information already supplied to individuals on previous requests. The burdens of tracking requests and the information provided pursuant to requests outweigh the burdens of providing the access requested. A covered entity may, however, discuss the scope of the request for access with the individual to facilitate the timely provision of access. For example, if the individual agrees, the covered entity could supply only the information created or received since the date access was last granted.

Disclosure

Comment: A number of commenters asked that the definition of "disclosure" be modified so that it is clear that it does not include the release, transfer, provision of access to, or divulging in any other manner of protected health information to the individual who is the subject of that information. It was suggested that we revise the definition in this way to clarify that a health care provider may release protected health information to the subject of the information without first requiring that the patient complete an authorization form.

Response: We agree with the commenters' concern, but accomplish this result through a different provision in the regulation. In § 164.502 of this final rule, we specify that disclosures of protected health information to the individual are not subject to the limitations on disclosure of protected health information otherwise imposed by this rule.

Comment: A number of commenters stated that the regulation should not apply to disclosures occurring within or among different subsidiaries or components of the same entity. One commenter interpreted "disclosure" to mean outside the agency or, in the case of a state Department of Health, outside sister agencies and offices that directly assist the Secretary in performing Medicaid functions and are listed in the state plan as entitled to receive Medicaid data.

Response: We agree that there are circumstances under which related organizations may be treated as a single covered entity for purposes of protecting the privacy of health information, and modify the rule to accommodate such circumstances. In § 164.504 of the final rule, we specify the conditions under which affiliated companies may combine into a single covered entity and similarly describe which components of a larger organization must comply with the requirements of this rule. For example, transfers of information within the designated component or affiliated entity are uses while transfers of information outside the designated component or affiliated entity are disclosures. See the discussion of § 164.504 for further information and rationale. It is not clear from these comments whether the particular organizational arrangements described could constitute a single covered entity.

Comment: A commenter noted that the definition of "disclosure" should reflect that health plan correspondence containing protected health information, such as Explanation of Benefits (EOBs), is frequently sent to the policyholder. Therefore, it was suggested that the words "provision of access to" be deleted from the definition and that a "disclosure" be clarified to include the conveyance of protected health information to a third party.

Response: The definition is, on its face, broad enough to cover the transfers of information described and so is not changed. We agree that health plans must be able to send EOBs to policyholders. Sending EOB correspondence to a policyholder by a covered entity is a disclosure for purposes of this rule, but it is a disclosure for purposes of payment. Therefore, subject to the provisions of § 164.522(b) regarding Confidential Communications, it is permitted even if it discloses to the policyholder protected health information about another individual (see below).

Health care operations

Comment: Several commenters stated that the list of activities within the definition of health care operations was too broad and should be narrowed. They asserted that the definition should be limited to exclude activities that have little or no connection to the care of a particular patient or to only include emergency treatment situations or situations constituting a clear and present danger to oneself or others.

Response: We disagree. We believe that narrowing the definition in the manner requested will place serious burdens on covered entities and impair their ability to conduct legitimate business and management functions.

Comment: Many commenters, including physician groups, consumer groups, and privacy advocates, argued that we should limit the information that can be used for health care operations to de-identified data. They ***82608** argued that if an activity could be done with de-identified data, it should not be incorporated in the definition of health care operations.

Response: We disagree. We believe that many activities necessary for the business and administrative operations of health plans and health care providers are not possible with de-identified information or are possible only under unduly burdensome circumstances. For example, identified information may be used or disclosed during an audit of claims, for a plan to contact a provider about alternative treatments for specific patients, and in reviewing the competence of health care professionals. Further, not all covered entities have the same ability to de-identify protected health information. Covered entities with highly automated information systems will be able to use de-identified data for many purposes. Other covered entities maintain most of their records on paper, so a requirement to de-identify information would place too great a burden on the legitimate and routine business functions included in the definition of health care operations. Small business, which are most likely to have largely paper records, would find such a blanket requirement particularly burdensome.

Protected health information that is de-identified pursuant to § 164.514(a) is not subject to this rule. We hope this provides covered entities capable of de-identifying information with the incentive to do so.

Comment: Some commenters requested that we permit the use of demographic data (geographic, location, age, gender, and race) separate from all other data for health care operations. They argued that demographic data was needed to establish provider networks and monitor providers to ensure that the needs of ethnic and minority populations were being addressed.

Response: The use of demographic data for the stated purposes is within the definition of health care operations; a special rule is not necessary.

Comment: Some commenters pointed out that the definition of health care operations is similar to, and at times overlaps with, the definition of research. In addition, a number of commenters questioned whether or not research conducted by the covered entity or its business partner must only be applicable to and used within the covered entity to be considered health care operations. Others questioned whether such studies or research performed internal to a covered entity are “health care operations” even if generalizable results may be produced.

Response: We agree that some health care operations have many of the characteristics of research studies and in the NPRM asked for comments on how to make this distinction. While a clear answer was not suggested in any of the comments, the comments generally together with our fact finding lead to the provisions in the final rule. The distinction between health care operations and research rests on whether the primary purpose of the study is to produce “generalizable knowledge.” We have modified the definition of health care operations to include “quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities.” If the primary purpose of the activity is to produce generalizable knowledge, the activity fits within this rule's definition of “research” and the covered entity must comply with §§ 164.508 or 164.512, including obtaining an authorization or the approval of an institutional review board or privacy board. If not and the activity otherwise

meets the definition of health care operations, the activity is not research and may be conducted under the health care operations provisions of this rule.

In some instances, the primary purpose of the activity may change as preliminary results are analyzed. An activity that was initiated as an internal outcomes evaluation may produce information that the covered entity wants to generalize. If the purpose of a study changes and the covered entity does intend to generalize the results, the covered entity should document the change in status of the activity to establish that they did not violate the requirements of this rule. (See definition of “research,” below, for further information on the distinction between “research” and “health care operations.”)

We note that the difficulty in determining when an activity is for the internal operations of an entity and when it is a research activity is a long-standing issue in the industry. The variation among commenters' views is one of many indications that, today, there is not consensus on how to draw this line. We do not resolve the larger issue here, but instead provide requirements specific to the information covered by this rule.

Comment: Several commenters asked that disease management and disability management activities be explicitly included in the definition of health care operations. Many health plans asserted that they would not be able to provide disease management, wellness, and health promotion activities if the activity were solely captured in the rule's definition of “treatment.” They also expressed concern that “treatment” usually applies to an individual, not to a population, as is the practice for disease management.

Response: We were unable to find generally accepted definitions of the terms “disease management” and “disability management.” Rather than rely on this label, we include many of the functions often included in discussions of disease management in this definition or in the definition of treatment, and modify both definitions to address the commenters' concerns. For example, we have revised the definition of health care operations to include population-based activities related to improving health or reducing health care costs. This topic is discussed further in the comment responses regarding the definition of “treatment,” below.

Comment: Several commenters urged that the definition of health care operations be illustrative and flexible, rather than structured in the form of a list as in the proposed rule. They believed it would be impossible to identify all the activities that constitute health care operations. Commenters representing health plans were concerned that the “static” nature of the definition would stifle innovation and could not reflect the new functions that health plans may develop in the future that benefit consumers, improve quality, and reduce costs. Other commenters, expressed support for the approach taken in the proposed rule, but felt the list was too broad.

Response: In the final rule, we revise the proposed definition of health care operations to broaden the list of activities included, but we do not agree with the comments asking for an illustrative definition rather than an inclusive list. Instead, we describe the activities that constitute health care operations in broad terms and categories, such as “quality assessment” and “business planning and development.” We believe the use of broadly stated categories will allow industry innovation, but without the privacy risks entailed in an illustrative approach.

Comment: Several commenters noted that utilization review and internal quality review should be included in the definition. They pointed out that both of these activities were discussed in the preamble to the proposed rule but were not incorporated into the regulation text. ***82609**

Response: We agree and have modified the regulation text to incorporate quality assessment and improvement activities, including the development of clinical guidelines and protocol development.

Comment: Several commenters stated that the proposal did not provide sufficient guidance regarding compiling and analyzing information in anticipation of or for use in legal proceedings. In particular, they raised concerns about the lack of specificity as to when "anticipation" would be triggered.

Response: We agree that this provision was confusing and have replaced it with a broader reference to conducting or arranging for legal services generally.

Comment: Hospital representatives pointed out the pressure on health care facilities to improve cost efficiencies, make cost-effectiveness studies, and benchmark essential health care operations. They emphasized that such activities often use identifiable patient information, although the products of the analyses usually do not contain identifiable health information. Commenters representing state hospital associations pointed out that they routinely receive protected health information from hospitals for analyses that are used by member hospitals for such things as quality of care benchmark comparisons, market share analysis, determining physician utilization of hospital resources, and charge comparisons.

Response: We have expanded the definition of health care operations to include use and disclosure of protected health information for the important functions noted by these commenters. We also allow a covered entity to engage a business associate to provide data aggregation services. See § 164.504(e).

Comment: Several commenters argued that many activities that are integral to the day-to-day operations of a health plan have not been included in the definition. Examples provided by the commenters include: issuing plan identification cards, customer service, computer maintenance, storage and back-up of radiologic images, and the installation and servicing of medical equipment or computer systems.

Response: We agree with the commenters that there are activities not directly part of treatment or payment that are more closely associated with the administrative or clerical functions of the plan or provider that need to be included in the definition. To include such activities in the definition of health care operations, we eliminate the requirement that health care operations be directly related to treatment and payment, and we add to this definition the new categories of business management (including general administrative activities) and business planning activities.

Comment: One commenter asked for clarification on whether cost-related analyses could also be done by providers as well as health plans.

Response: Health care operations, including business management functions, are not limited to health plans. Any covered entity can perform health care operations.

Comment: One commenter stated that the proposed rule did not address what happens to records when a covered entity is sold or merged with another entity.

Response: We agree and add to the definition of health care operations disclosures of protected health information for due diligence to a covered entity that is a potential successor in interest. This provision includes disclosures pursuant to the sale of a covered entity's business as a going concern, mergers, acquisitions, consolidations, and other similar types of corporate restructuring between covered entities, including a division of a covered entity, and to an entity that is not a covered entity but will become a covered entity if the reorganization or sale is completed. Other types of sales of assets, or disclosures to organizations that are not and would not become covered entities, are not included in the definition of health care operations and could only occur if the covered entity obtained valid authorization for such disclosure in accordance with § 164.508 or if the disclosure is otherwise permitted under this rule.

Once a covered entity is sold or merged with another covered entity, the successor in interest becomes responsible for complying with this regulation with respect to the transferred information.

Comment: Several commenters expressed concern that the definition of health care operations failed to include the use of protected health information for the underwriting of new health care policies and took issue with the exclusion of uses and disclosures of protected health information of prospective enrollees. They expressed the concern that limiting health care operations to the underwriting and rating of existing members places a health plan in the position of not being able to evaluate prudently and underwrite a consumer's health care risk.

Response: We agree that covered entities should be able to use the protected health information of prospective enrollees to underwrite and rate new business and change the definition of health care operations accordingly. The definition of health care operations below includes underwriting, premium rating, and other activities related to the creation of a contract of health insurance.

Comment: Several commenters stated that group health plans needed to be able to use and disclose protected health information for purposes of soliciting a contract with a new carrier and rate setting.

Response: We agree and add "activities relating to the * * * replacement of a contract of insurance" to cover such disclosures. See § 164.504 for the rules for plan sponsors of group health plans to obtain such information.

Comment: Commenters from the business community supported our recognition of the importance of financial risk transfer mechanisms in the health care marketplace by including "reinsurance" in the definition of health care operations. However, they stated that the term "reinsurance" alone was not adequate to capture "stop-loss insurance" (also referred to as excess of loss insurance), another type of risk transfer insurance.

Response: We agree with the commenters that stop-loss and excess of loss insurance are functionally equivalent to reinsurance and add these to the definition of health care operations.

Comment: Commenters from the employer community explained that there is a trend among employers to contract with a single insurer for all their insurance needs (health, disability, workers' compensation). They stated that in these integrated systems, employee health information is shared among the various programs in the system. The commenters believed the existing definition poses obstacles for those employers utilizing an integrated health system because of the need to obtain authorizations before being permitted to use protected health information from the health plan to administer or audit their disability or workers' compensation plan.

Other commenters representing employers stated that some employers wanted to combine health information from different insurers and health plans providing employee benefits to their workforces, including its group health plan, workers' compensation insurers, and disability insurers, so that they could have more information in order to better manage the occurrences of disability and illness among their workforces. They expressed concern ***82610** that the proposed rule would not permit such sharing of information.

Response: While we agree that integrating health information from different benefit programs may produce efficiencies as well as benefits for individuals, the integration also raises significant privacy concerns, particularly if there are no safeguards on uses and disclosures from the integrated data. Under HIPAA, we do not have jurisdiction over many types of insurers that use health information, such as workers' compensation insurers or insurers providing disability income benefits, and we cannot address the extent to which they provide individually identifiable health information to a health plan, nor do we prohibit a health plan from receiving such information. Once a health plan receives identifiable health information, however, the information becomes protected and may only be used and disclosed as otherwise permitted by this rule.

We clarify, however, that a covered entity may provide data and statistical analyses for its customers as a health care operation, provided that it does not disclose protected health information in a way that would otherwise violate this rule. A group health

plan or health insurance issuer or HMO, or their business associate on their behalf, may perform such analyses for an employer customer and provide the results in de-identified form to the customer, using integrated data received from other insurers, as long as protected health information is not disclosed in violation of this rule. See the definition of "health care operations," § 164.501. If the employer sponsors more than one group health plan, or if its group health plan provides coverage through more than one health insurance issuer or HMO, the different covered entities may be an organized health care arrangement and be able to jointly participate in such an analysis as part of the health care operations of such organized health care arrangement. See the definitions of "health care operations" and "organized health care arrangement," § 164.501. We further clarify that a plan sponsor providing plan administration to a group health plan may participate in such an analysis, provided that the requirements of § 164.504(f) and other parts of this rule are met.

The results described above are the same whether the health information that is being combined is from separate insurers or from one entity that has a health component and also provides excepted benefits. See the discussion relating to health care components, § 164.504.

We note that under the arrangements described above, the final rule provides substantial flexibility to covered entities to provide general data and statistical analyses, resulting in the disclosure of de-identified information, to employers and other customers. An employer also may receive protected health information from a covered entity for any purpose, including those described in comment above, with the authorization of the individual. See § 164.508.

Comment: A number of commenters asserted that the proposed definition appeared to limit training and educational activities to that of health care professionals, students, and trainees. They asked that we expand the definition to include other education-related activities, such as continuing education for providers and training of non-health care professionals as needed for supporting treatment or payment.

Response: We agree with the commenters that the definition of health care operations was unnecessarily limiting with respect to educational activities and expand the definition of health care operations to include "conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers." We clarify that medical rounds are considered treatment, not health care operations.

Comment: A few commenters outlined the need to include the training of non-health care professionals, such as health data analysts, administrators, and computer programmers within the definition of health care operations. It was argued that, in many cases, these professionals perform functions which support treatment and payment and will need access to protected health information in order to carry out their responsibilities.

Response: We agree and expand the definition of health care operations to include training of non-health care professionals.

Comment: One commenter stated that the definition did not explicitly include physician credentialing and peer review.

Response: We have revised the definition to specifically include "licensing or credentialing activities." In addition, peer review activities are captured in the definition as reviewing the competence or qualifications of health care professionals and evaluating practitioner and provider performance.

Health Oversight Agency

Comment: Some commenters sought to have specific organizations defined as health oversight agencies. For example, some commenters asked that the regulation text, rather than the preamble, explicitly list state insurance departments as an example of health oversight agencies. Medical device manufacturers recommended expanding the definition to include government contractors such as coding committees, which provide data to HCFA to help the agency make reimbursement decisions.

One federal agency sought clarification that several of its sub-agencies were oversight agencies; it was concerned about its status in part because the agency fits into more than one of the categories of health oversight agency listed in the proposed rule.

Other commenters recommended expanding the definition of oversight agency to include private-sector accreditation organizations. One commenter recommended stating in the final rule that private companies providing information to insurers and employers are not included in the definition of health oversight agency.

Response: Because the range of health oversight agencies is so broad, we do not include specific examples in the definition. We include many examples in the preamble above and provide further clarity here.

As under the NPRM, state insurance departments are an example of a health oversight agency. A commenter concerned about state trauma registries did not describe the registries' activities or legal charters, so we cannot clarify whether such registries may be health oversight agencies. Government contractors such as coding committees, which provide data to HCFA to support payment processes, are not thereby health oversight agencies under this rule. We clarify that public agencies may fit into more than one category of health oversight agency.

The definition of health oversight agency does not include private-sector accreditation organizations. While their work can promote quality in the health care delivery system, private accreditation organizations are not authorized by law to oversee the health care system or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant. Under the final rule, we consider private accrediting groups to be performing a health care operations function for covered entities. Thus, disclosures to private accrediting organizations are ***82611** disclosures for health care operations, not for oversight purposes.

When they are performing accreditation activities for a covered entity, private accrediting organizations will meet the definition of business associate, and the covered entity must enter into a business associate contract with the accrediting organization in order to disclose protected health information. This is consistent with current practice; today, accrediting organizations perform their work pursuant to contracts with the accredited entity. This approach is also consistent with the recommendation by the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance, which stated in their report titled Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment (1998) that “Oversight organizations, including accrediting bodies, states, and federal agencies, should include in their contracts terms that describe their responsibility to maintain the confidentiality of any personally identifiable health information that they review.”

We agree with the commenter who believed that private companies providing information to insurers and employers are not performing an oversight function; the definition of health oversight agency does not include such companies.

In developing and clarifying the definition of health oversight in the final rule, we seek to achieve a balance in accounting for the full range of activities that public agencies may undertake to perform their health oversight functions while establishing clear and appropriate boundaries on the definition so that it does not become a catch-all category that public and private agencies could use to justify any request for information.

Individual

Comment: A few commenters stated that foreign military and diplomatic personnel, and their dependents, and overseas foreign national beneficiaries, should not be excluded from the definition of “individual.”

Response: We agree with concerns stated by commenters and eliminate these exclusions from the definition of “individual” in the final rule. Special rules for use and disclosure of protected health information about foreign military personnel are stated in § 164.512(k). Under the final rule, protected health information about diplomatic personnel is not accorded special treatment. While the exclusion of overseas foreign national beneficiaries has been deleted from the definition of “individual,” we have

revised § 164.500 to indicate that the rule does not apply to the Department of Defense or other federal agencies or non-governmental organizations acting on its behalf when providing health care to overseas foreign national beneficiaries. This means that the rule will not cover any health information created incident to the provision of health care to foreign nationals overseas by U.S. sponsored missions or operations. (See § 164.500 and its corresponding preamble for details and the rationale for this policy.)

Comment: Several commenters expressed concern about the interrelationship of the definition of "individual" and the two year privacy protection for deceased persons.

Response: In the final rule, we eliminate the two year limit on privacy protection for protected health information about deceased individuals and require covered entities to comply with the requirements of the rule with respect to the protected health information of deceased individuals as long as they hold such information. See discussion under § 164.502.

Individually Identifiable Health Information

Comment: A number of commenters suggested that HHS revise the definitions of health information and individually identifiable health information to include consistent language in paragraph (1) of each respective definition. They observed that paragraph (1) of the definition of health information reads: "(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse * * *;" in contrast to paragraph (1) of the definition of individually identifiable health information, which reads: "(1) Is created by or received from a health care provider, health plan, employer, or health care clearinghouse * * *" [Emphasis added.]

Another commenter asked that we delete from the definition of health information, the words "health or" to make the definition more consistent with the definition of "health care," as well as the words "whether oral or."

Response: We define these terms in the final rule as they are defined by Congress in sections 1171(4) and 1171(6) of the Act, respectively. We have, however, changed the word "from" in the definition of "individually identifiable health information" to conform to the statute.

Comment: Several commenters urged that the definition of individually identifiable health information include information created or received by a researcher. They reasoned that it is important to ensure that researchers using personally identifiable health information are subject to federal privacy standards. They also stated that if information created by a school regarding the health status of its students could be labeled "health information," then information compiled by a clinical researcher regarding an individual also should be considered health information.

Response: We are restricted to the statutory limits of the terms. The Congress did not include information created or received by a researcher in either definition, and, consequently, we do not include such language in the rule's definitions.

Comment: Several commenters suggested modifying the definition of individually identifiable health information to state as a condition that the information provide a direct means of identifying the individual. They commented that the rule should support the need of those (e.g., researchers) who need "ready access to health information * * * that remains linkable to specific individuals."

Response: The Congress included in the statutory definition of individually identifiable health information the modifier "reasonable basis" when describing the condition for determining whether information can be used to identify the individual. Congress thus intended to go beyond "direct" identification and to encompass circumstances in which a reasonable likelihood of identification exists. Even after removing "direct" or "obvious" identifiers of information, a risk or probability of identification of the subject of the information may remain; in some instances, the risk will not be inconsequential. Thus, we agree with the Congress that "reasonable basis" is the appropriate standard to adequately protect the privacy of individuals' health information.

Comment: A number of commenters suggested that the Secretary eliminate the distinction between protected health information and individually identifiable health information. One commenter asserted that all individually identifiable health information should be protected. One commenter observed that the terms individually identifiable health information and protected health information are defined differently in the rule and requested clarification as to the precise scope of coverage of the standards. Another commenter stated ***82612** that the definition of individually identifiable health information includes "employer," whereas protected health information pertains only to covered entities for which employers are not included. The commenter argued that this was an "incongruity" between the definitions of individually identifiable health information and protected health information and recommended that we remove "employer" from the definition of individually identifiable health information.

Response: We define individually identifiable health information in the final rule generally as it is defined by Congress in section 1171(6) of the Act. Because "employer" is included in the statutory definition, we cannot accept the comment to remove the word "employer" from the regulatory definition.

We use the phrase 'protected health information' to distinguish between the individually identifiable health information that is used or disclosed by the entities that are subject to this rule and the entire universe of individually identifiable health information. 'Individually identifiable health information' as defined in the statute is not limited to health information used or disclosed by covered entities, so the qualifying phrase 'protected health information' is necessary to define that individually identifiable health information to which this rule applies.

Comment: One commenter noted that the definition of individually identifiable health information in the NPRM appeared to be the same definition used in the other HIPAA proposed rule, Security and Electronic Signature Standards (63 FR 43242). However, the commenter stated that the additional condition in the privacy NPRM, that protected health information is or has been electronically transmitted or electronically maintained by a covered entity and includes such information in any other form, appears to create potential disparity between the requirements of the two rules. The commenter questioned whether the provisions in proposed § 164.518(c) were an attempt to install similar security safeguards for such situations.

Response: The statutory definition of individually identifiable health information applies to the entire Administrative Simplification subtitle of HIPAA and, thus, was included in the proposed Security Standards. At this time, however, the final Security Standards have not been published, so the definition of protected health information is relevant only to HIPAA's privacy standards and is, therefore, included in subpart E of part 164 only. We clarify that the requirements in the proposed Security Standards are distinct and separate from the privacy safeguards promulgated in this final rule.

Comment: Several commenters expressed confusion and requested clarification as to what is considered health information or individually identifiable health information for purposes of the rule. For example, one commenter was concerned that information exists in collection agencies, credit bureaus, etc., which could be included under the proposed regulation but may or may not have been originally obtained by a covered entity. The commenter noted that generally this information is not clinical, but it could be inferred from the data that a health care provider provided a person or member of person's family with health care services. The commenter urged the Secretary to define more clearly what and when information is covered.

One commenter queried how a non-medical record keeper could tell when personal information is health information within the meaning of rule, e.g., when a worker asks for a low salt meal in a company cafeteria, when a travel voucher of an employee indicates that the traveler returned from an area that had an outbreak of fever, or when an airline passenger requests a wheel chair. It was suggested that the rule cover health information in the hands of schools, employers, and life insurers only when they receive individually identifiable health information from a covered entity or when they create it while providing treatment or making payment.

Response: This rule applies only to individually identifiable health information that is held by a covered entity. Credit bureaus, airlines, schools, and life insurers are not covered entities, so the information described in the above comments is not protected health information. Similarly, employers are not covered entities under the rule. Covered entities must comply with this

regulation in their health care capacity, not in their capacity as employers. For example, information in hospital personnel files about a nurses' sick leave is not protected health information under this rule.

Comment: One commenter recommended that the privacy of health information should relate to actual medical records. The commenter expressed concern about the definition's broadness and contended that applying prescriptive rules to information that health plans hold will not only delay processing of claims and coverage decisions, but ultimately affect the quality and cost of care for health care consumers.

Response: We disagree. Health information about individuals exists in many types of records, not just the formal medical record about the individual. Limiting the rule's protections to individually identifiable health information contained in medical records, rather than individually identifiable health information in any form, would omit a significant amount of individually identifiable health information, including much information in covered transactions.

Comment: One commenter voiced a need for a single standard for individually identifiable health information and disability and workers' compensation information; each category of information is located in their one electronic data base, but would be subjected to a different set of use and transmission rules.

Response: We agree that a uniform, comprehensive privacy standard is desirable. However, our authority under the HIPAA is limited to individually identifiable health information as it is defined in the statute. The legislative history of HIPAA makes clear that workers' compensation and disability benefits programs were not intended to be covered by the rule. Entities are of course free to apply the protections required by this rule to all health information they hold, including the excepted benefits information, if they wish to do so (for example, in order to reduce administrative burden).

Comment: Commenters recommended that the definition of individually identifiable health information not include demographic information that does not have any additional health, treatment, or payment information with it. Another commenter recommended that protected health information should not include demographic information at all.

Response: Congress explicitly included demographic information in the statutory definition of this term, so we include such language in our regulatory definition of it.

Comments: A number of commenters expressed concern about whether references to personal information about individuals, such as “John Doe is fit to work as a pipe fitter * * *” or “Jane Roe can stand no more than 2 hours * * *”, would be considered individually identifiable health information. They argued that such “fitness-to-work” and “fitness for duty” statements are not health care because they do not reveal the type of ***82613** information (such as the diagnosis) that is detrimental to an individual's privacy interest in the work environment.

Response: References to personal information such as those suggested by the commenters could be individually identifiable health information if the references were created or received by a health care provider, health plan, employer, or health care clearinghouse and they related to the past, present, or future physical or mental health or condition, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual. Although these fitness for duty statements may not reveal a diagnosis, they do relate to a present physical or mental condition of an individual because they describe the individual's capacity to perform the physical and mental requirements of a particular job at the time the statement is made (even though there may be other non-health-based qualifications for the job). If these statements were created or received by one of more of the entities described above, they would be individually identifiable health information.

Law Enforcement Official

Comment: Some commenters, particularly those representing health care providers, expressed concern that the proposed definition of “law enforcement official” could have allowed many government officials without health care oversight duties to obtain access to protected health information without patient consent.

Response: We do not intend for the definition of "law enforcement official" to be limited to officials with responsibilities directly related to health care. Law enforcement officials may need protected health information for investigations or prosecutions unrelated to health care, such as investigations of violent crime, criminal fraud, or crimes committed on the premises of health care providers. For these reasons, we believe it is not appropriate to limit the definition of "law enforcement official" to persons with responsibilities of oversight of the health care system.

Comment: A few commenters expressed concern that the proposed definition could include any county or municipal official, even those without traditional law enforcement training.

Response: We do not believe that determining training requirements for law enforcement officials is appropriately within the purview of this regulation; therefore, we do not make the changes that these commenters requested.

Comment: Some commenters, particularly those from the district attorney community, expressed general concern that the proposed definition of "law enforcement official" was too narrow to account for the variation in state interpretations of law enforcement officials' power. One group noted specifically that the proposed definition could have prevented prosecutors from gaining access to needed protected health information.

Response: We agree that protected health information may be needed by law enforcement officials for both investigations and prosecutions. We did not intend to exclude the prosecutorial function from the definition of "law enforcement official," and accordingly we modify the definition of law enforcement official to reflect their involvement in prosecuting cases. Specifically, in the final rule, we define law enforcement official as an official of any agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, or an Indian tribe, who is empowered by law to: (1) Investigate or conduct an inquiry into a potential violation of law; or (2) prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Comment: One commenter recommended making the definition of law enforcement official broad enough to encompass Medicaid program auditors, because some matters requiring civil or criminal law enforcement action are first identified through the audit process.

Response: We disagree. Program auditors may obtain protected health information necessary for their audit functions under the oversight provision of this regulation (§ 164.512(d)).

Comment: One commenter suggested that the proposed definition of "law enforcement official" could be construed as limited to circumstances in which an official "knows" that law has been violated. This commenter was concerned that, because individuals are presumed innocent and because many investigations, such as random audits, are opened without an agency knowing that there is a violation, the definition would not have allowed disclosure of protected health information for these purposes. The commenter recommended modifying the definition to include investigations into "whether" the law has been violated.

Response: We do not intend for lawful disclosures of protected health information for law enforcement purposes to be limited to those in which a law enforcement official knows that law has been violated. Accordingly, we revise the definition of "law enforcement official" to include investigations of "potential" violations of law.

Marketing

Comments related to "marketing" are addressed in the responses to comments regarding § 164.514(e).

Payment

Comment: One commenter urged that the Department not permit protected health information to be disclosed to a collection agency for collecting payment on a balance due on patient accounts. The commenter noted that, at best, such a disclosure would only require the patient's and/or insured's address and phone number.

Response: We disagree. A collection agency may require additional protected health information to investigate and assess payment disputes for the covered entity. For example, the collection agency may need to know what services the covered entity rendered in order to resolve disputes about amounts due. The information necessary may vary, depending on the nature of the dispute. Therefore we do not specify the information that may be used or disclosed for collection activities. The commenter's concern may be addressed by the minimum necessary requirements in § 164.514. Under those provisions, when a covered entity determines that a collection agency only requires limited information for its activities, it must make reasonable efforts to limit disclosure to that information.

Comment: A number of commenters supported retaining the expansive definition in the proposed rule so that current methods of administering the claims payment process would not be hindered by blocking access to protected health information.

Response: We agree and retain the proposed overall approach to the definition.

Comment: Some commenters argued that the definition of "payment" should be narrowly interpreted as applying only to the individual who is the subject of the information.

Response: We agree with the commenter and modify the definition to clarify that payment activities relate to the individual to whom health care is provided.

Comment: Another group of commenters asserted that the doctor-patient relationship was already being interfered with by the current practices of managed care. For example, it was argued that the definition expanded the ***82614** power of government and other third party "payors," turning them into controllers along with managed care companies. Others stated that activities provided for under the definition occur primarily to fulfill the administrative function of managed health plans and that an individual's privacy is lost when his or her individually identifiable health information is shared for administrative purposes.

Response: Activities we include in the definition of payment reflect core functions through which health care and health insurance services are funded. It would not be appropriate for a rule about health information privacy to hinder mechanisms by which health care is delivered and financed. We do not through this rule require any health care provider to disclose protected health information to governmental or other third party payors for the activities listed in the payment definition. Rather, we allow these activities to occur, subject to and consistent with the requirements of this rule.

Comment: Several commenters requested that we expand the definition to include "coordination of benefits" as a permissible activity.

Response: We agree and modify the definition accordingly.

Comment: A few commenters raised concerns that the use of "medical data processing" was too restrictive. It was suggested that a broader reference such as "health related" data processing would be more appropriate.

Response: We agree and modify the definition accordingly.

Comment: Some commenters suggested that the final rule needed to clarify that drug formulary administration activities are payment related activities.

Response: While we agree that uses and disclosures of protected health information for drug formulary administration and development are common and important activities, we believe these activities are better described as health care operations and that these activities come within that definition.

Comment: Commenters asked that the definition include calculation of prescription drug costs, drug discounts, and maximum allowable costs and copayments.

Response: Calculations of drug costs, discounts, or copayments are payment activities if performed with respect to a specific individual and are health care operations if performed in the aggregate for a group of individuals.

Comment: We were urged to specifically exclude "therapeutic substitution" from the definition.

Response: We reject this suggestion. While we understand that there are policy concerns regarding therapeutic substitution, those policy concerns are not primarily about privacy and thus are not appropriately addressed in this regulation.

Comment: A few commenters asked that patient assistance programs (PAPS) should be excluded from the definition of payment. Such programs are run by or on behalf of manufacturers and provide free or discounted medications to individuals who could not afford to purchase them. Commenters were concerned that including such activities in the definition of payment could harm these programs.

For example, a university school of pharmacy may operate an outreach program and serve as a clearinghouse for information on various pharmaceutical manufacturer PAPS. Under the program state residents can submit a simple application to the program (including medication regimen and financial information), which is reviewed by program pharmacists who study the eligibility criteria and/or directly call the manufacturer's program personnel to help evaluate eligibility for particular PAPS. The program provides written guidance to the prescribing physicians that includes a suggested approach for helping their indigent patients obtain the medications that they need and enrollment information for particular PAPS.

Response: We note that the concerns presented are not affected by definition of "payment." The application of this rule to patient assistance programs activities will depend on how the individual programs operate and are affected primarily by the definition of treatment. Each of these programs function differently, so it is not possible to state a blanket rule for whether and how the rule affects such programs.

Under the example provided, the physician who contacts the program on behalf of a patient is managing the patient's care. If the provider is also a covered entity, he or she would be permitted to make such a "treatment" disclosure of protected health information if a general consent had been obtained from the patient. Depending on the particular facts, the manufacturer, by providing the prescription drugs for an individual, could also be providing health care under this rule. Even so, however, the manufacturer may or may not be a covered entity, depending on whether or not it engages in any of the standard electronic transactions (See the definition of a covered entity). It also may be an indirect treatment provider, since it may be providing the product through another provider, not directly to the patient. In this example, the relevant disclosures of protected health information by any covered health care provider with a direct treatment relationship with the patient would be permitted subject to the general consent requirements of § 164.506.

Whether and how this rule affects the school of pharmacy is equally dependent on the specific facts. For example, if the school merely provides a patient or a physician with the name of a manufacturer and a contact phone number, it would not be functioning as a health care provider and would not be subject to the rule. However, if the school is more involved in the care of the individual, its activities could come in within the definition of "health care provider" under this rule.

Comment: Commenters pointed out that drugs may or may not be "covered" under a plan. Individuals, on the other hand, may or may not be "eligible" for benefits under a plan. The definition should incorporate both terms to clarify that determinations of both coverage and eligibility are payment activities.

Response: We agree and modify the rule to include "eligibility".

Comment: Several commenters urged that "concurrent and retrospective review" were significant utilization review activities and should be incorporated.

Response: We agree and modify the definition accordingly.

Comment: Commenters noted that the proposed rule was not clear as to whether protected health information could be used to resolve disputes over coverage, including appeals or complaints regarding quality of care.

Response: We modify the definition of payment to include resolution of payment and coverage disputes; the final definition of payment includes "the adjudication * * * of health benefit claims." The other examples provided by commenters, such as arranging, conducting, or assistance with primary and appellate level review of enrollee coverage appeals, also fall within the scope of adjudication of health benefits claims. Uses and disclosures of protected health information to resolve disputes over quality of care may be made under the definition of "health care operations" (see above).

Comment: Some commenters suggested that if an activity falls within the scope of payment it should not be considered marketing. Commenters supported an approach that would bar such an activity from being construed as "marketing" even if performing that ***82615** activity would result in financial gain to the covered entity.

Response: We agree that the proposed rule did not clearly define "marketing," leaving commenters to be concerned about whether payment activities that result in financial gain might be considered marketing. In the final rule we add a definition of marketing and clarify when certain activities that would otherwise fall within that definition can be accomplished without authorization. We believe that these changes will clarify the distinction between marketing and payment and address the concerns raised by commenters.

Comment: Commenters asserted that HHS should not include long-term care insurance within the definition of "health plan." If they are included, the commenters argued that the definition of payment must be modified to reflect the activities necessary to support the payment of long-term care insurance claims. As proposed, commenters argued that the definition of payment would not permit long term care insurers to use and disclose protected health information without authorization to perform functions that are "compatible with and directly relate to * * * payment" of claims submitted under long term care policies.

Response: Long-term care policies, except for nursing home fixed-indemnity policies, are defined as health plans by the statute (see definition of "health plan," above). We disagree with the assertion that the definition of payment does not permit long term care insurers to undertake these necessary activities. Processing of premium payments, claims administration, and other activities suggested for inclusion by the commenters are covered by the definition. The rule permits protected health information to be used or disclosed by a health plan to determine or fulfill its responsibility for provision of benefits under the health plan.

Comment: Some commenters argued that the definition needs to be expanded to include the functions of obtaining stop-loss and ceding reinsurance.

Response: We agree that use and disclosure of protected health information for these activities should be permitted without authorization, but have included them under health care operation rather than payment.

Comment: Commenters asked that the definition be modified to include collection of accounts receivable or outstanding accounts. Commenters raised concern that the proposed rule, without changes, might unintentionally prevent the flow of information between medical providers and debt collectors.

Response: We agree that the proposed definition of payment did not explicitly provide for "collection activities" and that this oversight might have impeded a covered entity's debt collection efforts. We modify the regulatory text to add "collection activities."

Comment: The preamble should clarify that self-insured group health and workers' compensation plans are not covered entities or business partners.

Response: The statutory definition of health plan does not include workers' compensation products. See the discussion of "health plan" under § 160.103 above.

Comment: Certain commenters explained that third party administrators usually communicate with employees through Explanation of Benefit (EOB) reports on behalf of their dependents (including those who might not be minor children). Thus, the employee might be apprised of the medical encounters of his or her dependents but not of medical diagnoses unless there is an over-riding reason, such as a child suspected of drug abuse due to multiple prescriptions. The commenters urged that the current claim processing procedures be allowed to continue.

Response: We agree. We interpret the definition of payment and, in particular the term "claims management," to include such disclosures of protected health information.

Comment: One private company noted that pursuant to the proposed Transactions Rule standard for payment and remittance advice, the ASC X12N 835 can be used to make a payment, send a remittance advice, or make a payment and send remittance advice by a health care payor and a health care provider, either directly or through a designated financial institution. Because a remittance advice includes diagnostic or treatment information, several private companies and a few public agencies believed that the proposed Transactions Rule conflicted with the proposed privacy rule. Two health plans requested guidance as to whether, pursuant to the ASC X12N 835 implementation guide, remittance advice information is considered "required" or "situational." They sought guidance on whether covered entities could include benefits information in payment of claims and transfer of remittance information.

One commenter asserted that if the transmission of certain protected health information were prohibited, health plans may be required to strip remittance advice information from the ASC X12N 835 when making health care payments. It recommended modifying the proposed rule to allow covered entities to provide banks or financial institutions with the data specified in any transaction set mandated under the Transactions Rule for health care claims payment.

Similarly, a private company and a state health data organization recommended broadening the scope of permissible disclosures pursuant to the banking section to include integrated claims processing information, as contained in the ASC X12N 835 and proposed for adoption in the proposed Transactions Rule; this transaction standard includes diagnostic and treatment information. The company argued that inclusion of diagnostic and treatment information in the data transmitted in claims processing was necessary for comprehensive and efficient integration in the provider's patient accounting system of data corresponding with payment that financial institutions credit to the provider's account.

A state health data organization recommended applying these rules to financial institutions that process electronic remittance advice pursuant to the Transactions Rule.

Response: The Transactions Rule was published August 17, 2000, after the issuance of the privacy proposed rule. As noted by the commenters, the ASC X12N 835 we adopted as the "Health Care Payment and Remittance Advice" standard in the

Transactions Rule has two parts. They are the electronic funds transfer (EFT) and the electronic remittance advice (ERA). The EFT part is optional and is the mechanism that payors use to electronically instruct one financial institution to move money from one account to another at the same or at another financial institution. The EFT includes information about the payor, the payee, the amount, the payment method, and a reassociation trace number. Since the EFT is used to initiate the transfer of funds between the accounts of two organizations, typically a payor to a provider, it includes no individually identifiable health information, not even the names of the patients whose claims are being paid. The funds transfer information may also be transmitted manually (by check) or by a variety of other electronic means, including various formats of electronic transactions sent through a payment network, such as the Automated Clearing House (ACH) Network.

The ERA, on the other hand, contains specific information about the patients and the medical procedures for which ***82616** the money is being paid and is used to update the accounts receivable system of the provider. This information is always needed to complete a standard Health Care Payment and Remittance Advice transaction, but is never needed for the funds transfer activity of the financial institution. The only information the two parts of this transaction have in common is the reassociation trace number.

Under the ASC X12N 835 standard, the ERA may be transmitted alone, directly from the health plan to the health care provider and the reassociation trace number is used by the provider to match the ERA information with a specific payment conducted in some other way (e.g., EFT or paper check). The standard also allows the EFT to be transmitted alone, directly to the financial institution that will initiate the payment. It also allows both parts to be transmitted together, even though the intended recipients of the two parts are different (the financial institution and the provider). For example, this would be done when the parties agree to use the ACH system to carry the ERA through the provider's bank to the provider when it is more efficient than sending the ERA separately through a different electronic medium.

Similarly, the ASC X12N 820 standard for premium payments has two parts, an EFT part (identical to that of the 835) and a premium data part containing identity and health information about the individuals for whom health insurance premiums are being paid.

The transmission of both parts of the standards are payment activities under this rule, and permitted subject to certain restrictions. Because a financial institution does not require the remittance advice or premium data parts to conduct funds transfers, disclosure of those parts by a covered entity to it (absent a business associate arrangement to use the information to conduct other activities) would be a violation of this rule.

We note that additional requirements may be imposed by the final Security Rule. Under the proposed Security Rule, the ACH system and similar systems would have been considered “open networks” because transmissions flow unpredictably through and become available to member institutions who are not party to any business associate agreements (in a way similar to the internet). The proposed Security Rule would require any protected health information transferred through the ACH or similar system to be encrypted.

Comment: A few commenters noted the Gramm-Leach-Bliley (GLB) Act (Pub. L. 106-102) allows financial holding companies to engage in a variety of business activities, such as insurance and securities, beyond traditional banking activities. Because the term “banking” may take on broader meaning in light of these changes, the commenter recommended modifying the proposed rule to state that disclosure of diagnostic and treatment information to banks along with payment information would constitute a violation of the rule. Specifically, the organization recommended clarifying in the final rule that the provisions included in the proposed section on banking and payment processes (proposed § 164.510(i)) govern payment processes only and that all activities of financial institutions that did not relate directly to payment processes must be conducted through business partner contracts. Furthermore, this group recommended clarifying that if financial institutions act as payors, they will be covered entities under the rule.

Response: We recognize that implementation of the GLB Act will expand significantly the scope of activities in which financial holding companies engage. However, unless a financial institution also meets the definition of a "covered entity," it cannot be a covered entity under this rule.

We agree with the commenters that disclosure of diagnostic and specific treatment information to financial institutions for many banking and funds processing purposes may not be consistent with the minimum necessary requirements of this final rule. We also agree with the commenters that financial institutions are business associates if they receive protected health information when they engage in activities other than funds processing for covered entities. For example, if a health care provider contracts with a financial institution to conduct "back office" billing and accounts receivable activities, we require the provider to enter into a business associate contract with the institution.

Comment: Two commenters expressed support for the proposed rule's approach to disclosure for banking and payment processes. On the other hand, many other commenters were opposed to disclosure of protected health information without authorization to banks. One commenter said that no financial institution should have individually identifiable health information for any reason, and it said there were technological means for separating identity from information necessary for financial transactions. Some commenters believed that implementation of the proposed rule's banking provisions could lead banks to deny loans on the basis of individuals' health information.

Response: We seek to achieve a balance between protecting patient privacy and facilitating the efficient operation of the health care system. While we agree that financial institutions should not have access to extensive information about individuals' health, we recognize that even the minimal information required for processing of payments may effectively reveal a patient's health condition; for example, the fact that a person has written a check to a provider suggests that services were rendered to the person or a family member. Requiring authorization for disclosure of protected health information to a financial institution in order to process every payment transaction in the health care system would make it difficult, if not impossible, for the health care system to operate effectively. See also discussion of section 1179 of the Act above.

Comment: Under the proposed rule, covered entities could have disclosed the following information without consent to financial institutions for the purpose of processing payments: (1) The account holder's name and address; (2) the payor or provider's name and address; (3) the amount of the charge for health services; (4) the date on which services were rendered; (5) the expiration date for the payment mechanism, if applicable (e.g., credit card expiration date); and (6) the individual's signature. The proposed rule solicited comments on whether additional data elements would be necessary to process payment transactions from patients to covered entities.

One commenter believed that it was unnecessary to include this list in the final rule, because information that could have been disclosed under the proposed minimum necessary rule would have been sufficient to process banking and payment information. Another private company said that its extensive payment systems experience indicated that we should avoid attempts to enumerate a list of information allowed to be disclosed for banking and payment processing. Furthermore, the commenter said, the proposed rule's list of information allowed to be disclosed was not sufficient to perform the range of activities necessary for the operation of modern electronic payment systems. Finally, the commenter said, inclusion of specific data elements allowed to be ***82617** disclosed for banking and payment processes rule would stifle innovation in continually evolving payment systems. Thus, the commenter recommended that in the final rule, we eliminate the minimum necessary requirement for banking and payment processing and that we do not include a list of specific types of information allowed to be disclosed for banking and payment processes.

On the other hand, several other commenters supported applying the minimum necessary standard to covered entities' disclosures to financial institutions for payment processing. In addition, these groups said that because financial institutions are not covered entities under the proposed rule, they urged Congress to enact comprehensive privacy legislation to limit financial institutions' use and re-disclosure of the minimally necessary protected health information they could receive under the proposed rule. Several of these commenters said that, in light of the increased ability to manipulate data electronically, they were concerned

that financial institutions could use the minimal protected health information they received for making financial decisions. For example, one of these commenters said that a financial institution could identify an individual who had paid for treatment of domestic violence injuries and subsequently could deny the individual a mortgage based on that information.

Response: We agree with the commenters who were concerned that a finite list of information could hamper systems innovation, and we eliminate the proposed list of data items. However, we disagree with the commenters who argued that the requirement for minimum necessary disclosures not apply to disclosures to financial institution or for payment activities. They presented no persuasive reasons why these disclosures differ from others to which the standard applies, nor did they suggest alternative means of protecting individuals' privacy. Further, with elimination of the proposed list of items that may be disclosed, it will be necessary to rely on the minimum necessary disclosure requirement to ensure that disclosures for payment purposes do not include information unnecessary for that purposes. In practice, the following is the information that generally will be needed: the name and address of the individual; the name and address of the payor or provider; the amount of the charge for health services; the date on which health services were rendered; the expiration date for the payment mechanism, if applicable (i.e., credit card expiration date); the individual's signature; and relevant identification and account numbers.

Comment: One commenter said that the minimum necessary standard would be impossible to implement with respect to information provided on its standard payment claim, which, it said, was used by pharmacies for concurrent drug utilization review and that was expected to be adopted by HHS as the national pharmacy payment claim.

Two other commenters also recommended clarifying in the final rule that pharmacy benefit cards are not considered a type of “other payment card” pursuant to the rule's provisions governing payment processes. These commenters were concerned that if pharmacy benefit cards were covered by the rule's payment processing provisions, their payment claim, which they said was expected to be adopted by HHS as the national pharmacy payment claim, may have to be modified to comply with the minimum necessary standard that would have been required pursuant to proposed § 164.510(i) on banking and payment processes. One of these commenters noted that its payment claim facilitates concurrent drug utilization review, which was mandated by Congress pursuant to the Omnibus Budget Reconciliation Act of 1990 and which creates the real-time ability for pharmacies to gain access to information that may be necessary to meet requirements of this and similar state laws. The commenter said that information on its standard payment claim may include information that could be used to provide professional pharmacy services, such as compliance, disease management, and outcomes programs. The commenter opposed restricting such information by applying the minimum necessary standard.

Response: We make an exception to the minimum necessary disclosure provision of this rule for the required and situational data elements of the standard transactions adopted in the Transactions Rule, because those elements were agreed to through the ANSI-accredited consensus development process. The minimum necessary requirements do apply to optional elements in such standard transactions, because industry consensus has not resulted in precise and unambiguous situation specific language to describe their usage. This is particularly relevant to the NCPDP standards for retail pharmacy transactions referenced by these commenters, in which the current standard leaves most fields optional. For this reason, we do not accept this suggestion.

The term ‘payment card’ was intended to apply to a debit or credit card used to initiate payment transactions with a financial institution. We clarify that pharmacy benefit cards, as well as other health benefit cards, are used for identification of individual, plan, and benefits and do not qualify as “other payment cards.”

Comment: Two commenters asked the following questions regarding the banking provisions of the proposed rule: (1) Does the proposed regulation stipulate that disclosures to banks and financial institutions can occur only once a patient has presented a check or credit card to the provider, or pursuant to a standing authorization?; and (2) Does the proposed rule ban disclosure of diagnostic or other related detailed payment information to financial institutions?

Response: We do not ban disclosure of diagnostic information to financial institutions, because some such information may be evident simply from the name of the payee (e.g., when payment is made to a substance abuse clinic). This type of disclosure,

however, is permitted only when reasonably necessary for the transaction (see requirements for minimum necessary disclosure of protected health information, in § 164.502 and § 164.514).

Similarly, we do not stipulate that such disclosure may be made only once a patient has presented a check or credit card, because some covered entities hire financial institutions to perform services such as management of accounts receivables and other back office functions. In providing such services to covered entities, the financial institution will need access to protected health information. (In this situation, the disclosure will typically be made under a business associate arrangement that includes provisions for protection of the information.)

Comment: One commenter was concerned that the proposed rule's section on financial institutions, when considered in conjunction with the proposed definition of "protected health information," could have been construed as making covered entities' disclosures of consumer payment history information to consumer reporting agencies subject to the rule. It noted that covered entities' reporting of payment history information to consumer reporting agencies was not explicitly covered by the proposed rule's provisions regarding disclosure of protected health information without authorization. It was also concerned that the proposed rule's minimum necessary standard could have been interpreted to ***82618** prevent covered entities and their business partners from disclosing appropriate and complete information to consumer reporting agencies. As a result, it said, consumer reporting agencies might not be able to compile complete consumer reports, thus potentially creating an inaccurate picture of a consumer's credit history that could be used to make future credit decisions about the individual.

Furthermore, this commenter said, the proposed rule could have been interpreted to apply to any information disclosed to consumer reporting agencies, thus creating the possibility for conflicts between the rule's requirements and those of the Fair Credit Reporting Act. They indicated that areas of potential overlap included: limits on subsequent disclosures; individual access rights; safeguards; and notice requirements.

Response: We have added to the definition of "payment" disclosure of certain information to consumer reporting agencies. With respect to the remaining concerns, this rule does not apply to consumer reporting agencies if they are not covered entities.

Comment: Several commenters recommended prohibiting disclosure of psychotherapy notes under this provision and under all of the sections governing disclosure without consent for national priority purposes.

Response: We agree that psychotherapy notes should not be disclosed without authorization for payment purposes, and the final rule does not allow such disclosure. See the discussion under § 164.508.

Protected Health Information

Comment: An overwhelmingly large number of commenters urged the Secretary to expand privacy protection to all individually identifiable health information, regardless of form, held or transmitted by a covered entity. Commenters provided many arguments in support of their position. They asserted that expanding the scope of covered information under the rule would increase patient confidence in their health care providers and the health care system in general. Commenters stated that patients may not seek care or honestly discuss their health conditions with providers if they do not believe that all of their health information is confidential. In particular, many suggested that this fear would be particularly strong with certain classes of patients, such as persons with disabilities, who may be concerned about potential discrimination, embarrassment or stigmatization, or domestic violence victims, who may hide the real cause of their injuries.

In addition, commenters felt that a more uniform standard that covered all records would reduce the complexity, burden, cost, and enforcement problems that would result from the NPRM's proposal to treat electronic and non-electronic records differently. Specifically, they suggested that such a standard would eliminate any confusion regarding how to treat mixed records (paper records that include information that has been stored or transmitted electronically) and would eliminate the need for health care providers to keep track of which portions of a paper record have been (or will be) stored or transmitted electronically, and which are not. Many of these commenters argued that limiting the definition to information that is or has at one time been

electronic would result in different protections for electronic and paper records, which they believe would be unwarranted and give consumers a false sense of security. Other comments argued that the proposed definition would cause confusion for providers and patients and would likely cause difficulties in claims processing. Many others complained about the difficulty of determining whether information has been maintained or transmitted electronically. Some asked us to explicitly list the electronic functions that are intended to be excluded, such as voice mail, fax, etc. It was also recommended that the definitions of "electronic transmission" and "electronic maintenance" be deleted. It was stated that the rule may apply to many medical devices that are regulated by the FDA. A commenter also asserted that the proposal's definition was technically flawed in that computers are also involved in analog electronic transmissions such as faxes, telephone, etc., which is not the intent of the language. Many commenters argued that limiting the definition to information that has been electronic would create a significant administrative burden, because covered entities would have to figure out how to apply the rule to some but not all information.

Others argued that covering all individually identifiable health information would eliminate any disincentives for covered entities to convert from paper to computerized record systems. These commenters asserted that under the proposed limited coverage, contrary to the intent of HIPAA's administrative simplification standards, providers would avoid converting paper records into computerized systems in order to bypass the provisions of the regulation. They argued that treating all records the same is consistent with the goal of increasing the efficiency of the administration of health care services.

Lastly, in the NPRM, we explained that while we chose not to extend our regulatory coverage to all records, we did have the authority to do so. Several commenters agreed with our interpretation of the statute and our authority and reiterated such statements in arguing that we should expand the scope of the rule in this regard.

Response: We find these commenters' arguments persuasive and extend protections to individually identifiable health information transmitted or maintained by a covered entity in any form (subject to the exception for "education records" governed by FERPA and records described at 20 U.S.C. 1232g(a)(4)(B)(iv)). We do so for the reasons described by the commenters and in our NPRM, as well as because we believe that the approach in the final rule creates a logical, consistent system of protections that recognizes the dynamic nature of health information use and disclosure in a continually shifting health care environment. Rules that are specific to certain formats or media, such as "electronic" or "paper," cannot address the privacy threats resulting from evolving forms of data capture and transmission or from the transfer of the information from one form to another. This approach avoids the somewhat artificial boundary issues that stem from defining what is and is not electronic.

In addition, we have reevaluated our reasons for not extending privacy protections to all paper records in the NPRM and after review of comments believe such justifications to be less compelling than we originally thought. For example, in the NPRM, we explained that we chose not to cover all paper records in order to focus on the public concerns about health information confidentiality in electronic communications, and out of concern that the potential additional burden of covering all records may not be justified because of the lower privacy risks presented by records that are in paper form only. As discussed above however, a great many commenters asserted that dealing with a mixture of protected and non-protected records is more burdensome, and that public concerns over health information confidentiality are not at all limited to electronic communications.

We note that medical devices in and of themselves, for example, pacemakers, are not protected health information for purposes of this regulation. However, information in or from the device may ***82619** be protected health information to the extent that it otherwise meets the definition.

Comment: Numerous commenters argued that the proposed coverage of any information other than that which is transmitted electronically and/or in a HIPAA transaction exceeds the Secretary's authority under section 264(c)(1) of HIPAA. The principal argument was that the initial language in section 264(c)(1) ("If language governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act * * * is not enacted by [August 21, 1999], the Secretary * * * shall promulgate final regulations containing such standards* * *") limits the privacy standards to "information transmitted in connection with the [HIPAA] transactions." The precise argument made by some commenters was that the grant of authority is contained in the words "such standards,"

and that the referent of that phrase was "standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a)* * *".

Commenters also argued that this limitation on the Secretary's authority is discernible from the statutory purpose statement at section 261 of HIPAA, from the title to section 1173(a) ("Standards to Enable Electronic Exchange"), and from various statements in the legislative history, such as the statement in the Conference Report that the "Secretary would be required to establish standards and modifications to such standards regarding the privacy of individually identifiable health information that is in the health information network." H. Rep. No. 104-736,104th Cong., 2d Sess., at 265. It was also argued that extension of coverage beyond the HIPAA transactions would be inconsistent with the underlying statutory trade-off between facilitating accessibility of information in the electronic transactions for which standards are adopted under section 1173(a) and protecting that information through the privacy standards.

Other commenters argued more generally that the Secretary's authority was limited to information in electronic form only, not information in any other form. These comments tended to focus on the statutory concern with regulating transactions in electronic form and argued that there was no need to have the privacy standards apply to information in paper form, because there is significantly less risk of breach of privacy with respect to such information.

The primary justifications provided by commenters for restricting the scope of covered individually identifiable health information under the regulation were that such an approach would reduce the complexity, burden, cost, and enforcement problems that would result from a rule that treats electronic and non-electronic records differently; would appropriately limit the rule's focus to the security risks that are inherent in electronic transmission or maintenance of individually identifiable health information; and would conform these provisions of the rule more closely with their interpretation of the HIPAA statutory language.

Response: We disagree with these commenters. We believe that restricting the scope of covered information under the rule consistent with any of the comments described above would generate a number of policy concerns. Any restriction in the application of privacy protections based on the media used to maintain or transmit the information is by definition arbitrary, unrelated to the potential use or disclosure of the information itself and therefore not responsive to actual privacy risks. For example, information contained in a paper record may be scanned and transmitted worldwide almost as easily as the same information contained in an electronic claims transaction, but would potentially not be protected.

In addition, application of the rule to only the standard transactions would leave large gaps in the amount of health information covered. This limitation would be particularly harmful for information used and disclosed by health care providers, who are likely to maintain a great deal of information never contained in a transaction.

We disagree with the arguments that the Secretary lacks legal authority to cover all individually identifiable health information transmitted or maintained by covered entities. The arguments raised by these comments have two component parts: (1) That the Secretary's authority is limited by form, to individually identifiable health information in electronic form only; and (2) that the Secretary's authority is limited by content, to individually identifiable health information that is contained in what commenters generally termed the "HIPAA transactions," i.e., information contained in a transaction for which a standard has been adopted under section 1173(a) of the Act.

With respect to the issue of form, the statutory definition of "health information" at section 1171(4) of the Act defines such information as "any information, whether oral or recorded in any form or medium" (emphasis added) which is created or received by certain entities and relates to the health condition of an individual or the provision of health care to an individual (emphasis added). "Individually identifiable health information", as defined at section 1171(6) of the Act, is information that is created or received by a subset of the entities listed in the definition of "health information", relates to the same subjects as "health information," and is, in addition, individually identifiable. Thus, "individually identifiable health information" is, as the term itself implies, a subset of "health information." As "health information," "individually identifiable health information"

means, among other things, information that is "oral or recorded in any form or medium." Therefore, the statute does not limit "individually identifiable health information" to information that is in electronic form only.

With respect to the issue of content, the limitation of the Secretary's authority to information in HIPAA transactions under section 264(c)(1) is more apparent than real. While the first sentence of section 264(c)(1) may be read as limiting the regulations to standards with respect to the privacy of individually identifiable health information "transmitted in connection with the [HIPAA] transactions," what that sentence in fact states is that the privacy regulations must "contain" such standards, not be limited to such standards. The first sentence thus sets a statutory minimum, first for Congress, then for the Secretary. The second sentence of section 264(c)(1) directs that the regulations "address at least the subjects in subsection (b) (of section 264)." Section 264(b), in turn, refers only to "individually identifiable health information", with no qualifying language, and refers back to subsection (a) of section 264, which is not limited to HIPAA transactions. Thus, the first and second sentences of section 264(c)(1) can be read as consistent with each other, in which case they direct the issuance of privacy standards with respect to individually identifiable health information. Alternatively, they can be read as ambiguous, in which case one must turn to the legislative history.

The legislative history of section 264 does not reflect the content limitation of the first sentence of section 264(c)(1). Rather, the Conference Report ***82620** summarizes this section as follows: "If Congress fails to enact privacy legislation, the Secretary is required to develop standards with respect to privacy of individually identifiable health information not later than 42 months from the date of enactment." Id., at 270. This language indicates that the overriding purpose of section 264(c)(1) was to postpone the Secretary's duty to issue privacy standards (which otherwise would have been controlled by the time limits at section 1174(a)), in order to give Congress more time to pass privacy legislation. A corollary inference, which is also supported by other textual evidence in section 264 and Part C of title XI, is that if Congress failed to act within the time provided, the original statutory scheme was to kick in. Under that scheme, which is set out in section 1173(e) of the House bill, the standards to be adopted were "standards with respect to the privacy of individually identifiable health information." Thus, the legislative history of section 264 supports the statutory interpretation underlying the rules below.

Comment: Many commenters were opposed to the rule covering specific forms of communication or records that could potentially be considered covered information, i.e., faxes, voice mail messages, etc. A subset of these commenters took issue particularly with the inclusion of oral communications within the scope of covered information. The commenters argued that covering information when it takes oral form (e.g., verbal discussions of a submitted claim) makes the regulation extremely costly and burdensome, and even impossible to administer. Another commenter also offered that it would make it nearly impossible to discuss health information over the phone, as the covered entity cannot verify that the person on the other end is in fact who he or she claims to be.

Response: We disagree. Covering oral communications is an important part of keeping individually identifiable health information private. If the final rule were not to cover oral communication, a conversation about a person's protected health information could be shared with anyone. Therefore, the same protections afforded to paper and electronically based information must apply to verbal communication as well. Moreover, the Congress explicitly included "oral" information in the statutory definition of health information.

Comment: A few commenters supported, without any change, the approach proposed in the NPRM to limit the scope of covered information to individually identifiable health information in any form once the information is transmitted or maintained electronically. These commenters asserted that our statutory authority limited us accordingly. Therefore, they believed we had proposed protections to the extent possible within the bounds of our statutory authority and could not expand the scope of such protections without new legislative authority.

Response: We disagree with these commenters regarding the limitations under our statutory authority. As explained above, we have the authority to extend the scope of the regulation as we have done in the final rule. We also note here that most of these commenters who supported the NPRM's proposed approach, voiced strong support for extending the scope of coverage to all

individually identifiable health information in any form, but concluded that we had done what we could within the authority provided.

Comment: One commenter argued that the term "transaction" is generally understood to denote a business matter, and that the NPRM applied the term too broadly by including hospital directory information, communication with a patient's family, researchers' use of data and many other non-business activities.

Response: This comment reflects a misunderstanding of our use of the term "transaction." The uses and disclosures described in the comment are not "transactions" as defined in § 160.103. The authority to regulate the types of uses and disclosures described is provided under section 264 of Pub. L. 104-191. The conduct of the activities noted by the commenters are not related to the determination of whether a health care provider is a covered entity. We explain in the preamble that a health care provider is a covered entity if it transmits health information in electronic form in connection with transactions referred to in section 1173(a)(1) of the Act.

Comment: A few commenters asserted that the Secretary has no authority to regulate "use" of protected health information. They stated that although section 264(b) mentions that the Secretary should address "uses and disclosures," no other section of HIPAA employs the term "use."

Response: We disagree with these commenters. As they themselves note, the authority to regulate use is given in section 264(b) and is sufficient.

Comment: Some commenters requested clarification as to how certain types of health information, such as photographs, faxes, X-Rays, CT-scans, and others would be classified as protected or not under the rule.

Response: All types of individually identifiable health information in any form, including those described, when maintained or transmitted by a covered entity are covered in the final rule.

Comment: A few commenters requested clarification with regard to the differences between the definitions of individually identifiable health information and protected health information.

Response: In expanding the scope of covered information in the final rule, we have simplified the distinction between the two definitions. In the final rule, protected health information is the subset of individually identifiable health information that is maintained or transmitted by covered entity, and thereby protected by this rule. For additional discussion of protected health information and individually identifiable health information, see the descriptive summary of § 164.501.

Comment: A few commenters remarked that the federal government has no right to access or control any medical records and that HHS must get consent in order to store or use any individually identifiable health information.

Response: We understand the commenters' concern. It is not our intent, nor do we through this rule create any government right of access to medical records, except as needed to investigate possible violations of the rule. Some government programs, such as Medicare, are authorized under other law to gain access to certain beneficiary records for administrative purposes. However, these programs are covered by the rule and its privacy protections apply.

Comment: Some commenters asked us to clarify how schools would be treated by the rule. Some of these commenters worried that privacy would be compromised if schools were exempted from the provisions of the final rule. Other commenters thought that school medical records were included in the provisions of the NPRM.

Response: We agree with the request for clarification and provide guidance regarding the treatment of medical records in schools in the "Relationship to Other Federal Laws" preamble discussion of FERPA, which governs the privacy of education records.

Comment: One commenter was concerned that only some information from a medical chart would be included as covered information. The commenter was especially concerned that transcribed material might not be considered covered information. ***82621**

Response: As stated above, all individually identifiable health information in any form, including transcribed or oral information, maintained or transmitted by a covered entity is covered under the provisions of the final rule.

Comment: In response to our solicitation of comments on the scope of the definition of protected health information, many commenters asked us to narrow the scope of the proposed definition to include only information in electronic form. Others asked us to include only information from the HIPAA standard transactions.

Response: For the reasons stated by the commenters who asked us to expand the proposed definition, we reject these comments. We reject these approaches for additional reasons, as well. Limiting the protections to electronic information would, in essence, protect information only as long as it remained in a computer or other electronic media; the protections in the rule could be avoided simply by printing out the information. This approach would thus result in the illusion, but not the reality, of privacy protections. Limiting protection to information in HIPAA transactions has many of the problems in the proposed approach: it would fail to protect significant amounts of health information, would force covered entities to figure out which information had and had not been in such a transaction, and could cause the administrative burdens the commenters feared would result from protecting some but not all information.

Comment: A few commenters asserted that the definition of protected health information should explicitly include “genetic” information. It was argued that improper disclosure and use of such information could have a profound impact on individuals and families.

Response: We agree that the definition of protected health information includes genetic information that otherwise meets the statutory definition. But we believe that singling out specific types of protected health information for special mention in the regulation text could wrongly imply that other types are not included.

Comment: One commenter recommended that the definition of protected health information be modified to clarify that an entity does not become a ‘covered entity’ by providing a device to an individual on which protected health information may be stored, provided that the company itself does not store the individual's health information.”

Response: We agree with the commenter's analysis, but believe the definition is sufficiently clear without a specific amendment to this effect.

Comment: One commenter recommended that the definition be amended to explicitly exclude individually identifiable health information maintained, used, or disclosed pursuant to the Fair Credit Reporting Act, as amended, 15 U.S.C. 1681. It was stated that a disclosure of payment history to a consumer reporting agency by a covered entity should not be considered protected health information. Another commenter recommended that health information, billing information, and a consumer's credit history be exempted from the definition because this flow of information is regulated by both the Fair Credit Reporting Act (FCRA) and the Fair Debt Collection Practices Act (FDCPA).

Response: We disagree. To the extent that such information meets the definition of protected health information, it is covered by this rule. These statutes are designed to protect financial, not health, information. Further, these statutes primarily regulate entities that are not covered by this rule, minimizing the potential for overlap or conflict. The protections in this rule are more appropriate for protecting health information. However, we add provisions to the definition of payment which should address these concerns. See the definition of ‘payment’ in § 164.501.

Comment: An insurance company recommended that the rule require that medical records containing protected health information include a notation on a cover sheet on such records.

Response: Since we have expanded the scope of protected health information, there is no need for covered entities to distinguish among their records, and such a notation is not needed. This uniform coverage eliminates the mixed record problem and resultant potential for confusion.

Comment: A government agency requested clarification of the definition to address the status of information that flows through dictation services.

Response: A covered entity may disclose protected health information for transcription of dictation under the definition of health care operations, which allows disclosure for "general administrative" functions. We view transcription and clerical services generally as part of a covered entity's general administrative functions. An entity transcribing dictation on behalf of a covered entity meets this rule's definition of business associate and may receive protected health information under a business associate contract with the covered entity and subject to the other requirements of the rule.

Comment: A commenter recommended that information transmitted for employee drug testing be exempted from the definition.

Response: We disagree that is necessary to specifically exclude such information from the definition of protected health information. If a covered entity is involved, triggering this rule, the employer may obtain authorization from the individuals to be tested. Nothing in this rule prohibits an employer from requiring an employee to provide such an authorization as a condition of employment.

Comment: A few commenters addressed our proposal to exclude individually identifiable health information in education records covered by FERPA. Some expressed support for the exclusion. One commenter recommended adding another exclusion to the definition for the treatment records of students who attend institutions of post secondary education or who are 18 years old or older to avoid confusion with rules under FERPA. Another commenter suggested that the definition exclude health information of participants in "Job Corps programs" as it has for educational records and inmates of correctional facilities.

Response: We agree with the commenter on the potential for confusion regarding records of students who attend post-secondary schools or who are over 18, and therefore in the final rule we exclude records defined at 20 U.S.C. 1232g(a)(4)(B)(iv) from the definition of protected health information. For a detailed discussion of this change, refer to the "Relationship to Other Federal Laws" section of the preamble. We find no similar reason to exclude "Job Corps programs" from the requirements of this regulation.

Comment: Some commenters voiced support for the exclusion of the records of inmates from the definition of protected health information, maintaining that correctional agencies have a legitimate need to share some health information internally without authorization between health service units in various facilities and for purposes of custody and security. Other commenters suggested that the proposed exclusion be extended to individually identifiable health information: created by covered entities providing services to inmates or detainees under contract to such facilities; of "former" inmates; and of persons who are in the custody of law enforcement officials, such as the United States Marshals Service and local police agencies. They stated that ***82622** corrections and detention facilities must be able to share information with law enforcement agencies such as the United States Marshals Service, the Immigration and Naturalization Services, county jails, and U.S. Probation Offices.

Another commenter said that there is a need to have access to records of individuals in community custody and explained that these individuals are still under the control of the state or local government and the need for immediate access to records for inspections and/or drug testing is necessary.

A number of commenters were opposed to the proposed exclusion to the definition of protected health information, arguing that the proposal was too sweeping. Commenters stated that while access without consent is acceptable for some purposes, it is not acceptable in all circumstances. Some of these commenters concurred with the sharing of health care information with other medical facilities when the inmate is transferred for treatment. These commenters recommended that we delete the exception for jails and prisons and substitute specific language about what information could be disclosed and the limited circumstances or purposes for which such disclosures could occur.

Others recommended omission of the proposed exclusion entirely, arguing that excluding this information from protection sends the message that, with respect to this population, abuses do not matter. Commenters argued that inmates and detainees have a right to privacy of medical records and that individually identifiable health information obtained in these settings can be misused, e.g., when communicated indiscriminately, health information can trigger assaults on individuals with stigmatized conditions by fellow inmates or detainees. It can also lead to the denial of privileges, or inappropriately influence the deliberations of bodies such as parole boards.

A number of commenters explicitly took issue with the exclusion relative to individuals, and in particular youths, with serious mental illness, seizure disorders, and emotional or substance abuse disorders. They argued that these individuals come in contact with criminal justice authorities as a result of behaviors stemming directly from their illness and assert that these provisions will cause serious problems. They argue that disclosing the fact that an individual was treated for mental illness while incarcerated could seriously impair the individual's reintegration into the community. Commenters stated that such disclosures could put the individual or family members at risk of discrimination by employers and in the community at large.

Some commenters asserted that the rule should be amended to prohibit jails and prisons from disclosing private medical information of individuals who have been discharged from these facilities. They argued that such disclosures may seriously impair individuals' rehabilitation into society and subject them to discrimination as they attempt to re-establish acceptance in the community.

Response: We find commenters' arguments against a blanket exemption from privacy protection for inmates persuasive. We agree health information in these settings may be misused, which consequently poses many risks to the inmate or detainee and in some cases, their families as described above by the commenters. Accordingly, we delete this exception from the definition of “protected health information” in the final rule. The final rule considers individually identifiable health information of individuals who are prisoners and detainees to be protected health information to the extent that it meets the definition and is maintained or transmitted by a covered entity.

At the same time, we agree with those commenters who explained that correctional facilities have legitimate needs for use and sharing of individually identifiable health information inmates without authorization. Therefore, we add a new provision (§ 164.512(k)(5)) that permits a covered entity to disclose protected health information about inmates without individual consent, authorization, or agreement to correctional institutions for specified health care and other custodial purposes. For example, covered entities are permitted to disclose for the purposes of providing health care to the individual who is the inmate, or for the health and safety of other inmates or officials and employees of the facility. In addition, a covered entity may disclose protected health information as necessary for the administration and maintenance of the safety, security, and good order of the institution. See the preamble discussion of the specific requirements at § 164.512(k)(5), as well as discussion of certain limitations on the rights of individuals who are inmates with regard to their protected health information at §§ 164.506, 164.520, 164.524, and 164.528.

We also provide the following clarifications. Covered entities that provide services to inmates under contract to correctional institutions must treat protected health information about inmates in accordance with this rule and are permitted to use and disclose such information to correctional institutions as allowed under § 164.512(k)(5).

As to former inmates, the final rule considers such persons who are released on parole, probation, supervised release, or are otherwise no longer in custody, to be individuals who are not inmates. Therefore, the permissible disclosure provision at § 164.512(k)(5) does not apply in such cases. Instead, a covered entity must apply privacy protections to the protected health information about former inmates in the same manner and to the same extent that it protects the protected health information of other individuals. In addition, individuals who are former inmates hold the same rights as all other individuals under the rule.

As to individuals in community custody, the final rule considers inmates to be those individuals who are incarcerated in or otherwise confined to a correctional institution. Thus, to the extent that community custody confines an individual to a particular facility, § 164.512(k)(5) is applicable.

Psychotherapy Notes

Comment: Some commenters thought the definition of psychotherapy notes was contrary to standard practice. They claimed that reports of psychotherapy are typically part of the medical record and that psychologists are advised, for ethical reasons and liability risk management purposes, not to keep two separate sets of notes. Others acknowledged that therapists may maintain separate notations of therapy sessions for their own purpose. These commenters asked that we make clear that psychotherapy notes, at least in summary form, should be included in the medical record. Many plans and providers expressed concern that the proposed definition would encourage the creation of "shadow" records which may be dangerous to the patient and may increase liability for the health care providers. Some commenters claimed that psychotherapy notes contain information that is often essential to treatment.

Response: We conducted fact-finding with providers and other knowledgeable parties to determine the standard practice of psychotherapists and determined that only some psychotherapists keep separate files with notes pertaining to psychotherapy sessions. These notes are often referred to as "process notes," distinguishable from "progress notes," "the medical record," or "official records." These process notes capture the therapist's ***82623** impressions about the patient, contain details of the psychotherapy conversation considered to be inappropriate for the medical record, and are used by the provider for future sessions. We were told that process notes are often kept separate to limit access, even in an electronic record system, because they contain sensitive information relevant to no one other than the treating provider. These separate "process notes" are what we are calling "psychotherapy notes." Summary information, such as the current state of the patient, symptoms, summary of the theme of the psychotherapy session, diagnoses, medications prescribed, side effects, and any other information necessary for treatment or payment, is always placed in the patient's medical record. Information from the medical record is routinely sent to insurers for payment.

Comment: Various associations and their constituents asked that the exceptions for psychotherapy notes be extended to health care information from other health care providers. These commenters argued that psychotherapists are not the only providers or even the most likely providers to discuss sensitive and potentially embarrassing issues, as treatment and counseling for mental health conditions, drug abuse, HIV/AIDS, and sexual problems are often provided outside of the traditional psychiatric settings. One writer stated, "A prudent health care provider will always assess the past and present psychiatric medical history and symptoms of a patient."

Many commenters believed that the psychotherapy notes should include frequencies of treatment, results of clinical tests, and summary of diagnosis, functional status, the treatment plan, symptoms, prognosis and progress to date. They claimed that this information is highly sensitive and should not be released without the individual's written consent, except in cases of emergency. One commenter suggested listing the types of mental health information that can be requested by third party payors to make payment determinations and defining the meaning of each term.

Response: As discussed above and in the NPRM, the rationale for providing special protection for psychotherapy notes is not only that they contain particularly sensitive information, but also that they are the personal notes of the therapist, intended to help him or her recall the therapy discussion and are of little or no use to others not involved in the therapy. Information in these notes is not intended to communicate to, or even be seen by, persons other than the therapist. Although all psychotherapy

information may be considered sensitive, we have limited the definition of psychotherapy notes to only that information that is kept separate by the provider for his or her own purposes. It does not refer to the medical record and other sources of information that would normally be disclosed for treatment, payment, and health care operations.

Comment: One commenter was particularly concerned that the use of the term "counseling" in the definition of psychotherapy notes would lead to confusion because counseling and psychotherapy are different disciplines.

Response: In the final rule, we continue to use the term "counseling" in the definition of "psychotherapy." During our fact-finding, we learned that "counseling" had no commonly agreed upon definition, but seemed to be widely understood in practice. We do not intend to limit the practice of psychotherapy to any specific professional disciplines.

Comment: One commenter noted that the public mental health system is increasingly being called upon to integrate and coordinate services among other providers of mental health services and they have developed an integrated electronic medical record system for state-operated hospitals, part of which includes psychotherapy notes, and which cannot be easily modified to provide different levels of confidentiality. Another commenter recommended allowing use or disclosure of psychotherapy notes by members of an integrated health care facility as well as the originator.

Response: The final rule makes it clear that any notes that are routinely shared with others, whether as part of the medical record or otherwise, are, by definition, not psychotherapy notes, as we have defined them. To qualify for the definition and the increased protection, the notes must be created and maintained for the use of the provider who created them i.e., the originator, and must not be the only source of any information that would be critical for the treatment of the patient or for getting payment for the treatment. The types of notes described in the comment would not meet our definition for psychotherapy notes.

Comment: Many providers expressed concern that if psychotherapy notes were maintained separately from other protected health information, other health providers involved in the individual's care would be unable to treat the patient properly. Some recommended that if the patient does not consent to sharing of psychotherapy notes for treatment purposes, the treating provider should be allowed to decline to treat the patient, providing a referral to another provider.

Response: The final rule retains the policy that psychotherapy notes be separated from the remainder of the medical record in order to receive additional protection. We based this decision on conversations with mental health providers who have told us that information that is critical to the treatment of individuals is normally maintained in the medical record and that psychotherapy notes are used by the provider who created them and rarely for other purposes. A strong part of the rationale for the special treatment of psychotherapy notes is that they are the personal notes of the treating provider and are of little or no use to others who were not present at the session to which the notes refer.

Comment: Several commenters requested that we clarify that the information contained in psychotherapy notes is being protected under the rule and not the notes themselves. They were concerned that the protection for psychotherapy notes would not be meaningful if health plans could demand the same information in a different format.

Response: This rule provides special protection for the information in psychotherapy notes, but it does not extend that protection to the same information that may be found in other locations. We do not require the notes to be in a particular format, such as hand-written. They may be typed into a word processor, for example. Copying the notes into a different format, per se, would not allow the information to be accessed by a health plan. However, the requirement that psychotherapy notes be kept separate from the medical record and solely for the use of the provider who created them means that the special protection does not apply to the same information in another location.

Public Health Authority

Comment: A number of the comments called for the elimination of all permissible disclosures without authorization, and some specifically cited the public health section and its liberal definition of public health authority as an inappropriately broad loophole that would allow unfettered access to private medical information by various government authorities.

Other commenters generally supported the provision allowing disclosure to public health authorities and to non-governmental entities ***82624** authorized by law to carry out public health activities. They further supported the broad definition of public health authority and the reliance on broad legal or regulatory authority by public health entities although explicit authorities were preferable and better informed the public.

Response: In response to comments arguing that the provision is too broad, we note that section 1178(b) of the Act, as explained in the NPRM, explicitly carves out protection for state public health laws. This provision states that: "[N]othing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth or death, public health surveillance, or public health investigation or intervention." In light of this broad Congressional mandate not to interfere with current public health practices, we believe the broad definition of "public health authority" is appropriate to achieve that end.

Comment: Some commenters said that they performed public health activities in analyzing data and information. These comments suggested that activities conducted by provider and health plan organizations that compile and compare data for benchmarking performance, monitoring, utilization, and determining the health needs of a given market should be included as part of the public health exemption. One commenter recommended amending the regulation to permit covered entities to disclose protected health information to private organizations for public health reasons.

Response: We disagree that such a change should be made. In the absence of some nexus to a government public health authority or other underlying legal authority, covered entities would have no basis for determining which data collections are "legitimate" and how the confidentiality of the information will be protected. In addition, the public health functions carved out for special protection by Congress are explicitly limited to those established by law.

Comment: Two commenters asked for additional clarification as to whether the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) would be considered public health authorities as indicated in the preamble. They suggested specific language for the final rule. Commenters also suggested that we specify that states operating OSHA-approved programs also are considered public health authorities. One comment applauded the Secretary's recognition of OSHA as both a health oversight agency and public health authority. It suggested adding OSHA-approved programs that operate in states to the list of entities included in these categories. In addition, the comment requested the final regulation specifically mention these entities in the text of the regulation as well.

Response: We agree that OSHA, MSHA and their state equivalents are public health authorities when carrying out their activities related to the health and safety of workers. We do not specifically reference any agencies in the regulatory definition, because the definition of public health authority and this preamble sufficiently address this issue. As defined in the final rule, the definition of "public health authority" at § 164.501 continues to include OSHA as a public health authority. State agencies or authorities responsible for public health matters as part of their official mandate, such as OSHA-approved programs, also come within this definition. See discussion of § 164.512(b) below. We have refrained, however, from listing specific agencies and have retained a general descriptive definition.

Comments: Several commenters recommended expanding the definition of public health authority to encompass other governmental entities that may collect and hold health data as part of their official duties. One recommended changing the definition of public health authority to read as follows: Public health authority means an agency or authority * * * that is responsible for public health matters or the collection of health data as part of its official mandate.

Response: We do not adopt this recommendation. The public health provision is not intended to cover agencies that are not responsible for public health matters but that may in the course of their responsibilities collect health-related information. Disclosures to such authorities may be permissible under other provision of this rule.

Comment: Many commenters asked us to include a formal definition of "required by law" incorporating the material noted in this preamble and additional suggested disclosures.

Response: We agree generally and modify the definition accordingly. See discussion above.

Research

Comment: We received many comments from supporting the proposed definition of "research." These commenters agreed that the definition of "research" should be the same as the definition in the Common Rule. These commenters argued that it was important that the definition of "research" be consistent with the Common Rule's definition to ensure the coherent oversight of medical research. In addition, some of these commenters also supported this definition because they believed it was already well-understood by researchers and provided reasonably clear guidance needed to distinguish between research and health care operations.

Some commenters, believed that the NPRM's definition was too narrow. Several of these commenters agreed that the Common Rule's definition should be adopted in the final rule, but argued that the proposed definition of "generalizable knowledge" within the definition of "research," which limited generalizable knowledge to knowledge that is "related to health," was too narrow. For example, one commenter stated that gun shot wound, spousal abuse, and other kinds of information from emergency room statistics are often used to conduct research with ramifications for social policy, but may not be "related to health." Several of these commenters recommended that the definition of research be revised to delete the words "related to health." Additional commenters who argued that the definition was too narrow raised the following concerns: the difference between "research" and "health care operations" is irrelevant from the patients' perspective, and therefore, the proposed rule should have required documentation of approval by an IRB or privacy board before protected health information could be used or disclosed for either of these purposes, and the proposed definition was too limited because it did not capture research conducted by non-profit entities to ensure public health goals, such as disease-specific registries.

Commenters who argued that the definition was too broad recommended that certain activities should be explicitly excluded from the definition. In general, these commenters were concerned that if certain activities were considered to be "research" the rule's research requirements would represent a problematic level of regulation on industry initiatives. Some activities that these commenters recommended be explicitly excluded from the definition of "research" included: marketing research, health and productivity management, quality assessment and improvement activities, and internal research conducted to improve health.

Response: We agree that the final rule's definition of "research" should be ***82625** consistent with the Common Rule's definition of this term. We also agree that our proposal to limit "generalizable knowledge" to knowledge that is "related to health," and "knowledge that could be applied to populations outside of the population served by the covered entity," was too narrow. Therefore, in the final rule, we retain the Common Rule's definition of "research" and eliminate the further elaboration of "generalizable knowledge." We understand knowledge to be generalizable when it can be applied to either a population inside or outside of the population served by the covered entity. Therefore, knowledge may be "generalizable" even if a research study uses only the protected health information held within a covered entity, and the results are generalizable only to the population served by the covered entity. For example, generalizable knowledge could be generated from a study conducted by the HCFA, using only Medicare data held by HCFA, even if the knowledge gained from the research study is applicable only to Medicare beneficiaries.

We rejected the other arguments claiming that the definition of "research" was either too narrow or too broad. While we agree that it is sometimes difficult to distinguish between "research" and "health care operations," we disagree that the difference between these activities is irrelevant from the patients' perspective. We believe, based on many of the comments, that individuals expect

that individually identifiable health information about themselves will be used for health care operations such as reviewing the competence or qualifications of health care professionals, evaluating provider and plan performance, and improving the quality of care. A large number of commenters, however, indicated that they did not expect that individually identifiable health information about themselves would be used for research purposes without their authorization. Therefore, we retain more stringent protections for research disclosures without patient authorization.

We also disagree with the commenters who were concerned that the proposed definition was too limited because it did not capture research conducted by non-profit entities to ensure public health goals, such as disease-specific registries. Such activities conducted by either non-profit or for-profit entities could meet the rule's definition of research, and therefore are not necessarily excluded from this definition.

We also disagree with many of the commenters who argued that certain activities should be explicitly excluded from the definition of research. We found no persuasive evidence that, when particular activities are also systematic investigations designed to contribute to generalizable knowledge, they should be treated any different from other such activities.

We are aware that the National Bioethics Advisory Commission (NBAC) is currently assessing the Common Rule's definition of "research" as part of a report they are developing on the implementation and adequacy of the Common Rule. Since we agree that a consistent definition is important to the conduct and oversight of research, if the Common Rule's definition of "research" is modified in the future, the Department of Health and Human Services will consider whether the definition should also be modified for this subpart.

Comment: Some commenters urged the Department to establish precise definitions for "health care operations" and "research" to provide clear guidance to covered entities and adequate privacy protections for the subjects of the information whose information is disclosed for these purposes. One commenter supported the definition of "research" proposed in the NPRM, but was concerned about the "crossover" from data analyses that begin as health care operations but later become "research" because the analytical results are of such importance that they should be shared through publication, thereby contributing to generalizable knowledge. To distinguish between the definitions of "health care operations" and "research," a few commenters recommended that the rule make this distinction based upon whether the activity is a "use" or a "disclosure." These commenters recommend that the "use" of protected health information for research without patient authorization should be exempt from the proposed research provisions provided that protected health information was not disclosed in the final analysis, report, or publication.

Response: We agree with commenters that at times it may be difficult to distinguish projects that are health operations and projects that are research. We note that this ambiguity exists today, and disagree that we can address this issue with more precise definitions of research and health care operations. Today, the issue is largely one of intent. Under the Common Rule, the ethical and regulatory obligations of the researcher stem from the intent of the activity. We follow that approach here. If such a project is a systematic investigation that designed to develop or contribute to generalizable knowledge, it is considered to be "research," not "health care operations."

In some instances, the primary purpose of the activity may change as preliminary results are analyzed. An activity that was initiated as an internal outcomes evaluation may produce information that could be generalized. If the purpose of a study changes and the covered entity does intend to generalize the results, the covered entity should document the fact as evidence that the activity was not subject to § 164.512(i) of this rule.

We understand that for research that is subject to the Common Rule, this is not the case. The Office for Human Research Protection interprets 45 CFR part 46 to require IRB review as soon as an activity meets the definition of research, regardless of whether the activity began as "health care operations" or "public health," for example. The final rule does not affect the Office of Human Research Protection's interpretation of the Common Rule.

We were not persuaded that an individual's privacy interest is of less concern when covered entities use protected health information for research purposes than when covered entities disclose protected health information for research purposes. We do not agree generally that internal activities of covered entities do not potentially compromise the privacy interests of individuals. Many persons within a covered entity may have access to protected health information. When the activity is a systematic investigation, the number of persons who may be involved in the records review and analysis may be substantial. We believe that IRB or privacy board approval of the waiver of authorization will provide important privacy protections to individuals about whom protected health information is used or disclosed for research. If a covered entity wishes to use protected health information about its enrollees for research purposes, documentation of an IRBs' or privacy board's assessment of the privacy impact of such a use is as important as if the same research study required the disclosure of protected health information. This conclusion is consistent with the Common Rule's requirement for IRB review of all human subjects research.

Treatment

Comment: Some commenters advocated for a narrow interpretation of ***82626** treatment that applies only to the individual who is the subject of the information. Other commenters asserted that treatment should be broadly defined when activities are conducted by health care providers to improve or maintain the health of the patient. A broad interpretation may raise concerns about potential misuse of information, but too limited an interpretation will limit beneficial activities and further contribute to problems in patient compliance and medical errors.

Response: We find the commenters' arguments for a broad definition of treatment persuasive. Today, health care providers consult with one another, share information about their experience with particular therapies, seek advice about how to handle unique or challenging cases, and engage in a variety of other discussions that help them maintain and improve the quality of care they provide. Quality of care improves when providers exchange information about treatment successes and failures. These activities require sharing of protected health information. We do not intend this rule to interfere with these important activities. We therefore define treatment broadly and allow use and disclosure of protected health information about one individual for the treatment of another individual.

Under this definition, only health care providers or a health care provider working with a third party can perform treatment activities. In this way, we temper the breadth of the definition by limiting the scope of information sharing. The various codes of professional ethics also help assure that information sharing among providers for treatment purposes will be appropriate.

We note that poison control centers are health care providers for purposes of this rule. We consider the counseling and follow-up consultations provided by poison control centers with individual providers regarding patient outcomes to be treatment. Therefore, poison control centers and other health care providers can share protected health information about the treatment of an individual without a business associate contract.

Comment: Many commenters suggested that “treatment” activities should include services provided to both a specific individual and larger patient populations and therefore urged that the definition of treatment specifically allow for such activities, sometimes referred to as “disease management” activities. Some argued that an analysis of an overall population is integral to determining which individuals would benefit from disease management services. Thus, an analysis of health care claims for enrolled populations enables proactive contact with those identified individuals to notify them of the availability of services. Certain commenters noted that “disease management” services provided to their patient populations, such as reminders about recommended tests based on nationally accepted clinical guidelines, are integral components of quality health care.

Response: We do not agree that population based services should be considered treatment activities. The definition of “treatment” is closely linked to the § 160.103 definition of “health care,” which describes care, services and procedures related to the health of an individual. The activities described by “treatment,” therefore, all involve health care providers supplying health care to a particular patient. While many activities beneficial to patients are offered to entire populations or involve examining health information about entire populations, treatment involves health services provided by a health care provider and tailored to the specific needs of an individual patient. Although a population-wide analysis or intervention may prompt a health care

provider to offer specific treatment to an individual, we consider the population-based analyses to improve health care or reduce health care costs to be health care operations (see definition of "health care operations," above).

Comment: A number of commenters requested clarification about whether prescription drug compliance management programs would be considered "treatment." One commenter urged HHS to clarify that provision by a pharmacy to a patient of customized prescription drug information about the risks, benefits, and conditions of use of a prescription drug being dispensed is considered a treatment activity. Others asked that the final rule expressly recognize that prescription drug advice provided by a dispensing pharmacist, such as a customized pharmacy letter, is within the scope of treatment.

Response: The activities that are part of prescription drug compliance management programs were not fully described by these commenters, so we cannot state a general rule regarding whether such activities constitute treatment. We agree that pharmacists' provision of customized prescription drug information and advice about the prescription drug being dispensed is a treatment activity. Pharmacists' provisions of information and counseling about pharmaceuticals to their customers constitute treatment, and we exclude certain communications made in the treatment context from the definition of marketing. (See discussion above.)

Comment: Some commenters noted the issues and recommendations raised in the Institutes of Medicine report "To Err Is Human" and the critical need to share information about adverse drug and other medical events, evaluation of the information, and its use to prevent future medical errors. They noted that privacy rules should not be so stringent as to prohibit the sharing of patient data needed to reduce errors and optimize health care outcomes. To bolster the notion that other programs associated with the practice of pharmacy must be considered as integral to the definition of health care and treatment, they reference OBRA '90 (42 U.S.C. 1396r-8) and the minimum required activities for dispensing drugs; they also note that virtually every state Board of Pharmacy adopted regulations imposing OBRA'90 requirements on pharmacies for all patients and not just Medicaid recipients.

Response: We agree that reducing medical errors is critical, and do not believe that this regulation impairs efforts to reduce medical errors. We define treatment broadly and include quality assessment and improvement activities in the definition of health care operations. Covered pharmacies may conduct such activities, as well as treatment activities appropriate to improve quality and reduce errors. We believe that respect for the privacy rights of individuals and appropriate protection of the confidentiality of their health information are compatible with the goal of reducing medical errors.

Comment: Some commenters urged us to clarify that health plans do not perform "treatment" activities; some of these were concerned that a different approach in this regulation could cause conflict with state corporate practice of medicine restrictions. Some commenters believed that the proposed definition of treatment crossed into the area of cost containment, which would seem to pertain more directly to payment. They supported a narrower definition that would eliminate any references to third party payors. One commenter argued that the permissible disclosure of protected health information to carry out treatment is too broad for health plans and that health plans that have no responsibility for treatment or care coordination should have no authority to release health information without authorization for treatment purposes.

Response: We do not consider the activities of third party payors, including health plans, to be ***82627** "treatment." Only health care providers, not health plans, conduct "treatment" for purposes of this rule. A health plan may, however, disclose protected health information without consent or authorization for treatment purposes if that disclosure is made to a provider. Health plans may have information the provider needs, for example information from other providers or information about the patient's treatment history, to develop an appropriate plan of care.

Comment: We received many comments relating to "disease management" programs and whether activities described as disease management should be included in the definition of treatment. One group of commenters supported the proposed definition of treatment that includes disease management. One commenter offered the position that disease management services are more closely aligned with treatment because they involve the coordination of treatment whereas health care operations are more akin to financial and ministerial functions of plans.

Some recommended that the definition of treatment be limited to direct treatment of individual patients and not allow for sharing of information for administrative or other programmatic reasons. They believed that allowing disclosures for disease management opens a loophole for certain uses and disclosures, such as marketing, that should only be permitted with authorization. Others recommended that the definition of disease management be restricted to prevent unauthorized use of individual health records to target individuals in a health plan or occupational health program. Many asked that the definition of disease management be clarified to identify those functions that, although some might consider them to be subsumed by the term, are not permitted under this regulation without authorization, such as marketing and disclosures of protected health information to employers. They suggested that disease management may describe desirable activities, but is subject to abuse and therefore should be restricted and controlled. One commenter recommends that we adopt a portion of the definition adopted by the Disease Management Association of America in October 1999.

On the other hand, many comments urged that disease management be part of the "treatment" definition or the "health care operations" definition and asked that specific activities be included in a description of the term. They viewed disease management as important element of comprehensive health care services and cost management efforts. They recommended that the definition of disease management include services directed at an entire population and not just individual care, in order to identify individuals who would benefit from services based on accepted clinical guidelines. They recommended that disease management be included under health care operations and include population level services. A commenter asserted that limiting disease management programs to the definition of treatment ignores that these programs extend beyond providers, especially since NCQA accreditation standards strongly encourage plans and insurers to provide these services.

Response: Disease management appeared to represent different activities to different commenters. Our review of the literature, industry materials, state and federal statutes,[FN6] and discussions with physician groups, health plan groups and disease management associations confirm that a consensus definition from the field has not yet evolved, although efforts are underway. Therefore, rather than rely on this label, we delete "disease management" from the treatment definition and instead include the functions often discussed as disease management activities in this definition or in the definition of health care operations and modify both definitions to address the commenters' concerns.

We add population-based activities to improve health care or reduce health care costs to the definition of health care operations. Outreach programs as described by the commenter may be considered either health care operations or treatment, depending on whether population-wide or patient-specific activities occur, and if patient-specific, whether the individualized communication with a patient occurs on behalf of health care provider or a health plan. For example, a call placed by a nurse in a doctor's office to a patient to discuss follow-up care is a treatment activity. The same activity performed by a nurse working for a health plan would be a health care operation. In both cases, the database analysis that created a list of patients that would benefit from the intervention would be a health care operation. Use or disclosure of protected health information to provide education materials to patients may similarly be either treatment or operations, depending on the circumstances and on who is sending the materials. We cannot say in the abstract whether any such activities constitute marketing under this rule. See §§ 164.501 and 164.514 for details on what communications are marketing and when the authorization of the individual may be required.

Comment: Many commenters were concerned that the definition of treatment would not permit Third Party Administrators (TPAs) to be involved with disease management programs without obtaining authorization. They asserted that while the proposed definition of treatment included disease management conducted by health care providers it did not recognize the role of employers and TPAs in the current disease management process.

Response: Covered entities disclose protected health information to other persons, including TPAs, that they hire to perform services for them or on their behalf. If a covered entity hires a TPA to perform the disease management activities included in the rule's definitions of treatment and health care operations that disclosure will not ***82628** require authorization. The relationship between the covered entity and the TPA may be subject to the business associate requirements of §§ 164.502 and 164.504. Disclosures by covered entities to plan sponsors, including employers, for the purpose of plan administration are addressed in § 164.504.

Comment: Commenters suggested that as disease management is defined only as an element of treatment, it could only be carried out by health care providers, and not health plans. They opposed this approach because health plans also conduct such programs, and are indeed required to do it by accreditation standards and HCFA Managed Care Organization standards.

Response: We agree that the placement of disease management in the proposed definition of treatment suggested that health plans could not conduct such programs. We revise the final rule to clarify that health plans may conduct population based care management programs as a health care operation activity.

Comment: Some commenters stated that the rule should require that disease management only be done with the approval of the treating physician or at least with the knowledge of the physician.

Response: We disagree with this comment because we do not believe that this privacy rule is an appropriate venue for setting policies regarding the management of health care costs or treatment.

Comment: Some industry groups stated that if an activity involves selling products, it is not disease management. They asked for a definition that differentiates use of information for the best interests of patient from uses undertaken for "ulterior purposes" such as advertising, marketing, or promoting separate products.

Response: We eliminate the definition of "disease management" from the rule. Often however, treatment decisions involve discussing the relevant advantages and disadvantages of products and services. Health plans, as part of payment and operations, sometimes communicate with individuals about particular products and services. We address these distinctions in the definitions of marketing and "health care operations" in § 164.501, and in the requirements for use and disclosure of protected health information for marketing in § 164.514.

Comment: Some health care providers noted that there is a danger that employers will "force" individual employees with targeted conditions into self-care or compliance programs in ways that violate both the employee's privacy interest and his or her right to control own medical care.

Response: Employers are not covered entities under HIPAA, so we cannot prohibit them under this rule from undertaking these or other activities with respect to health information. In § 164.504 we limit disclosure of health information from group health plans to the employers sponsoring the plans. However, other federal and/or state laws, such as disability nondiscrimination laws, may govern the rights of employees under such circumstances.

Comment: Many commenters urged that disease management only be allowed with the written consent of the individual. Others also desired consent but suggested that an opt-out would be sufficient. Other commenters complained that the absence of a definition for disease management created uncertainty in view of the proposed rule's requirement to get authorization for marketing. They were concerned that the effect would be to require patient consent for many activities that are desirable, not practicably done if authorization is required, and otherwise classifiable as treatment, payment, or health care operations. Examples provided include reminders for appointments, reminders to get preventive services like mammograms, and information about home management of chronic illnesses.

Response: We agree with the commenters who stated that the requirement for specific authorization for certain activities considered part of disease management could impede the ability of health plans and covered providers to implement effective health care management and cost containment programs. In addition, this approach would require us to distinguish activities undertaken as part of a formal disease management program from the same activities undertaken outside the context of disease management program. For example, we see no clear benefit to privacy in requiring written authorization before a physician may call a patient to discuss treatment options in all cases, nor do we see a sound basis for requiring it only when the physician was following a formal protocol as part of a population based intervention. We also are not persuaded that the risk to privacy

for these activities warrants a higher degree of protection than do other payment, health care operations or treatment activities for which specific authorization was not suggested by commenters.

Comment: A few commenters asked that we clarify that disclosure of protected health information about a prospective patient to a health care provider (e.g., a possible admission to an assisted living facility from a nursing facility) is a treatment activity that does not require authorization.

Response: We agree that the described activity is "treatment," because it constitutes referral and coordination of health care.

Comment: Comments called for the removal of "other services" from the definition.

Response: We disagree with the concept that only health care services are appropriately included in the treatment definition. We have modified this definition to instead include "the provision, coordination, or management of health care and related services." This definition allows health care providers to offer or coordinate social, rehabilitative, or other services that are associated with the provision of health care. Our use of the term "related" prevents "treatment" from applying to the provision of services unrelated to health care.

Comment: Several commenters stated that the definition of treatment should include organ and tissue recovery activities. They asserted that the information exchanged and collected to request consent, evaluate medical information about a potential donor and perform organ recoveries relates to treatment and are not administrative activities. When hospitals place a patient on the UNOS list it is transferring individually identifiable health information. Also, when an organ procurement organization registers a donor with UNOS it could be disclosing protected health information. Commenters questioned whether these activities would be administrative or constitute treatment.

Response: In the proposed rule we included in the definition of "health care" activities related to the procurement or organs, blood, eyes and other tissues. This final rule deletes those activities from the definition of "health care." We do so because, while organ and tissue procurement organizations are integral components of the health care system, we do not believe that the testing, procurement, and other procedures they undertake describe "health care" offered to the donors of the tissues or organs themselves. See the discussion under the definition of "health care" in § 160.103.

Comment: Some commenters recommended including health promotion activities in the definition of health care. ***82629**

Response: We consider health promotion activities to be preventive care, and thus within the definition of health care. In addition, such activities that are population based are included in the definition of health care operations.

Comment: We received a range of comments regarding the proper placement of case and disease management in the definitions and the perceived overlap between health care operations and treatment. Some consider that these activities are a function of improving quality and controlling costs. Thus, they recommend that the Secretary move risk assessment, case and disease management to the definition of health care operations.

Response: In response to these comments, we remove these terms from the definition of treatment and add case management to the definition of health care operations. We explain our treatment of disease management in responses to comments above. Whether an activity described as disease or case management falls under treatment or health care operations would depend in part on whether the activity is focused on a particular individual or a population. A single program described as a "case management" effort may include both health care operations activities (e.g., records analysis, protocol development, general risk assessment) and treatment activities (e.g., particular services provided to or coordinated for an individual, even if applying a standardized treatment protocol).

Comment: We received comments that argued for the inclusion of "disability management" in the treatment definition. They explained that through disability management, health care providers refer and coordinate medical management and they require contemporaneous exchange of an employee's specific medical data for the provider to properly manage.

Response: To the extent that a covered provider is coordinating health care services, the provider is providing treatment. We do not include the term "disability management" because the scope of the activities covered by that term is not clear. In addition, the commenters did not provide enough information for us to make a fact-based determination of how this rule applies to the uses and disclosures of protected health information that are made in a particular "disability management" program.

Use

Comment: One commenter asserted that the scope of the proposal had gone beyond the intent of Congress in addressing uses of information within the covered entity, as opposed to transactions and disclosures outside the covered entity. This commenter argued that, although HIPAA mentions use, it is unclear that the word "use" in the proposed rule is what Congress intended. The commenter pointed to the legislative history to argue that "use" is related to an information exchange outside of the entity.

Response: We disagree with the commenter regarding the Congress' intent. Section 264 of HIPAA requires that the Secretary develop and send to Congress recommendations on standards with respect to the privacy of individually identifiable health information (which she did on September 11, 1997) and prescribes that the recommendations address among other items "the uses and disclosures of such information that should be authorized or required." Section 264 explicitly requires the Secretary to promulgate standards that address at least the subjects described in these recommendations. It is therefore our interpretation that Congress intended to cover "uses" as well as disclosures of individually identifiable health information. We find nothing in the legislative history to indicate that Congress intended to deviate from the common meaning of the term "use."

Comment: One commenter observed that the definition could encompass the processing of data by computers to execute queries. It was argued that this would be highly problematic because computers are routinely used to identify subsets of data sets. It was explained that in performing this function, computers examine each record in the data set and return only those records in the data set that meet specific criteria. Consequently, a human being will see only the subset of data that the computer returns. Thus, the commenter stated that it is only this subset that could be used or disclosed.

Response: We interpret "use" to mean only the uses of the product of the computer processing, not the internal computer processing that generates the product.

Comments: Some commenters asked that the Department clarify that individualized medical information obtained through a fitness for duty examination is not subject to the privacy protections under the regulation.

Response: As discussed above, we have clarified that the definition of "treatment" to include assessments of an individual. If the assessment is performed by a covered health care provider, the health information resulting from the assessment is protected health information. We note that a covered entity is permitted to condition the provision of health care when the sole purpose is to create protected health information for the benefit of a third person. See § 164.508(b). For example, a covered health care provider may condition the provision of a fitness for duty examination to an individual on obtaining an authorization from the individual for disclosure to the employer who has requested the examination.

Section 164.502—Uses and Disclosures of Protected Health Information: General Rules

Section 164.502(a)—General Standard

Comment: A few commenters requested an exemption from the rule for the Social Security and Supplemental Security Income Disability Programs so that disability claimants can be served in a fair and timely manner. The commenters were concerned

that the proposal would be narrowly interpreted, thereby impeding the release of medical records for the purposes of Social Security disability programs.

Another commenter similarly asked that a special provision be added to the proposal's general rule for uses and disclosures without authorization for treatment, payment, and health care operations purposes to authorize disclosure of all medical information from all sources to the Social Security Administration, including their contracted state agencies handling disability determinations.

Response: A complete exemption for disclosures for these programs is not necessary. Under current practice, the Social Security Administration obtains authorization from applicants for providers to release an individual's records to SSA for disability and other determinations. Thus, there is no reason to believe that an exemption from the authorization required by this rule is needed to allow these programs to function effectively. Further, such an exemption would reduce privacy protections from current levels. When this rule goes into effect, those authorizations will need to meet the requirements for authorization under § 164.508 of this rule.

We do, however, modify other provisions of the proposed rule to accommodate the special requirements of these programs. In particular, Social Security Disability and other federal programs, and public benefits programs run by the states, are authorized by law ***82630** to share information for eligibility purposes. Where another public body has determined that the appropriate balance between need for efficient administration of public programs and public funds and individuals' privacy interests is to allow information sharing for these limited purposes, we do not upset that determination. Where the sharing of enrollment and eligibility information is required or expressly authorized by law, this rule permits such sharing of information for eligibility and enrollment purposes (see § 164.512(k)(6)(i)), and also excepts these arrangements from the requirements for business associate agreements (see § 164.502(e)(1)).

Comment: A few commenters asked that the rule be revised to authorize disclosures to clergy, for directory purposes, to organ and tissue procurement organizations, and to the American Red Cross without patient authorization.

Response: We agree and revise the final rule accordingly. The new policies and the rationale for these policies are found in §§ 164.510 and 164.512, and the corresponding preamble.

Comment: One commenter recommended that the rule apply only to the “disclosure” of protected health information by covered entities, rather than to both “use” and “disclosure.” The commenter stated that the application of the regulation to a covered entity's use of individually identifiable health information offers little benefit in terms of protecting protected health information, yet imposes costs and may hamper many legitimate activities, that fall outside the definition of treatment, payment or health care operations.

Another commenter similarly urged that the final regulation draw substantive distinctions between restrictions on the “use” of individually identifiable health information and on the “disclosure” of such information, with broader latitude for “uses” of such information. The commenter believed that internal “uses” of such information generally do not raise the same issues and concerns that a disclosure of that information might raise. It was argued that any concerns about the potential breadth of use of this information could be addressed through application of the “minimum necessary” standard. The commenter also argued that Congressional intent was that a “disclosure” of individually identifiable health information is potentially much more significant than a “use” of that information.

Response: We do not accept the commenter's broad recommendation to apply the regulation only to the “disclosure” of protected health information and not to “use” of such information. Section 264 charges the Secretary with promulgating standards that address, among other things, “the uses and disclosures” of individually identifiable health information. We also do not agree that applying the regulation to “use” offers little benefit to protecting protected health information. The potential exists for misuse of protected health information within entities. This potential is even greater when the covered entity also provides services

or products outside its role as a health care provider, health plan, or health care clearinghouse for which "use" of protected health information offers economic benefit to the entity. For example, if this rule did not limit "uses" generally to treatment, payment and health care operations, a covered entity that also offered financial services could be able to use protected health information without authorization to market or make coverage or rate decisions for its financial services products. Without the minimum necessary standard for uses, a hospital would not be constrained from allowing their appointment scheduling clerks free access to medical records.

We agree, however, that it is appropriate to apply somewhat different requirements to uses and disclosures of protected health information permitted by this rule. We therefore modify the application of the minimum necessary standard to accomplish this. See the preamble to § 164.514 for a discussion of these changes.

Comment: A commenter argued that the development, implementation, and use of integrated computer-based patient medical record systems, which requires efficient information sharing, will likely be impeded by regulatory restrictions on the "use" of protected health information and by the minimum necessary standard.

Response: We have modified the proposed approach to regulating "uses" of protected health information within an entity, and believe our policy is compatible with the development and implementation of computer-based medical record systems. In fact, we drew part of the revised policy on "minimum necessary" use of protected health information from the role-based access approach used in several computer-based records systems today. These policies are described further in § 164.514.

Comment: One commenter asked that the general rules for uses and disclosures be amended to permit covered entities to disclose protected health information for purposes relating to property and casualty benefits. The commenter argued that the proposal could affect its ability to obtain protected health information from covered entities, thereby constricting the flow of medical information needed to administer property and casualty benefits, particularly in the workers' compensation context. It was stated that this could seriously impede property and casualty benefit providers' ability to conduct business in accordance with state law.

Response: We disagree that the rule should be expanded to permit all uses and disclosures that relate to property and casualty benefits. Such a broad provision is not in keeping with protecting the privacy of individuals. Although we generally lack the authority under HIPAA to regulate the practices of this industry, the final rule addresses when covered entities may disclose protected health information to property and casualty insures. We believe that the final rule permits property and casualty insurers to obtain the protected health information that they need to maintain their promises to their policyholders. For example, the rule permits a covered entity to use or disclose protected health information relating to an individual when authorized by the individual. Property and casualty insurers are free to obtain authorizations from individuals for release by covered entities of the health information that the insurers need to administer claims, and this rule does not affect their ability to condition payment on obtaining such an authorization from insured individuals. Property and casualty insurers providing payment on a third-party basis have an opportunity to obtain authorization from the individual and to condition payment on obtaining such authorization. The final rule also permits covered entities to make disclosures to obtain payment, whether from a health plan or from another person such as a property and casualty insurer. For example, where an automobile insurer is paying for medical benefits on a first-party basis, a health care provider may disclose protected health information to the insurer as part of a request for payment. We also include in the final rule a new provision that permits covered entities to use or disclose protected health information as authorized by workers' compensation or similar programs established by law addressing work-related injuries or illness. See § 164.512(l). These statutory programs establish channels of information sharing that are necessary ***82631** to permit compensation of injured workers.

Comment: A few commenters suggested that the Department specify "prohibited" uses and disclosures rather than "permitted" uses and disclosures.

Response: We reject these commenters' because we believe that the best privacy protection in most instances is to require the individual's authorization for use or disclosure of information, and that the role of this rule is to specify those uses and disclosures

for which the balance between the individuals' privacy interest and the public's interests dictates a different approach. The opposite approach would require us to anticipate the much larger set of all possible uses of information that do not implicate the public's interest, rather than to specify the public interests that merit regulatory protection.

Comment: A commenter recommended that the rule be revised to more strongly discourage the use of individually identifiable health information where de-identified information could be used.

Response: We agree that the use of de-identified information wherever possible is good privacy practice. We believe that by requiring covered entities to implement these privacy restrictions only with respect to individually identifiable health information, the final rule strongly encourages covered entities to use de-identified information as much as practicable.

Comment: One commenter recommended that when information from health records is provided to authorized external users, this information should be accompanied by a statement prohibiting use of the information for other than the stated purpose; prohibiting disclosure by the recipient to any other party without written authorization from the patient, or the patient's legal representative, unless such information is urgently needed for the patient's continuing care or otherwise required by law; and requiring destruction of the information after the stated need has been fulfilled.

Response: We agree that restricting other uses or re-disclosure of protected health information by a third party that may receive the information for treatment, payment, and health care operations purposes or other purposes permitted by rule would be ideal with regard to privacy protection. However, as described elsewhere in this preamble, once protected health information leaves a covered entity the Department no longer has jurisdiction under the statute to apply protections to the information. Since we would have no enforcement authority, the costs and burdens of requiring covered entities to produce and distribute such a statement to all recipients of protected heath information, including those with whom the covered entity has no on-going relationship, would outweigh any benefits to be gained from such a policy. Similarly, where protected health information is disclosed for routine treatment, payment and operations purposes, the sheer volume of these disclosures makes the burden of providing such a statement unacceptable. Appropriate protection for these disclosures requires law or regulation directly applicable to the recipient of the information, not further burden on the disclosing entity. Where, however, the recipient of protected health information is providing a service to or on behalf of the covered entity this balance changes. It is consistent with long-standing legal principles to hold the covered entity to a higher degree of responsibility for the actions of its agents and contractors. See § 164.504 for a discussion of the responsibilities of covered entities for the actions of their business associates with respect to protected health information.

Section 164.502(b)—Minimum Necessary

Comments on the minimum necessary standard are addressed in the preamble to § 164.514(d).

Section 164.502(c)—Uses or Disclosures of Protected Health Information Subject to an Agreed Upon Restriction

Comments on the agreed upon restriction standard are addressed in the preamble to § 164.522(a).

Section 164.502(d)—Uses and Disclosures of De-Identified Protected Health Information

Comments on the requirements for de-identifying information are addressed in the preamble to § 164.514(a)-(c).

Section 164.502(e)—Business Associates

Comments on business associates are addressed in the preamble to § 164.504(e).

Section 164.502(f)—Deceased Individuals

Comment: Most commenters on this topic generally did not approve of the Secretary's proposal with regard to protected health information about deceased individuals. The majority of these commenters argued that our proposal was not sufficiently protective of such information. Commenters agreed with the statements made in the preamble to the proposed rule that the privacy concerns addressed by this policy are not limited to the confidential protection of the deceased individual but instead also affects the decedent's family, as genetic information and information pertinent to hereditary diseases and risk factors for surviving relatives and direct family members may be disclosed through the disclosure of the deceased individual's confidential data. It was argued that the proposal would be inadequate to protect the survivors who could be negatively affected and in most cases will outlive the two-year period of protection. A number of medical associations asserted that individuals may avoid genetic testing, diagnoses, and treatment and suppress information important to their health care if they fear family members will suffer discrimination from the release of their medical information after their death. One commenter pointed out that ethically little distinction can be made between protecting an individual's health information during life and protecting it post-mortem. Further, it was argued that the privacy of the deceased individual and his or her family is far more important than allowing genetic information to be abstracted by an institutional or commercial collector of information. A few commenters asked that we provide indefinite protection on the protected health information about a deceased person contained in psychotherapy notes. One commenter asked that we extend protections on records of children who have died of cancer for the lifetime of a deceased child's siblings and parents.

The majority of commenters who supported increased protections on the protected health information about the deceased asked that we extend protections on such information indefinitely or for as long as the covered entity maintains the information. It was also argued that the administrative burden of perpetual protection would be no more burdensome than it is now as current practice is that the confidentiality of identifiable patient information continues after death. A number of others pointed out that there was no reason to set a different privacy standard for deceased individuals than we had for living individuals and that it has been standard practice to release the information of deceased individuals with a valid consent of the executor, next of kin, or specific court order. In addition, commenters referenced Hawaii's health care information privacy law (see ***82632** Haw. Rev. Stat. section 323C-43) as at least one example of a state law where the privacy and access provisions of the law continue to apply to the protected health information of a deceased individual following the death of that individual.

Response: We find the arguments raised by these commenters persuasive. We have reconsidered our position and believe these arguments for maintaining privacy on protected health information without temporal limitations outweigh any administrative burdens associated with maintaining such protections. As such, in the final rule we revise our policy to extend protections on the protected health information about a deceased individual to remain in effect for as long as the covered entity maintains the information.

For purposes of this regulation, this means that, except for uses and disclosures for research purposes (see § 164.512(i)), covered entities must under this rule protect the protected health information about a deceased individual in the same manner and to the same extent as required for the protected health information of living individuals. This policy alleviates the burden on the covered entity from having to determine whether or not the person has died and if so, how long ago, when determining whether or not the information can be released.

Comment: One commenter asked us to delete our standard for deceased individuals, asserting that the deceased have no constitutional right to privacy and state laws are sufficient to maintain protections for protected health information about deceased individuals.

Response: We understand that traditional privacy law has historically stripped privacy protection on information at the time the subject of the information dies. However, as we pointed out in the preamble to the proposed rule, the dramatic proliferation of electronic-based interchanges and maintenance of information has enabled easier and more ready access to information that once may have been de facto protected for most people because of the difficulty of its collection and aggregation. It is also our understanding that current state laws vary widely with regard to the privacy protection of a deceased individual's individually identifiable health information. Some are less protective than others and may not take into account the implications of disclosure

of genetic and hereditary information on living individuals. For these reasons, a regulatory standard is needed here in order to adequately protect the privacy interests of those who are living.

Comment: Another commenter expressed concern over the administrative problems that the proposed standard would impose, particularly in the field of retrospective health research.

Response: For certain research purposes, we permit a covered entity to use and disclose the protected health information of a deceased individual without authorization by a personal representative and absent review by an IRB or privacy board. The verification standard (§ 164.514(h)) requires that covered entities obtain an oral or written representation that the protected health information sought will be used or disclosed solely for research, and § 164.512(i)(1)(iii) requires the covered entity to obtain from the researcher documentation of the death of the individual. We believe the burden on the covered entity will be small, because it can reasonably rely on the representation of purpose and documentation of death presented by the researcher.

Comment: A few commenters argued that the standard in the proposed rule would cause significant administrative burdens on their record retention and storage policies. Commenters explained that they have internal policy record-retention guidelines which do not envision the retention of records beyond a few years. Some commenters complained about the burden of having to track dates of death, as the commenters are not routinely notified when an individual has died.

Response: The final rule does not dictate any record retention requirements for the records of deceased individuals. Since we have modified the NPRM to cover protected health information about deceased individuals for as long as the covered entity maintains the information, there will be no need for the covered entity to track dates of death.

Comment: A few commenters voiced support for the approach proposed in the proposal to maintain protections for a period of two years.

Response: After consideration of public comments, we chose not to retain this approach because the two-year period would be both inadequate and arbitrary. As discussed above, we agree with commenter arguments in support of providing indefinite protection.

Comment: A few commenters expressed concern that the regulations may be interpreted as providing a right of access to a deceased's records only for a two-year period after death. They asked the Department to clarify that the right of access of an individual, including the representatives of a deceased individual, exists for the entire period the information is held by a covered entity.

Response: We agree with these comments, given the change in policy discussed above.

Comment: A few commenters suggested that privacy protections on protected health information about deceased individuals remain in effect for a specified time period longer than 2 years, arguing that two years was not long enough to protect the privacy rights of living individuals. These commenters, however, were not in agreement as to what other period of protection should be imposed, suggesting various durations from 5 to 20 years.

Response: We chose not to extend protections in this way because specifying another time period would raise many of the same concerns voiced by the commenters regarding our proposed two year period and would not reduce the administrative burden of having to track or learn dates of death. We believe that the policy in this final rule extending protections for as long as the covered entity maintains the information addresses commenter concerns regarding the need for increased protections on the protected health information about the deceased.

Comment: Some commenters asserted that information on the decedent from the death certificate is important for assessment and research purposes and requested that the Department clarify accordingly that death certificate data be allowed for use in traditional public health assessment activities.

Response: Nothing in the final rule impedes reporting of death by covered entities as required or authorized by other laws, or access to death certificate data to the extent that such data is available publicly from non-covered entities. Death certificate data maintained by a covered entity is protected health information and must only be used or disclosed by a covered entity in accordance with the requirements of this regulation. However, the final rule permits a covered entity to disclose protected health information about a deceased individual for research purposes without authorization and absent IRB or privacy board approval.

Comment: A few commenters asked that we include in the regulation a mechanism to provide for notification of date of death. These commenters questioned how a covered entity or business partner would be notified of a death and subsequently be able to determine whether the two-year period of protection had expired and if they ***82633** were permitted to use or disclose the protected health information about the deceased. One commenter further stated that absent such a mechanism, a covered entity would continue to protect the information as if the individual were still living. This commenter recommended that the burden for providing notification and confirmation of death be placed on any authorized entity requesting information from the covered entity beyond the two-year period.

Response: In general, such notification is no longer necessary as, except for uses and disclosures for research purposes, the final rule protects the protected health information about a deceased individual for as long as the covered entity holds the record. With regard to uses and disclosures for research, the researcher must provide covered entities with appropriate documentation of proof of death, the burden is not on the covered entity.

Comment: A few commenters pointed to the sensitivity of genetic and hereditary information and its potential impact on the privacy of living relatives as a reason for extending protections on the information about deceased individuals for as long as the covered entity maintains the information. However, a few commenters recommended additional protections for genetic and hereditary information. For example, one commenter suggested that researchers should be able to use sensitive information of the deceased but then be required to publish findings in de-identified form. Another commenter recommended that protected health information about a deceased individual be protected as long as it implicates health problems that could be developed by living relatives.

Response: We agree with many of the commenters regarding the sensitivity of genetic or hereditary information and, in part for this reason, extended protections on the protected health information of deceased individuals. Our reasons for retaining the exception for research are explained above.

We agree with and support the practice of publishing research findings in de-identified form. However, we cannot regulate researchers who are not otherwise covered entities in this regulation.

Comment: One commenter asked that the final rule allow for disclosure of protected health information to funeral directors as necessary for facilitating funeral and disposition arrangements. The commenter believed that our proposal could seriously disrupt a family's ability to make funeral arrangements as hospitals, hospices, and other health care providers would not be allowed to disclose the time of death and other similar information critical to funeral directors for funeral preparation. The commenter also noted that funeral directors are already precluded by state licensing regulations and ethical standards from inappropriately disclosing confidential information about the deceased.

Further, the commenter stated that funeral directors have legitimate needs for protected health information of the deceased or of an individual when death is anticipated. For example, often funeral directors are contacted when death is foreseen in order to begin the process of planning funeral arrangements and prevent unnecessary delays. In addition, the embalming of the body is affected by the medical condition of the body.

In addition, it was noted that funeral directors need to be aware of the presence of a contagious or infectious disease in order to properly advise family members of funeral and disposition options and how they may be affected by state law. For example, certain states may prohibit cremation of remains for a certain period unless the death was caused by a contagious or infectious disease, or prohibit family members from assisting in preparing the body for disposition if there is a risk of transmitting a communicable disease from the corpse.

Response: We agree that disclosures to funeral directors for the above purposes should be allowed. Accordingly, the final rule at § 164.512(g)(2) permits covered entities to disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. Such disclosures are also permitted prior to, and in reasonable anticipation of, the individual's death.

Comment: Several commenters urged that the proposed standard for deceased individuals be clarified to allow access by a family member who has demonstrated a legitimate health-related reason for seeking the information when there is no executor, administrator, or other person authorized under applicable law to exercise the right of access of the individual.

Another commenter asked that the rule differentiate between blood relatives and family members and address their different access concerns, such as with genetic information versus information about transmittable diseases. They also recommended that the regulation allow access to protected health information by blood-related relatives prior to the end of the two-year period and provide them with the authority to extend the proposed two-year period of protection if they see fit. Lastly, the commenter suggested that the regulation address the concept of when the next-of-kin may not be appropriate to control a deceased person's health information.

Response: We agree that family members may need access to the protected health information of a deceased individual, and this regulation permits such disclosure in two ways. First, a family member may qualify as a "personal representative" of the individual (see § 164.502(g)). Personal representatives include anyone who has authority to act on behalf of a deceased individual or such individual's estate, not just legally-appointed executors. We also allow disclosure of protected health information to health care providers for purposes of treatment, including treatment of persons other than the individual. Thus, where protected health information about a deceased person is relevant to the treatment of a family member, the family member's physician may obtain that information. Because we limit these disclosures to disclosures for treatment purposes, there is no need to distinguish between disclosure of information about communicable diseases and disclosure of genetic information.

With regard to fitness to control information, we defer to existing state and other laws that address this matter.

Section 164.502(g)—Personal Representative

Comment: It was observed that under the proposed regulation, legal representatives with "power of attorney" for matters unrelated to health care would have unauthorized access to confidential medical records. Commenters recommended that access to a person's protected health information be limited to those representatives with a "power of attorney" for health care matters only. Related comments asked that the rule limit the definition of "power of attorney" to include only those instruments granting specific power to deal with health care functions and health care records.

Response: We have deleted the reference to "power of attorney." Under the final rule, a person is a personal representative of a living individual if, under applicable law, such person has authority to act on behalf of an individual in making decisions related to health care. "Decisions relating to health care" is broader than consenting to treatment on behalf of an individual; ***82634** for example, it would include decisions relating to payment for health care. We clarify that the rights and authorities of a personal representative under this rule are limited to protected health information relevant to the rights of the person to make decisions about an individual under other law. For example, if a husband has the authority only to make health care decisions about his wife in an emergency, he would have the right to access protected health information related to that emergency, but he may not have the right to access information about treatment that she had received ten years ago.

We note that the rule for deceased individuals differs from that of living individuals. A person may be a personal representative of a deceased individual if they have the authority to act on behalf of such individual or such individual's estate for any decision, not only decisions related to health care. We create a broader scope for a person who is a personal representative of a deceased individual because the deceased individual can not request that information be disclosed pursuant to an authorization, whereas a living individual can do so.

Comment: Some commenters asked that the NPRM provision allowing informal decision-makers access to the protected health information of an incapacitated individual should be maintained in the final rule.

Response: We agree with the commenters, and retain permission for covered entities to share protected health information with informal decision-makers, under conditions specified in § 164.510(b). A person need not be a personal representative for such disclosure of protected health information to be made to an informal decision-maker.

Comment: Commenters urged that individuals with mental retardation, who can provide verbal agreement or authorization, should have control over dissemination of their protected health information, in order to increase the privacy rights of such individuals.

Response: Individuals with mental retardation have control over dissemination of their protected health information under this rule to the extent that state law provides such individuals with the capacity to act on their own behalf. We note that a covered entity need not disclose information pursuant to a consent or authorization. Therefore, even if state law determines that an individual with mental retardation is not competent to act and a personal representative provides authorization for a disclosure, a covered entity may choose not to disclose such information if the individual who lacks capacity to act expresses his or her desire that such information not be disclosed.

Comment: A commenter suggested that the final rule should provide health plans with a set of criteria for formally identifying an incapacitated individual's decision-maker. Such criteria would give guidance to health plans that would help in not releasing information to the wrong person.

Response: The determination about who is a personal representative under this rule is based on state or other applicable law. We require that a covered entity verify the authority of a personal representative, in accordance with § 164.514(h) in order to disclose information to such person.

Comment: Commenters were troubled by the inclusion of minors in the definition of "individual" and believed that the presumption should be that parents have the right to care for their children.

Response: We agree that a parent should have access to the protected health information about their unemancipated minor children, except in limited circumstances based on state law. The approach in the final rule helps clarify this policy. The definition of "individual" is simplified in the final rule to "the person who is the subject of protected health information." (§ 164.501). We created a new section (§ 164.502(g)) to address "personal representatives," which includes parents and guardians of unemancipated minors. Generally, we provide that if under applicable law a parent has authority to act on behalf of an unemancipated minor in making decisions relating to health care about the minor, a covered entity must treat the parent as the personal representative with respect to protected health information relevant to such personal representation. The regulation provides only three limited exceptions to this rule based upon current state law and physician practice.

Comment: Many commenters agreed with our approach in the NPRM to give minors who may lawfully access health care the rights to control the protected health information related to such health care.

Several commenters disagreed with this approach and recommended that where states allow minors too much independence from parents, the rule should not defer to state law. One commenter suggested that we give an individual the right to control protected health information only when the individual reaches the age of majority.

Response: In the final rule, the parent, as the personal representative of a minor child, controls the protected health information about the minor, except that the parent does not act as a personal representative of the minor under the rule in three limited circumstances based on state consent law and physician practice. The final rule defers to consent laws of each state and does not attempt to evaluate the amount of control a state gives to a parent or minor. If a state provides an alternative means for a minor to obtain health care, other than with the consent of a parent, this rule preserves the system put in place by the state.

The first two exceptions, whereby a parent is not the personal representative for the minor and the minor can act for himself or herself under the rule, occur if the minor consents to a health care service, and no other consent to such health care service is required by law, or when the minor may lawfully obtain a health care service without the consent of a parent, and the minor, a court, or another person authorized by law consents to such service. The third exception is based on guidelines of the American Pediatric Association, current practice, and agreement by parents. If a parent assents to an agreement of confidentiality between a covered provider and a minor with respect to a health care service, the parent is not the personal representative of the minor with respect to the protected health information created or received subject to that confidentiality agreement. In such circumstances, the minor would have the authority to act as an individual, with respect to such protected health information.

Comment: Some commenters requested that we permit minors to exercise the rights of an individual when applicable law requires parental notification as opposed to parental consent.

Response: We adopt this policy in the final rule. If the minor consents to a health care service, and no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained or notification to another person has been given, only the minor may be treated as the individual with respect to the protected health information relating to such health care service. The rule does not affect state law that authorizes or requires notification to a parent of a minor's decision to obtain a health care service to the extent authorized or required by such law. In addition, state parental notification laws do not affect the rights of minors under this regulation. ***82635**

Comment: Some commenters requested clarification that when a minor may obtain a health care service without parental consent and voluntarily chooses to involve a parent, the minor retains the rights, authorities and confidentiality protections established in this rule.

Response: We agree that minors should be encouraged to voluntarily involve a parent or other responsible adult in their health care decisions. The rule is not intended to require that minors choose between involving a parent and maintaining confidentiality protections. We have added language in § 164.502(g)(3)(i) to clarify that when a minor consents to a health care service and no other consent is required by law, if the minor voluntarily chooses to involve a parent or other adult, the minor nonetheless maintains the exclusive ability to exercise their rights under the rule. This is true even if a parent or other person also has consented to the health care service for which the minor lawfully consented. Under the rule, a minor may involve a parent and still preserve the confidentiality of their protected health information. In addition, a minor may choose to have a parent act as his or her personal representative even if the minor could act on his or her own behalf under the rule. If the minor requests that a covered entity treat a parent as his or her personal representative, the covered entity must treat such person as the minor's personal representative even if the minor consents to a health care service and no other consent to such health care service is required by law.

Comment: Some commenters requested that the rule provide for the preservation of patient confidences if a health care provider and a minor patient enter into an agreement of confidentiality and a parent assents to this arrangement.

Response: We have addressed this concern in the final rule by adding a provision that ensures that a minor maintains the confidentiality protections provided by the rule for information that is created or received pursuant to a confidential communication between a provider and a minor when the minor's parent assents to an agreement of confidentiality between the provider and the minor. (§ 164.502(g)(3)(ii)). The American Academy of Pediatrics Guidelines for Health Supervision III, which are meant to serve as "a framework to help clinicians focus on important issues at developmentally appropriate time intervals," recommends that physicians interview children alone beginning at the age of twelve (or as early as the age of ten if it is comfortable for the child). This recommendation is based on the fact that adolescents tend to underutilize existing health care resources, in part, because of a concern for confidentiality.[FN7] The recommended interview technique in the Guidelines states that the provider discuss the rules of confidentiality with the adolescent and the parent and that the adolescent's confidentiality should be respected. We do not intend to interfere with these established protocols or current practices. Covered entities will need to establish procedures to separate protected health information over which the minor maintains control from protected health information with respect to which the minor's parent has rights as a personal representative of the minor.

A covered provider may disclose protected health information to a parent, regardless of a confidentiality agreement, if there is an imminent threat to the minor or another person, in accordance with § 164.512(j)(1)(i).

Comment: Several commenters suggested that we add a provision in the final rule to provide minors and parents with concurrent rights under certain circumstances, particularly when the minor reaches 16 years of age or when a parent authorizes his or her minor child to exercise these rights concurrently.

Response: We do not add such provision in the final rule. We believe that establishing concurrent rights through this rule could result in problems that effect the quality of health care if the minor and the parent were to disagree on the exercise of their rights. The rule would not prevent a parent from allowing a minor child to make decisions about his or her protected health information and acting consistently with the minor's decision. In all cases, either the parent has the right to act for the individual with respect to protected health information, or the minor has the right to act for himself or herself. The rule does not establish concurrent rights for parents and minors.

Comment: Commenters requested clarification about the rights of an adult or emancipated minor with respect to protected health information concerning health care services rendered while the person was an unemancipated minor.

Response: Once a minor becomes emancipated or attains the age of majority, as determined by applicable state law, the parent is no longer the personal representative under § 164.502(g)(3) of such individual, unless the parent has the authority to act on behalf of the individual for some reason other than their authority as a parent. An adult or emancipated minor has rights under the rule with respect to all protected health information about them, including information obtained while the individual was an unemancipated minor.

Comment: One commenter pointed out that language in the definition of individual in the NPRM that grants a minor the rights of an individual when he or she "lawfully receives care without the consent of, or notification to, a parent * * *" would have the effect of granting rights to an infant minor who receives emergency care when the parent is not available.

Response: This result was not our intent. We have changed the language in § 164.502(g)(3)(i) of the final rule to provide a minor the right to act as an individual when the minor can obtain care without the consent of a parent and the minor consents to such care. Because an infant treated in an emergency situation would not be able to consent to care, the infant's parent would be treated as the personal representative of the infant. Section 164.502(g)(3)(ii) provides that the parent is not the personal representative of the minor under the rule if the minor may obtain health care without the consent of a parent and the minor, a court, or another person authorized by law consents to such service. If an infant obtains emergency care without the consent of a parent, a health care provider may provide such care without consent to treatment. This situation would fall outside the second exception, and the parent would remain the personal representative of the minor.

Comment: Commenters were concerned about the interaction of this rule with FERPA with respect to parents' right to access the medical records of their children.

Response: We direct the commenters to a discussion of the interaction between our rule and FERPA in the "Relationship to Other Federal Laws" section of the preamble.

Section 164.502(h)—Confidential Communications

Comments on confidential communications are addressed in the preamble to § 164.522(b). ***82636**

Section 164.502(i)—Uses and Disclosures Consistent With Notice

Comments on the notice requirements are addressed in the preamble to § 164.520.

Section 164.502(j)—Uses and Disclosures by Whistleblowers and Workforce Crime Victims

Comments: Some commenters wanted to see more limitations put on the ability to whistleblow in the final rule. These commenters were concerned about how disclosed protected health information would be used during and subsequent to the whistleblowing event and felt that adding additional limitations to the ability to whistleblow would help to alleviate these concerns. Some of these commenters were concerned that there was no protection against information later being leaked to the public or re-released after the initial whistleblowing event, and that this could put covered entities in violation of the law. Many commenters wanted to see the whistleblower provision deleted entirely. According to a number of health care associations who commented on this topic, current practices already include adequate mechanisms for informing law enforcement, oversight and legal counsel of possible violations without the need for patient identifiable information; thus, the provision allowing whistleblowers to share protected health information is unnecessary. Additionally, some commenters felt that the covered entity needs to be allowed to prohibit disclosures outside of legitimate processes. Some commenters were concerned about not having any recourse if the whistleblower's suspicions were unfounded.

Response: In this rule, we do not regulate the activities of whistleblowers. Rather, we regulate the activities of covered entities, and determine when they may be held responsible under this rule for whistleblowing activities of their workforce or business associates when that whistleblowing involves the disclosure of protected health information. Similarly, we regulate when covered entities must and need not sanction their workforce who disclose protected health information in violation of the covered entity's policies and procedures, when that disclosure is for whistleblowing purposes. See § 164.530(e). This rule does not address a covered entity's recourse against a whistleblower under other applicable law.

We do not hold covered entities responsible under this rule for whistleblowing disclosures of protected health information under the circumstances described in § 164.502(j). Our purpose in including this provision is to make clear that we are not erecting a new barrier to whistleblowing, and that covered entities may not use this rule as a mechanism for sanctioning workforce members or business associates for whistleblowing activity. We do not find convincing commenters' arguments for narrowing or eliminating the scope of the whistleblowing which triggers this protection.

Congress, as well as several states, have recognized the importance of whistleblower activity to help identify fraud and mismanagement and protect the public's health and safety. Whistleblowers, by their unique insider position, have access to critical information not otherwise easily attainable by oversight and enforcement organizations.

While we recognize that in many instances, de-identified or anonymous information can be used to accomplish whistleblower objectives, there are instances, especially involving patient care and billing, where this may not be feasible. Oversight investigative agencies such as the Department of Justice rely on identifiable information in order to issue subpoenas that are enforceable. Relevant court standards require the government agency issuing the subpoena to explain why the specific records requested are relevant to the subject of the investigation, and without such an explanation the subpoena will be quashed. Issuing

a subpoena for large quantities of individual records to find a few records involving fraud is cost prohibitive as well as likely being unenforceable.

We note that any subsequent inappropriate disclosure by a recipient of whistleblower information would not put the covered entity in violation of this rule, since the subsequent disclosure is not covered by this regulation.

Comments: A few commenters felt that the whistleblower should be held to a "reasonableness standard" rather than a "belief" that a violation has taken place before engaging in whistleblower activities. The commenters felt that a belief standard is too subjective. By holding the whistleblower to this higher standard, this would serve to protect protected health information from being arbitrarily released. Some commenters saw the whistleblower provision as a loophole that gives too much power to disgruntled employees to inappropriately release information in order to cause problems for the employer.

On the other hand, some commenters felt that all suspicious activities should be reported. This would ease potential whistleblowers' concerns over whether or not they had a legitimate concern by leaving this decision up to someone else. A number of commenters felt that employees should be encouraged to report violations of professional or clinical standards, or when a patient, employee, or the public would be put at risk. A small number of commenters felt that the whistleblower should raise the issue within the covered entity before going to the attorney, oversight agency, or law enforcement entity.

Response: We do not attempt to regulate the conduct of whistleblowers in this rule. We address uses and disclosures of protected health information by covered entities, and when a covered entity will violate this rule due to the actions of a workforce member or business associate. In the final rule, we provide that a covered entity is not in violation of the rule when a workforce member or business associate has a good faith belief that the conduct being reported is unlawful or otherwise violates professional or clinical standards, or potentially endangers patients, employees or the public. We concur that the NPRM language requiring only a "belief" was insufficient. Consequently, we have strengthened the standard to require a good faith belief that an inappropriate behavior has occurred.

Comment: A number of commenters believe that employees should be encouraged to report violations of professional or clinical standards, or report situations where patients, employees, or the public would be put at risk. Their contention is that employees, especially health care employees, may not know whether the problem they have encountered meets a legal threshold of wrongdoing, putting them at jeopardy of sanction if they are incorrect, even if the behavior did reflect violation of professional and clinical standards or put patients, employees, or the public at risk.

Response: We agree that covered entities should be protected when their employees and others engage in the conduct described by these commenters. We therefore modify the proposal to protect covered entities when the whistleblowing relates to violations of professional or clinical standards, or situations where the public may be at risk, and eliminate the reference to "evidence."

Comments: A significant number of those commenting on the whistleblower provision felt that this provision was contrary to the rest of the rule. ***82637** Whistleblowers could very easily release protected health information under this provision despite the fact that the rest of this rule works very hard to ensure privacy of protected health information in all other contexts. To this end, some commenters felt that whistleblowers should not be exempt from the minimum necessary requirement.

Response: As stated above, we do not regulate the conduct of whistleblowers. We discuss above the importance of whistleblowing, and our intention not to erect a new barrier to such activity. The minimum necessary standard applies to covered entities, not to whistleblowers.

Comments: Some commenters felt that disclosures of suspected violations should only be made to a law enforcement official or oversight agency. Other commenters said that whistleblowers should be able to disclose their concerns to long-term care ombudsmen or health care accreditation organizations, particularly because certain protected health information may contain evidence of abuse. Some commenters felt that whistleblowers should not be allowed to freely disclose information to attorneys.

They felt that this may cause more lawsuits within the health care industry and be costly to providers. Furthermore, allowing whistleblowers to go to attorneys increases the number of people who have protected health information without any jurisdiction for the Secretary to do anything to protect this information.

Response: We agree with the commenters who suggested that we recognize other appropriate entities to which workforce members and business associates might reasonably make a whistleblowing disclosure. In the final rule we expand the provision to protect covered entities for disclosures of protected health information made to accreditation organizations by whistleblowers. We agree with the commenters that whistleblowers may see these organizations as appropriate recipients of health information, and do not believe that covered entities should be penalized for such conduct.

We also agree that covered entities should be protected when whistleblowers disclose protected health information to any health oversight agency authorized by law to investigate or oversee the conditions of the covered entity, including state Long-Term Care Ombudsmen appointed in accordance with the Older Americans Act. Among their mandated responsibilities is their duty to identify, investigate and resolve complaints that are made by, or on behalf of, residents related to their health, safety, welfare, or rights. Nursing home staff often bring complaints regarding substandard care or abuse to ombudsmen. Ombudsmen provide a potentially more attractive outlet for whistleblowers since resolution of problems may be handled short of legal action or formal investigation by an oversight agency.

We disagree with commenters that the provision permitting disclosures to attorneys is too broad. Workforce members or business associates may not understand their legal options or their legal exposure when they come into possession of information about unlawful or other inappropriate or dangerous conduct. Permitting potential whistleblowers to consult an attorney provides them with a better understanding of their legal options. We rephrase the provision to improve its clarity.

Comment: One commenter suggested that a notice of information practices that omits disclosure for voluntary reporting of fraud will chill internal whistleblowers who will be led to believe—falsely—that they would violate federal privacy law, and be lawfully subject to sanction by their employer, if they reported fraud to health oversight agencies.

Response: The notice of information practices describes a covered entity's information practices. A covered entity does not make whistleblower disclosures of protected health information, nor can it be expected to anticipate any such disclosures by its workforce.

Comment: One commenter suggested that the whistleblower provisions could allow covered entities to make illegal disclosures to police through the back door by having an employee who believes there is a violation of law do the disclosing. Any law could have been violated and the violator could be anyone (a patient, a member of the patient's family, etc.)

Response: We have eliminated whistleblower disclosures for law enforcement purposes from the list of circumstances in which the covered entity will be protected under this rule. This provision is intended to protect the covered entity when a member of its workforce or a business associate discloses protected health information to whistleblow on the covered entity (or its business associates); it is not intended for disclosures of conduct by the individual who is the subject of the information or third parties.

Section 164.504—Uses and Disclosures—Organizational Requirements—Component Entities, Affiliated Entities, Business Associates and Group Health Plans

Section 164.504(a)-(c)—Health Care Component (Component Entities) and Section 164.504(d)—Affiliated Entities

Comment: A few commenters asked that the concept of "use" be modified to allow uses within an integrated healthcare delivery system. Commenters argued that the rule needs to ensure that the full spectrum of treatment is protected from the need for authorizations at the points where treatment overlaps entities. It was explained that, for example, treatment for a patient often includes services provided by various entities, such as by a clinic and hospital, or that treatment may also necessitate referrals

from one provider entity to another unrelated entity. Further, the commenter argued that the rule needs to ensure that the necessary payment and health care operations can be carried out across entities without authorizations.

Response: The Department understands that in today's health care industry, the organization of and relationships among health care entities are highly complex and varied. We modify the proposed rule significantly to allow affiliated entities to designate themselves as a single covered entity. A complex organization, depending on how it self-designates, may have one or several "health care component(s)" that are each a covered entity. Aggregation into a single covered entity will allow the entities to use a single notice of information practices and will allow providers that must obtain consent for uses and disclosures for treatment, payment, and operations to obtain a single consent.

We do not allow this type of aggregation for unrelated entities, as suggested by some commenters, because unrelated entities' information practices will be too disparate to be accurately reflected on a single consent or notice form. Our policies on when consent and authorization are required for sharing information among unrelated entities, and the rationale for these policies, is described in §§ 164.506 and 164.508 and corresponding preamble.

As discussed above, in the final rule we have added a definition of organized health care arrangement and permit covered entities participating in such arrangements to disclose protected health information to support the health care operations of the arrangement. See the preamble discussion of the definitions of organized health care ***82638** arrangement and health care operations, § 164.501.

Comment: Some commenters expressed concern that the requirement to obtain authorization for the disclosure of information to a non-health related division of the covered entity would impede covered entities' ability to engage in otherwise-permissible activities such as health care operations. Some of these commenters requested clarification that covered entities are only required to obtain authorization for disclosures to non-health related divisions if the disclosure is for marketing purposes.

Response: In the final rule, we remove the example of use and disclosure to non-health related divisions of the covered entity from the list of examples of uses and disclosures requiring authorization in § 164.508. We determined that the example could lead covered entities to the mistaken conclusion that some uses or disclosures that would otherwise be permitted under the rule without authorization would require authorization when made to a non-health related division of the covered entity. In the final rule, we clarify that disclosure to a non-health related division does not require authorization if the use or disclosure is otherwise permitted or required under the rule. For example, in § 164.501 we define health care operations to include conducting or arranging for legal and auditing services. A covered entity that is the health care component of a larger entity is permitted under the final rule to include the legal department of the larger entity as part of the health care component. The covered entity may not, however, generally permit the disclosure of protected health information from the health care component to non-health related divisions unless they support the functions of the health care component and there are policies and procedures in place to restrict the further use to the support of the health related functions.

Comment: Many commenters, especially those who employed providers, supported our position in the proposed rule to consider only the health care component of an entity to be the covered entity. They stated that this was a balanced approach that would allow them to continue conducting business. Some commenters felt that there was ambiguity in the regulation text of the proposed rule and requested that the final rule explicitly clarify that only the health care component is considered the covered entity, not the entity itself. Similarly, another commenter requested that we clarify that having a health care component alone did not make the larger entity a covered entity under the rule.

Response: We appreciate the support of the commenters on the health care component approach and we agree that there was some ambiguity in the proposed rule. The final rule creates a new § 164.504(b) for health care components. Under § 164.504(b), for a covered entity that is a single legal entity which predominantly performs functions other than the functions performed by a health plan, provider, or clearinghouse, the privacy rules apply only to the entity's health care component. A policy, plan, or program that is an "excepted benefit" under section 2791(c)(1) of HIPAA cannot be part of a health care component because it is

expressly excluded from the definition of "health plan" for the reasons discussed above. The health care component is prohibited from sharing protected health information outside of the component, except as otherwise permitted or required by the regulation.

At a minimum, the health care component includes the organizational units of the covered entity that operate as or perform the functions of the health plan, health care provider, or clearinghouse and does not include any unit or function of the excepted benefits plan, policy, or program. While the covered entity remains responsible for compliance with this rule because it is responsible for the actions of its workforce, we otherwise limit the responsibility to comply to the health care component of the covered entity. The requirements of this rule apply only to the uses and disclosures of the protected health information by the component entity. See § 164.504(b).

Comment: Some commenters stated that the requirement to erect firewalls between different components would unnecessarily delay treatment, payment, and health care operations and thereby increase costs. Other commenters stressed that it is necessary to create firewalls between the health care component and the larger entity to prevent unauthorized disclosures of protected health information.

Response: We believe that the requirement to implement firewalls or safeguards is necessary to provide meaningful privacy protections, particularly because the health care component is part of a larger legal organization that performs functions other than those covered under this rule. Without the safeguard requirement we cannot ensure that the component will not share protected health information with the larger entity. While we do not specifically identify the safeguards that are required, the covered entity must implement policies and procedures to ensure that: the health care component's use and disclose of protected health information complies with the regulation; members of the health care component who perform duties for the larger entity do not use and disclose protected health information obtained through the health care component while performing non-component functions unless otherwise permitted or required by the regulation; and when a covered entity conducts multiple functions regulated under this rule, the health care component adheres to the appropriate requirements (e.g. when acting as a health plan, adheres to the health plan requirements) and uses or discloses protected health information of individuals who receive limited functions from the component only for the appropriate functions. See §§ 164.504(c)(2) and 164.504(g). For example, a covered entity that includes both a hospital and a health plan may not use protected health information obtained from an individual's hospitalization for the health plan, unless the individual is also enrolled in the health plan. We note that covered entities are permitted to make a disclosure to a health care provider for treatment of an individual without restrictions.

Comment: One commenter stated that multiple health care components of a single organization should be able to be treated as a single component entity for the purposes of this rule. Under this approach, they argued, one set of policies and procedures would govern the entire component and protected health information could be shared among components without authorization. Similarly, other commenters stated that corporate subsidiaries and affiliated entities should not be treated as separate covered entities.

Response: We agree that some efficiencies may result from designating multiple component entities as a single covered entity. In the final rule we allow legally distinct covered entities that share common ownership or control to designate themselves or their health care components as a single covered entity. See § 164.504(d). Common ownership is defined as an ownership or equity interest of five percent or more. Common control exists if an entity has the power—directly or indirectly—to significantly influence or direct the actions or policies of another entity. If the affiliated entity contains health care components, it must implement safeguards to prevent the ***82639** larger entity from using protected health information maintained by the component entity. As stated above, organizations that perform multiple functions may designate a single component entity as long as it does not include the functions of an excepted benefit plan that is not covered under the rule. In addition, it must adhere to the appropriate requirements when performing its functions (e.g. when acting as a health plan, adhere to the health plan requirements) and uses or discloses protected health information of individuals who receive limited functions from the component only for the appropriate functions. At the same time, a component that is outside of the health care component may perform activities that otherwise are not permitted by a covered entity, as long as it does not use or disclose protected health information created or received by or on behalf of the health care component in ways that violate this rule.

Comment: Some commenters asked whether or not workers' compensation carriers could be a part of the health care component as described in the proposed rule. They argued that this would allow for sharing of information between the group health plan and workers' compensation insurers.

Response: Under HIPAA, workers' compensation is an excepted benefit program and is excluded from the definition of "health plan." As such, a component of a covered entity that provides such excepted benefits may not be part of a health care component that performs the functions of a health plan. If workforce members of the larger entity perform functions for both the health care component and the non-covered component, they may not use protected health information created or received by or on behalf of the health care component for the purposes of the non-covered component, unless otherwise permitted by the rule. For example, information may be shared between the components for coordination of benefits purposes.

Comment: Several commenters requested specific guidance on identifying the health care component entity. They argued that we underestimated the difficulty in determining the component and that many organizations have multiple functions with the same people performing duties for both the component and the larger entity.

Response: With the diversity of organizational structures, it is impossible to provide a single specific guidance for identifying health care components that will meet the needs of all organizations. Covered entities must designate their health care components consistent with the definition at § 164.504(a). We have tried to frame this definition to delineate what comes within a health care component and what falls outside the component.

Comment: A commenter representing a government agency recommended that only the component of the agency that runs the program be considered a covered entity, not the agency itself. In addition, this commenter stated that often subsets of other government agencies work in partnership with the agency that runs the program to provide certain services. For example, one state agency may provide maternity support services to the Medicaid program which is run by a separate agency. The commenter read the rule to mean that the agency providing the maternity support services would be a business associate of the Medicaid agency, but was unclear as to whether it would also constitute a health care component within its own agency.

Response: We generally agree. We expect that in most cases, government agencies that run health plans or provide health care services would typically meet the definition of a "hybrid entity" under § 164.504(a), so that such an agency would be required to designate the health care component or components that run the program or programs in question under § 164.504(c)(3), and the rules would not apply to the remainder of the agency's operations, under § 164.504(b). In addition, we have created an exception to the business associate contract requirement for government agencies who perform functions on behalf of other government agencies. Government agencies can enter into a memorandum of understanding with another government entity or adopt a regulation that applies to the other government entity in lieu of a business associate contract, as long as the memorandum or regulation contains certain terms. See § 164.504(e).

Comment: One commenter representing an insurance company stated that different product lines should be treated separately under the rule. For example, the commenter argued, because an insurance company offers both life insurance and health insurance, it does not mean that the insurance company itself is a covered entity, rather only the health insurance component is a covered entity. Another commenter requested clarification of the use of the term "product line" in the proposed rule. This commenter stated that product line should differentiate between different lines of coverage such as life vs. health insurance, not different variations of the same coverage, such as HMO vs. PPO. Finally, one commenter stated that any distinction among product lines is unworkable because insurance companies need to share information across product lines for coordinating benefits. This sharing of information, the commenter urged, should be able to take place whether or not all product lines are covered under the rule.

Response: We agree that many forms of insurance do not and should not come within the definition of "health plan," and we have excepted them from the definition of this term in § 160.103 applies. This point is more fully discussed in connection with

that definition. Although we do not agree that the covered entity is only the specific product line, as this comment suggests, the hybrid entity rules in § 164.504 address the substance of this concern. Under § 164.504(c)(3), an entity may create a health plan component which would include all its health insurance lines of business or separate health care components for each health plan product line. Finally, the sharing of protected health information across lines of business is allowed if it meets the permissive or required disclosures under the rule. The commenter's example of coordination of benefits would be allowed under the rule as payment.

Comment: Several commenters representing occupational health care providers supported our use of the component approach to prohibit unauthorized disclosures of protected health information. They requested that the regulation specifically authorize them to deny requests for disclosures outside of the component entity when the disclosure was not otherwise permitted or required by the regulation.

Response: We appreciate the commenters' support of the health care component approach. As members of a health care component, occupational health providers are prohibited from sharing protected health information with the larger entity (i.e., the employer), unless otherwise permitted or required by the regulation.

Comment: One commenter asked how the regulation affects employers who carry out research. The commenter questioned whether the employees carrying out the research would be component entities under the rule.

Response: If the employer is gathering its own information rather than obtaining it from an entity regulated by this rule, the information does not constitute protected health information since the employer is not a covered ***82640** entity. If the employer is obtaining protected health information from a covered entity, the disclosure by the covered entity must meet the requirements of § 164.512(i) regarding disclosures for research.

Comment: One commenter stated that the proposed rule did not clearly articulate whether employees who are health care providers are considered covered entities when they collect and use individually identifiable health information acting on behalf of an employer. Examples provided include, administering mandatory drug testing, making fitness-for-duty and return-to-work determinations, testing for exposure to environmental hazards, and making short and long term disability determinations. This commenter argued that if disclosing information gained through these activities requires authorization, many of the activities are meaningless. For example, an employee who fails a drug test is unlikely to give authorization to the provider to share the information with the employer.

Response: Health care providers are covered entities under this rule if they conduct standard transactions. A health care provider who is an employee and is administering drug testing on behalf of the employer, but does not conduct standard transactions, is not a covered entity. If the health care provider is a covered entity, then we require authorization for the provider to disclose protected health information to an employer. Nothing in this rule, however, prohibits the employer from conditioning an individual's employment on agreeing to the drug testing and requiring the individual to sign an authorization allowing his or her drug test results to be disclosed to the employer.

Comment: One commenter stated its belief that only a health center at an academic institution would be a covered entity under the component approach. This commenter believed it was less clear whether or not other components that may create protected health information “incidentally” through conducting research would also become covered entities.

Response: While a covered entity must designate as a health care component the functions that make it a health care provider, the covered entity remains responsible for the actions of its workforce. Components that create protected health information through research would be covered entities to the extent they performed one of the required transactions described in § 164.500; however, it is possible that the research program would not be part of the health care component, depending on whether the research program performed or supported covered functions.

Comment: Several commenters stated that employers need access to protected health information in order to provide employee assistance programs, wellness programs, and on-site medical testing to their employees.

Response: This rule does not affect disclosure of health information by employees to the employer if the information is not obtained from a covered entity. The employer's access to information from an EAP, wellness program, or on-site medical clinic will depend on whether the program or clinic is a covered entity.

Comment: One commenter stated that access to workplace medical records by the occupational medical physicians is fundamental to workplace and community health and safety. Access is necessary whether it is a single location or multiple sites of the same company, such as production facilities of a national company located throughout the country.

Response: Health information collected by the employer directly from providers who are not covered entities is outside the scope of this regulation. We note that the disclosures which this comment concerns should be covered by § 164.512(b).

Section 164.504(e)—Business Associates

Comment: Many commenters generally opposed the business partner standard and questioned the Secretary's legal authority under section 1172(a) of HIPAA to require business partner contracts. Others stated that the proposed rule imposed too great a burden on covered entities with regard to monitoring their business partners' actions. Commenters stated that they did not have the expertise to adequately supervise their business partners' activities—including billing, accounting, and legal activities—to ensure that protected health information is not inappropriately disclosed. Commenters argued that business partners are not "under the control" of health care providers, and that the rule would significantly increase the cost of medical care. Many commenters stated that the business partner provisions would be very time consuming and expensive to implement, noting that it is not unusual for a health plan or hospital to have hundreds of business partners, especially if independent physicians and local pharmacies are considered business partners. Many physician groups pointed out that their business partners are large providers, hospitals, national drug supplier and medical equipment companies, and asserted that it would be impossible, or very expensive, for a small physician group to attempt to monitor the activity of large national companies. Commenters stated that complex contract terms and new obligations would necessitate the investment of significant time and resources by medical and legal personnel, resulting in substantial expenses. Many commenters proposed that the duty to monitor be reduced to a duty to terminate the contractual arrangement upon discovery of a failure to comply with the privacy requirements.

In addition, many commenters argued that covered entities should have less responsibility for business partners' actions regarding the use and disclosure of protected health information. The proposed rule would have held covered entities responsible for the actions of their business partners when they "knew or reasonably should have known" of improper use of protected health information and failed to take reasonable steps to cure a breach of the business partner contract or terminate the contract. Many commenters urged that the term "knew or should have known" be clearly defined, with examples. Some commenters stated that covered entities should be liable only when they have actual knowledge of the material breach of the privacy rules by the business partner. Others recommended creation of a process by which a business partner could seek advice to determine if a particular disclosure would be appropriate. Some commenters stated that, in order to create an environment that would encourage covered entities to report misuses of protected health information, a covered entity should not be punished if it discovered an inappropriate disclosure.

Response: With regard to our authority to require business associate contracts, we clarify that Congress gave the Department explicit authority to regulate what uses and disclosures of protected health information by covered entities are "authorized." If covered entities were able to circumvent the requirements of these rules by the simple expedient of contracting out the performance of various functions, these rules would afford no protection to individually identifiable health information and be rendered meaningless. It is thus reasonable to place restrictions on disclosures to business associates that are designed to ensure that the personal medical information disclosed to them continues to be protected and used and further ***82641** disclosed only for appropriate (i.e., permitted or required) purposes.

We do not agree that business associate contracts would necessarily have complex terms or result in significant time and resource burdens. The implementation specifications for business associate contracts set forth in § 164.504 are straightforward and clear. Nothing prohibits covered entities from having standard contract forms which could require little or no modification for many business associates.

In response to comments that the "knew or should have known" standard in the proposed rule was too vague or difficult to apply, and concerns that we were asking too much of small entities in monitoring the activities of much larger business associates, we have changed the rule. Under the final rule, we put responsibility on the covered entity to take action when it "knew of a pattern of activity or practice of the business associate that constituted, respectively, a material breach or violation of the business associate's obligation under the contract * * *" This will preclude confusion about what a covered entity 'should have known.' We interpret the term "knew" to include the situation where the covered entity has credible evidence of a violation. Covered entities cannot avoid responsibility by intentionally ignoring problems with their contractors. In addition, we have eliminated the requirement that a covered entity actively monitor and ensure protection by its business associates. However, a covered entity must investigate credible evidence of a violation by a business associate and act upon any such knowledge.

In response to the concern that the covered entity should not be punished if it discovers an inappropriate disclosure by its business associate, § 164.504(e) provides that the covered entity is not in compliance with the rule if it fails to take reasonable steps to cure the breach or end the violation, while § 164.530(f) requires the covered entity to mitigate, to the extent practicable, any resultant harm. The breach itself does not cause a violation of this rule.

Comment: Some commenters voiced support for the concept of business partners. Moreover, some commenters urged that the rule apply directly to those entities that act as business partners, by restricting disclosures of protected health information after a covered entity has disclosed it to a business partner.

Response: We are pleased that commenters supported the business associate standard and we agree that there are advantages to legislation that directly regulates most entities that use or disclose protected health information. However, we reiterate that our jurisdiction under the statute limits us to regulate only those covered entities listed in § 160.102.

Comment: Many commenters strongly opposed the provision in the proposed rule requiring business partner contracts to state that individuals whose protected health information is disclosed under the contract are intended third party beneficiaries of the contract. Many noted that HIPAA did not create a private right of action for individuals to enforce a right to privacy of medical information, and questioned the Secretary's authority to create such a right through regulation. Others questioned whether the creation of such a right was appropriate in light of the inability of Congress to reach consensus on the question, and perceived the provision as a "back door" attempt to create a right that Congress did not provide. Some commenters noted that third party beneficiary law varies from state to state, and that a third party beneficiary provision may be unenforceable in some states. These commenters suggested that the complexity and variation of state third party beneficiary law would increase cost and confusion with limited privacy benefits.

Commenters predicted that the provision would result in a dramatic increase in frivolous litigation, increased costs throughout the health care system, and a chilling effect on the willingness of entities to make authorized disclosures of protected information. Many commenters predicted that fear of lawsuits by individuals would impede the flow of communications necessary for the smooth operation of the health care system, ultimately affecting quality of care. For example, some predicted that the provision would inhibit providers from making authorized disclosures that would improve care and reduce medical errors. Others predicted that it would limit vendors' willingness to support information systems requirements. One large employer stated that the provision would create a substantial disincentive for employers to sponsor group health plans. Another commenter noted that the provision creates an anomaly in that individuals may have greater recourse against business partners and covered entities that contract with them than against covered entities acting alone.

However, some commenters strongly supported the concept of providing individuals with a mechanism to enforce the provisions of the rule, and considered the provision among the most important privacy protections in the proposed rule.

Response: We eliminate the requirement that business associate contracts contain a provision stating that individuals whose protected health information is disclosed under the contract are intended third-party beneficiaries of the contract.

We do not intend this change to affect existing laws regarding when individuals may be third party beneficiaries of contracts. If existing law allows individuals to claim third party beneficiary rights, or prohibits them from doing so, we do not intend to affect those rules. Rather, we intend to leave this matter to such other law.

Comment: Some commenters objected to the proposed rule's requirement that the business partner must return or destroy all protected health information received from the covered entity at the termination of the business partner contract. Commenters argued that business partners will need to maintain business records for legal and/or financial auditing purposes, which would preclude the return or destruction of the information. Moreover, they argued that computer back-up files may contain protected health information, but business partners cannot be expected to destroy entire electronic back-up files just because part of the information that they contain is from a client for whom they have completed work.

Response: We modify the proposed requirement that the business associate must return or destroy all protected health information received from the covered entity when the business associate contract is terminated. Under the final rule, a business associate must return or destroy all protected health information when the contract is terminated if feasible and lawful. The business partner contract must state that privacy protections continue after the contract ends, if there is a need for the business associate to retain any of the protected health information and for as long as the information is retained. In addition, the permissible uses of information after termination of the contract must be limited to those activities that make return or destruction of the information not feasible.

Comment: Many commenters recommended that providers and plans be excluded from the definition of “business partner” if they are already governed by the rule as covered entities. Providers expressed particular concern about the inclusion of physicians with hospital privileges as business partners of the hospital, as each hospital would ***82642** be required to have written contracts with and monitor the privacy practices of each physician with privileges, and each physician would be required to do the same for the hospital. Another commenter argued that consultations between covered entities for treatment or referral purposes should not be subject to the business partner contracting requirement.

Response: The final rule retains the general requirement that, subject to the exceptions below, a covered entity must enter into a business associate contract with another covered entity when one is providing services to or acting on behalf of the other. We retain this requirement because we believe that a covered entity that is a business associate should be restricted from using or disclosing the protected health information it creates or receives through its business associate function for any purposes other than those that are explicitly detailed in its contract.

However, the final rule expands the proposed exception for disclosures of protected health information by a covered health care provider to another health care provider. The final rule allows such disclosures without a business associate contract for any activities that fall under the definition of “treatment.” We agree with the commenter that the administrative burdens of requiring contracts in staff privileges arrangements would not be outweighed by any potential privacy enhancements from such a requirement. Although the exception for disclosure of protected health information for treatment could be sufficient to relieve physicians and hospitals of the contract requirement, we also believe that this arrangement does not meet the true meaning of “business associate,” because both the hospital and physician are providing services to the patient, not to each other. We therefore also add an exception to § 164.502(e)(1) that explicitly states that a contract is not required when the association involves a health care facility and another health care provider with privileges at that facility, if the purpose is providing health care to the individual. We have also added other exceptions in § 164.502(e)(1)(ii) to the requirement to obtain “satisfactory assurances” under § 164.502(e)(1)(i). We do not require a business associate arrangement between group health plans and their

plan sponsors because other, albeit analogous, requirements apply under § 164.504(f) that are more tailored to the specifics of that legal relationship. We do not require business associate arrangements between government health plans providing public benefits and other agencies conducting certain functions for the health plan, because these arrangements are typically very constrained by other law.

Comment: Many commenters expressed concern that required contracts for federal agencies would adversely affect oversight activities, including investigations and audits. Some health plan commenters were concerned that if HMOs are business partners of an employer then the employer would have a right to all personal health information collected by the HMO. A commenter wanted to be sure that authorization would not be required for accreditation agencies to access information. A large manufacturing company wanted to make sure that business associate contracts were not required between affiliates and a parent corporation that provides administrative services for a sponsored health plan. Attorney commenters asserted that a business partner contract would undermine the attorney/client relationship, interfere with attorney/client privilege, and was not necessary to protect client confidences. A software vendor wanted to be excluded because the requirements for contracts were burdensome and government oversight intrusive. Some argued that because the primary purpose of medical device manufacturers is supplying devices, not patient care, they should be excluded.

Response: We clarify in the above discussion of the definition of "business associate" that a health insurance issuer or an HMO providing health insurance or health coverage to a group health plan does not become a business associate simply by providing health insurance or health coverage. The health insurance issuer or HMO may perform additional functions or activities or provide additional services, however, that would give rise to a business associate relationship. However, even when an health insurance issuer or HMO acts as a business associate of a group health plan, the group health plan has no right of access to the other protected health information maintained by the health insurance issuer or HMO. The business associate contract must constrain the uses and disclosures of protected health information obtained by the business associate through the relationship, but does not give the covered entity any right to request the business associate to disclose protected health information that it maintains outside of the business associate relationship to the group health plan. Under HIPAA, employers are not covered entities, so a health insurance issuer or HMO cannot act as a business associate of an employer. See § 164.504(f) with respect to disclosures to plan sponsors from a group health plan or health insurance issuer or HMO with respect to a group health plan.

With respect to attorneys generally, the reasons the commenters put forward to exempt attorneys from this requirement were not persuasive. The business associate requirements will not prevent attorneys from disclosing protected health information as necessary to find and prepare witness, nor from doing their work generally, because the business associate contract can allow disclosures for these purposes. We do not require business associate contracts to identify each disclosure to be made by the business associate; these disclosures can be identified by type or purpose. We believe covered entities and their attorneys can craft agreements that will allow for uses and disclosures of protected health information as necessary for these activities. The requirement for a business associate contract does not interfere with the attorney-client relationship, nor does it override professional judgement of business associates regarding the protected health information they need to discharge their responsibilities. We do not require covered entities to second guess their professional business associates' reasonable requests to use or disclose protected health information in the course of the relationship.

The attorney-client privilege covers only a small portion of information provided to attorneys and so is not a substitute for this requirement. More important, attorney-client privilege belongs to the client, in this case the covered entity, and not to the individual who is the subject of the information. The business associate requirements are intended to protect the subject of the information.

With regard to government attorneys and other government agencies, we recognize that federal and other law often does not allow standard legal contracts among governmental entities, but instead requires agreements to be made through the Economy Act or other mechanisms; these are generally reflected in a memorandum of understanding (MOU). We therefore modify the proposed requirements to allow government agencies to meet the required "satisfactory assurance" through such MOUs that contain the same provisions required of business associate contracts. As discussed elsewhere, we believe that direct regulation

of entities receiving protected health information can be as or more effective in protecting health ***82643** information as contracts. We therefore also allow government agencies to meet the required "satisfactory assurances" if law or regulations impose requirements on business associates consistent with the requirements specified for business associate contracts.

We do not believe that the requirement to have a business associate contract with agencies that are performing the specified services for the covered entity or undertaking functions or activities on its behalf undermines the government functions being performed. A business associate arrangement requires the business associate to maintain the confidentiality of the protected health information and generally to use and disclose the information only for the purposes for which it was provided. This does not undermine government functions. We have exempted from the business associate requirement certain situations in which the law has created joint uses or custody over health information, such as when law requires another government agency to determine the eligibility for enrollment in a covered health plan. In such cases, information is generally shared across a number of government programs to determine eligibility, and often is jointly maintained. We also clarify that health oversight activities do not give rise to a business associate relationship, and that protected health information may be disclosed by a covered entity to a health oversight agency pursuant to § 164.512(d).

We clarify for purposes of the final rule that accreditation agencies are business associates of a covered entity and are explicitly included within the definition. During accreditation, covered entities disclose substantial amounts of protected health information to other private persons. A business associate contract basically requires the business associate to maintain the confidentiality of the protected health information that it receives and generally to use and disclose such information for the purposes for which it was provided. As with attorneys, we believe that requiring a business associate contract in this instance provides substantial additional privacy protection without interfering with the functions that are being provided by the business associate.

With regard to affiliates, § 164.504(d) permits affiliates to designate themselves as a single covered entity for purposes of this rule. (See § 164.504(d) for specific organizational requirements.) Affiliates that choose to designate themselves as a single covered entity for purposes of this rule will not need business associate contracts to share protected health information. Absent such designation, affiliates are business associates of the covered entity if they perform a function or service for the covered entity that necessitates the use or disclosure of protected health information.

Software vendors are business associates if they perform functions or activities on behalf of, or provide specified services to, a covered entity. The mere provision of software to a covered entity would not appear to give rise to a business associate relationship, although if the vendor needs access to the protected health information of the covered entity to assist with data management or to perform functions or activities on the covered entity's behalf, the vendor would be a business associate. We note that when an employee of a contractor, like a software or IT vendor, has his or her primary duty station on-site at a covered entity, the covered entity may choose to treat the employee of the vendor as a member of the covered entity's workforce, rather than as a business associate. See the preamble discussion to the definition of workforce, § 160.103.

With regard to medical device manufacturers, we clarify that a device manufacturer that provides "health care" consistent with the rule's definition, including being a "supplier" under the Medicare program, is a health care provider under the final rule. We do not require a business associate contract when protected health information is shared among health care providers for treatment purposes. However, a device manufacturer that does not provide "health care" must be a business associate of a covered entity if that manufacturer receives or creates protected health information in the performance of functions or activities on behalf of, or the provision of specified services to, a covered entity.

As to financial institutions, they are business associates under this rule when they conduct activities that cause them to meet the definition of business associate. See the preamble discussion of the definition of "payment" in § 164.501, for an explanation of activities of a financial institution that do not require it to have a business associated contract.

Disease managers may be health care providers or health plans, if they otherwise meet the respective definitions and perform disease management activities on their own behalf. However, such persons may also be business associates if they perform disease management functions or services for a covered entity.

Comment: Other commenters recommended that certain entities be included within the definition of "business partner," such as transcription services; employee representatives; in vitro diagnostic manufacturers; private state and comparative health data organizations; state hospital associations; warehouses; "whistleblowers," credit card companies that deal with health billing; and patients.

Response: We do not list all the types of entities that are business associates, because whether an entity is a business associate depends on what the entity does, not what the entity is. That is, this is a definition based on function; any entity performing the function described in the definition is a business associate. Using one of the commenters' examples, a state hospital association may be a business associate if it performs a service for a covered entity for which protected health information is required. It is not a business associate by virtue of the fact that it is a hospital association, but by virtue of the service it is performing.

Comment: A few commenters urged that certain entities, i.e., collection agencies and case managers, be business partners rather than covered entities for purposes of this rule.

Response: Collection agencies and case managers are business associates to the extent that they provide specified services to or perform functions or activities on behalf of a covered entity. A collection agency is not a covered entity for purposes of this rule. However, a case manager may be a covered entity because, depending on the case manager's activities, the person may meet the definition of either a health care provider or a health plan. See definitions of "health care provider" and "health plan" in § 164.501.

Comment: Several commenters complained that the proposed HIPAA security regulation and privacy regulation were inconsistent with regard to business partners.

Response: We will conform these policies in the final Security Rule.

Comment: One commenter expressed concern that the proposal appeared to give covered entities the power to limit by contract the ability of their business partners to disclose protected health information obtained from the covered entity regardless of whether the disclosure was permitted under proposed § 164.510, "Uses and disclosures for which individual authorization is not required" (§ 164.512 in the final rule). Therefore, the commenter argued that the covered ***82644** entity could prevent the business partner from disclosing protected health information to oversight agencies or law enforcement by omitting them from the authorized disclosures in the contract.

In addition, the commenter expressed concern that the proposal did not authorize business partners and their employees to engage in whistleblowing. The commenter concluded that this omission was unintended since the proposal's provision at proposed § 164.518(c)(4) relieved the covered entity, covered entity's employees, business partner, and the business partner's employees from liability for disclosing protected health information to law enforcement and to health oversight agencies when reporting improper activities, but failed to specifically authorize business partners and their employees to engage in whistleblowing in proposed § 164.510(f), "Disclosures for law enforcement."

Response: Under our statutory authority, we cannot directly regulate entities that are not covered entities; thus, we cannot regulate most business associates, or 'authorize' them to use or disclose protected health information. We agree with the result sought by the commenter, and accomplish it by ensuring that such whistle blowing disclosures by business associates and others do not constitute a violation of this rule on the part of the covered entity.

Comment: Some commenters suggested that the need to terminate contracts that had been breached would be particularly problematic when the contracts were with single-source business partners used by health care providers. For example, one commenter explained that when the Department awards single-source contracts, such as to a Medicare carrier acting as a fiscal intermediary that then becomes a business partner of a health care provider, the physician is left with no viable alternative if required to terminate the contract.

Response: In most cases, we expect that there will be other entities that could be retained by the covered entity as a business associate to carry out those functions on its behalf or provide the necessary services. We agree that under certain circumstances, however, it may not be possible for a covered entity to terminate a contract with a business associate. Accordingly, although the rule still generally requires a covered entity to terminate a contract if steps to cure such a material breach fail, it also allows an exception to this to accommodate those infrequent circumstances where there simply are no viable alternatives to continuing a contract with that particular business associate. It does not mean, however, that the covered entity can choose to continue the contract with a non-compliant business associate merely because it is more convenient or less costly than doing business with other potential business associates. We also require that if a covered entity determines that it is not feasible to terminate a non-compliant business associate, the covered entity must notify the Secretary.

Comment: Another commenter argued that having to renegotiate every existing contract within the 2-year implementation window so a covered entity can attest to "satisfactory assurance" that its business partner will appropriately safeguard protected health information is not practical.

Response: The 2-year implementation period is statutorily required under section 1175(b) of the Act. Further, we believe that two years provides adequate time to come into compliance with the regulation.

Comment: A commenter recommended that the business partner contract specifically address the issue of data mining because of its increasing prevalence within and outside the health care industry.

Response: We agree that protected health information should only be used by business associates for the purposes identified in the business associate contract. We address the issue of data mining by requiring that the business associate contract explicitly identify the uses or disclosures that the business associate is permitted to make with the protected health information. Aside from disclosures for data aggregation and business associate management, the business associate contract cannot authorize any uses or disclosures that the covered entity itself cannot make. Therefore, data mining by the business associate for any purpose not specified in the contract is a violation of the contract and grounds for termination of the contract by the covered entity.

Comment: One commenter stated that the rule needs to provide the ability to contract with persons and organizations to complete clinical studies, provide clinical expertise, and increase access to experts and quality of care.

Response: We agree, and do not prohibit covered entities from sharing protected health information under a business associate contract for these purposes.

Comment: A commenter requested clarification as to whether sister agencies are considered business partners when working together.

Response: It is unclear from the comment whether the "sister agencies" are components of a larger entity, are affiliated entities, or are otherwise linked. Requirements regarding sharing protected health information among affiliates and components are found in § 164.504.

Comment: One commenter stated that some union contracts specify that the employer and employees jointly conduct patient quality of care reviews. The commenter requested clarification as to whether this arrangement made the employee a business partner.

Response: An employee organization that agrees to perform quality assurance for a group health plan meets the definition of a business associate. We note that the employee representatives acting on behalf of the employee organization would be performing the functions of the organization, and the employee organization would be responsible under the business associate contract to ensure that the representatives abided by the restrictions and conditions of the contract. If the employee organization is a plan sponsor of the group health plan, the similar provisions of § 164.504(f) would apply instead of the business associate requirements. See § 164.502(e)(1).

Comment: Some commenters supported regulating employers as business partners of the health plan. These commenters believed that this approach provided flexibility by giving employers access to information when necessary while still holding employers accountable for improper use of the information. Many commenters, however, stressed that this approach would turn the relationship between employers, employees and other agents "on its head" by making the employer subordinate to its agents. In addition, several commenters objected to the business partner approach because they alleged it would place employers at risk for greater liability.

Response: We do not require a business associate contract for disclosure of protected health information from group health plans to employers. We do, however, put other conditions on the disclosure of protected health information from group health plans to employers who sponsor the plan. See further discussion in § 164.504 on disclosure of protected health information to employers.

Comment: One commenter expressed concern that the regulation would discourage organizations from participating with Planned Parenthood since pro bono and volunteer services may have no contract signed. ***82645**

Response: We design the rule's requirements with respect to volunteers and pro bono services to allow flexibility to the covered entity so as not to disturb these arrangements. Specifically, when such volunteers work on the premises of the covered entity, the covered entity may choose to treat them as members of the covered entity's workforce or as business associates. See the definitions of business associate and workforce in § 160.103. If the volunteer performs its work off-site and needs protected health information, a business associate arrangement will be required. In this instance, where protected health information leaves the premises of the covered entity, privacy concerns are heightened and it is reasonable to require an agreement to protect the information. We believe that pro bono contractors will easily develop standard contracts to allow those activities to continue smoothly while protecting the health information that is shared.

Section 164.504(f)—Group Health Plans

Comment: Several commenters interpreted the preamble in the proposed rule to mean that only self-insured group health plans were covered entities. Another commenter suggested there was an error in the definition of group health plans because it only included plans with more than 50 participants or plans administered by an entity other than the employer (emphasis added by commenter). This commenter believed the "or" should be an "and" because almost all plans under 50 are administered by another entity and therefore this definition does not exclude most small plans.

Response: We did not intend to imply that only self-insured group health plans are covered health plans. We clarify that all group health plans, both self-insured and fully-funded, with 50 or more participants are covered entities, and that group health plans with fewer than 50 participants are covered health plans if they are administered by another entity. While we agree with the commenter that few group health plans with fewer than 50 participants are self-administered, the "or" is dictated by the statute. Therefore, the statute only exempts group health plans with fewer than 50 participants that are not administered by an entity other than the employer.

Comment: Several commenters stated that the proposed rule mis-characterized the relationship between the employer and the group health plan. The commenters stated that under ERISA and the Internal Revenue Code group health plans are separate legal entities from their employer sponsors. The group health plan itself, however, generally does not have any employees. Most operations of the group health plan are contracted out to other entities or are carried out by employees of the employer who

sponsors the plan. The commenters stressed that while group health plans are clearly covered entities, the Department does not have the statutory authority to cover employers or other entities that sponsor group health plans. In contrast, many commenters stated that without covering employers, meaningful privacy protection is unattainable.

Response: We agree that group health plans are separate legal entities from their plan sponsors and that the group health plan itself may be operated by employees of the plan sponsor. We make significant modification to the proposed rule to better reflect this reality. We design the requirements in the final regulation to use the existing regulatory tools provided by ERISA, such as the plan documents required by that law and the constellation of plan administration functions defined by that law that established and maintain the group health plan.

We recognize plan sponsors' legitimate need for health information in certain situations while, at the same time, protecting health information from being used for employment-related functions or for other functions related to other employee benefit plans or other benefits provided by the plan sponsor. We do not attempt to directly regulate plan sponsors, but pursuant to our authority to regulate health plans, we place restrictions on the flow of information from covered entities to non-covered entities. The final rule permits group health plans to disclose protected health information to plan sponsors, and allows them to authorize health insurance issuers or HMOs to disclose protected health information to plan sponsors, if the plan sponsors agree to use and disclose the information only as permitted or required by the regulation. The information may be used only for plan administration functions performed on behalf of the group health plan and specified in the plan documents. Hereafter, any reference to employer in a response to a comment uses the term “plan sponsor,” since employers can only receive protected health information in their role as plan sponsors, except as otherwise permitted under this rule, such as with an authorization.

Specifically, in order for a plan sponsor to obtain without authorization protected health information from a group health plan, health insurance issuer, or HMO, the documents under which the group health plan was established and is maintained must be amended to: (1) Describe the permitted uses and disclosures of protected health information by the plan sponsor (see above for further explanation); (2) specify that disclosure is permitted only upon receipt of a written certification that the plan documents have been amended; and (3) provide adequate firewalls. The firewalls must identify the employees or classes of employees or other persons under the plan sponsor's control who will have access to protected health information; restrict access to only the employees identified and only for the administrative functions performed on behalf of the group health plan; and provide a mechanism for resolving issues of noncompliance by the employees identified. Any employee of the plan sponsor who receives protected health information in connection with the group health plan must be included in the amendment to the plan documents. As required by ERISA, the named fiduciary is responsible for ensuring the accuracy of amendments to the plan documents.

Group health plans, and health insurance issuers or HMOs with respect to the group health plan, that disclose protected health information to plan sponsors are bound by the minimum necessary standard as described in § 164.514.

Group health plans, to the extent they provide health benefits only through an insurance contract with a health insurance issuer or HMO and do not create, receive, or maintain protected health information (except for summary information or enrollment and disenrollment information), are not required to comply with the requirements of §§ 164.520 or 164.530, except for the documentation requirements of § 164.530(j). In addition, because the group health plan does not have access to protected health information, the requirements of §§ 164.524, 164.526, and 164.528 are not applicable. Individuals enrolled in a group health plan that provides benefits only through an insurance contract with a health insurance issuer or HMO would have access to all rights provided by this regulation through the health insurance issuer or HMO, because they are covered entities in their own right.

Comment: We received several comments from self-insured plans who stated that the proposed rule did not fully appreciate the dual nature of an employer as a plan sponsor and as a insurer. These commenters stated that ***82646** the regulation should have an exception for employers who are also insurers.

Response: We believe the approach we have taken in the final rule recognizes the special relationship between plan sponsors and group health plans, including group health plans that provide benefits through a self-insured arrangement. The final rule allows

plan sponsors and employees of plan sponsors access to protected health information for purposes of plan administration. The group health plan is bound by the permitted uses and disclosures of the regulation, but may disclose protected health information to plan sponsors under certain circumstances. To the extent that group health plans do not provide health benefits through an insurance contract, they are required to establish a privacy officer and provide training to employees who have access to protected health information, as well as meet the other applicable requirements of the regulation.

Comment: Some commenters supported our position not to require individual consent for employers to have access to protected health information for purposes of treatment, payment, and health care operations. For employer sponsored insurance to continue to exist as it does today, the commenters stressed, this policy is essential. Other commenters encouraged the Department to amend the regulation to require authorization for disclosure of information to employers. These commenters stressed that because the employer was not a covered entity, individual consent is the only way to prohibit potential abuses of information.

Response: In the final regulation, we maintain the position in the proposed rule that a health plan, including a group health plan, need not obtain individual consent for use and disclosure of protected health information for treatment, payment and or health care operations purposes. However, we impose conditions (described above) for making such disclosures to the plan sponsor. Because employees of the plan sponsor often perform health care operations and payment (e.g. plan administration) functions, such as claims payment, quality review, and auditing, they may have legitimate need for such information. Requiring authorization from every participant in the plan could make such fundamental plan administration activities impossible. We therefore impose regulatory restrictions, rather than a consent requirement, to prevent abuses. For example, the plan sponsor must certify that any protected health information obtained by its employees through such plan administration activities will not be used for employment-related decisions.

Comment: Several commenters stressed that the regulation must require the establishment of firewalls between group health plans and employers. These commenters stated that firewalls were necessary to prevent the employer from accessing information improperly and using it in making job placements, promotions, and firing decisions. In addition, one commenter stated that employees with access to protected health information must be empowered through this regulation to deny unauthorized access to protected health information to corporate managers and executives.

Response: We agree with the commenters that firewalls are necessary to prevent unauthorized use and disclosure of protected health information. Among the conditions for group health plans to disclose information to plan sponsors, the plan sponsor must establish firewalls to prevent unauthorized uses and disclosures of information. The firewalls include: describing the employees or classes of employees with access to protected health information; restricting access to and use of the protected health information to the plan administration functions performed on behalf of the group health plan and described in plan documents; and providing an effective mechanism for resolving issues of noncompliance.

Comment: Several commenters supported our proposal to cover the health care component of an employer in its capacity as an administrator of the group health plan. These commenters felt the component approach was necessary to prevent the disclosure of protected health information to other parts of the employer where it might be used or disclosed improperly. Other commenters believed the component approach was unworkable and that distinguishing who was in the covered entity would not be as easy as assumed in the proposed rule. One commenter stated it was unreasonable for an employer to go through its workforce division by division and employee by employee designating who is included in the component and who is not. In addition, some commenters argued that we did not have the statutory authority to regulate employers at all, including their health care components.

One commenter requested more guidance with respect to identifying the health care component as proposed under the proposed rule. In particular, the commenter requested that the regulation clearly define how to identify such persons and what activities and functional areas may be included. The commenter alleged that identification of persons needing access to protected health information will be administratively burdensome. Another commenter requested clarification on distinguishing the component entity from non-component entities within an organization and how to administer such relationships. The commenter stated that

individuals included in the covered entity could change on a daily basis and advocated for a simpler set of rules governing intra-organizational relationships as opposed to inter-organizational relationships.

Response: While we have not adopted the component approach for plan sponsors in the final rule, plan sponsors who want protected health information must still identify who in the organization will have access to the information. Several of the changes we make to the NPRM will make this designation easier. First, we move from "component" to a more familiar functional approach. We limit the employees of the plan sponsor who may receive protected health information to those employees performing plan administration functions, as that term is understood with respect to ERISA compliance, and as limited by this rule's definitions of payment and health care operation. We also allow designation of a class of employees (e.g., all employees assigned to a particular department) or individual employees.

Although some commenters have asked for guidance, we have intentionally left the process flexible to accommodate different organizational structures. Plan sponsors may identify who will have access to protected health information in whatever way best reflects their business needs as long as participants can reasonably identify who will have access. For example, persons may be identified by naming individuals, job titles (e.g. Director of Human Resources), functions (e.g. employees with oversight responsibility for the outside third party claims administrator), divisions of the company (e.g. Employee Benefits) or other entities related to the plan sponsor. We believe this flexibility will also ease any administrative burden that may result from the identification process. Identification in terms such as "individuals who from time to time may need access to protected health information" or in other broad or generic ways, however, would not be sufficient.

Comment: In addition to the comments on the component approach itself, several commenters pointed out ***82647** that many employees wear two hats in the organization, one for the group health plan and one for the employer. The commenters stressed that these employees should not be regulated when they are performing group health plan functions. This arrangement is necessary, particularly in small employers where the plan fiduciary may also be in charge of other human resources functions. The commenter recommended that employees be allowed access to information when necessary to perform health plan functions while prohibiting them from using the information for non-health plan functions.

Response: We agree with the commenters that many employees perform multiple functions in an organization and we design these provisions specifically to accommodate this way of conducting business. Under the approach taken in the final regulation, employees who perform multiple functions (i.e. group health plan and employment-related functions) may receive protected health information from group health plans, but among other things, the plan documents must certify that these employees will not use the information for activities not otherwise permitted by this rule including for employment-related activities.

Comment: Several commenters pointed out that the amount of access needed to protected health information varies greatly from employer to employer. Some employers may perform many plan administration functions themselves which are not possible without access to protected health information. Other employers may simply offer health insurance by paying a premium to a health insurance issuer rather than provide or administer health benefits themselves. Some commenters argued that fully insured plans should not be covered under the rule. Similarly, some commenters argued that the regulation was overly burdensome on small employers, most of whom fully insure their group health plans. Other commenters pointed out that health insurance issuers —even in fully insured arrangements—are often asked for identifiable health information, sometimes for legitimate purposes such as auditing or quality assurance, but sometimes not. One commenter, representing an insurer, gave several examples of employer requests, including claims reports for employees, individual and aggregate amounts paid for employees, identity of employees using certain drugs, and the identity, diagnosis and anticipated future costs for "high cost" employees. This same commenter requested guidance in what types of information can be released to employers to help them determine the organization's responsibilities and liabilities.

Response: In the final regulation we recognize the diversity in plan sponsors' need for protected health information. Many plan sponsors need access to protected health information to perform plan administration functions, including eligibility and enrollment functions, quality assurance, claims processing, auditing, monitoring, trend analysis, and management of carve-

out plans (such as vision and dental plans). In the final regulation we allow group health plans to disclose protected health information to plan sponsors if the plan sponsor voluntarily agrees to use the information only in accordance with the purposes stated in the plan documents and as permitted by the regulation. We clarify, however, that plan administration does not include any employment-related decisions, including fitness for duty determinations, or duties related to other employee benefits or plans. Plan documents may only permit health insurance issuers to disclose protected health information to a plan sponsor as is otherwise permitted under this rule and consistent with the minimum necessary standard.

Some plan sponsors, including those with a fully insured group health plan, do not perform plan administration functions on behalf of group health plans, but still may require health information for other purposes, such as modifying, amending or terminating the plan or soliciting bids from prospective issuers or HMOs. In the ERISA context actions undertaken to modify, amend or terminate a group health plan may be known as "settlor" functions (see Lockheed Corp. v. Spink, 517 U.S. 882 (1996)). For example, a plan sponsor may require access to information to evaluate whether to adopt a three-tiered drug formulary. Additionally, a prospective health insurance issuer may need claims information from a plan sponsor in order to provide rating information. The final rule permits plan sponsors to receive summary health information with identifiers removed in order to carry out such functions. Summary health information is information that summarizes the claims history, expenses, or types of claims by individuals enrolled in the group health plan. In addition, the identifiers listed in § 164.514(b)(2)(i) must be removed prior to disclosing the information to a plan sponsor for purposes of modifying, amending, or terminating the plan. See § 164.504(a). This information does not constitute de-identified information because there may be a reasonable basis to believe the information is identifiable to the plan sponsor, especially if the number of participants in the group health plan is small. A group health plan, however, may not permit an issuer or HMO to disclose protected health information to a plan sponsor unless the requirement in § 164.520 states that this disclosure may occur.

Comment: Several commenters stated that health insurance issuers cannot be held responsible for employers' use of protected health information. They stated that the issuer is the agent of the employer and it should not be required to monitor the employer's use and disclosure of information.

Response: Under this regulation, health insurance issuers are covered entities and responsible for their own uses and disclosures of protected health information. A group health plan must require a health insurance issuer or HMO providing coverage to the group health plan to disclose information to the plan sponsor only as provided in the plan documents.

Comment: Several commenters urged us to require de-identified information to be used to the greatest extent possible when information is being shared with employers.

Response: De-identified information is not sufficient for many functions plan sponsors perform on behalf of their group health plans. We have created a process to allow plan sponsors and their employees access to protected health information when necessary to administer the plan. We note that all uses and disclosures of protected health information by the group health plan are bound by the minimum necessary standard.

Comment: One commenter representing church plans argued that the regulation should treat such plans differently from other group health plans. The commenter was concerned about the level of access to information the Secretary would have in performing compliance reviews and suggested that a higher degree of sensitivity is need for information related to church plans than information related to other group health plans. This sensitivity is needed, the commenter alleged, to reduce unnecessary intrusion into church operations. The commenter also advocated that church plans found to be out of compliance should be able to self-correct within a stated time frame (270 days) and avoid paying penalty taxes as allowed in the Internal Revenue Code.

Response: We do not believe there is sufficient reason to treat church plans differently than other covered entities. ***82648** The intent of the compliance reviews is to determine whether or not the plan is abiding by the regulation, not to gather information on the general operations of the church. As required by § 160.310(c), the covered entity must provide access only to information that is pertinent to ascertaining compliance with part 160 or subpart E of 164.

Comment: Several commenters stated that employers often advocate on behalf of their employees in benefit disputes and appeals, answer questions with regard to the health plan, and generally help them navigate their health benefits. These commenters questioned whether this type of assistance would be allowed under the regulation, whether individual consent was required, and whether this intervention would make them a covered entity.

Response: The final rule does nothing to hinder or prohibit plan sponsors from advocating on behalf of group health plan participants or providing assistance in understanding their health plan. Under the privacy rule, however, the plan sponsor could not obtain any information from the group health plan or a covered provider unless authorization was given. We do not believe obtaining authorization when advocating or providing assistance will be impractical or burdensome since the individual is requesting assistance and therefore should be willing to provide authorization. Advocating on behalf of participants or providing other assistance does not make the plan sponsor a covered entity.

Section 164.506—Consent for Treatment, Payment, and Health Care Operations

Comment: Many commenters supported regulatory authorization for treatment, payment, and health care operations. In particular, health plans, employers, and institutional providers supported the use of regulatory authorization for treatment, payment, and health care operations.

In contrast, a large number of commenters, particularly health care professionals, patients, and patient advocates, suggested that consent for treatment, payment, and health care operations should be required. Many commenters supported the use of consent for treatment, payment, and health care operations, considering this a requirement for maintaining the integrity of the health care system. Some commenters made a distinction between requiring and permitting providers to obtain consent.

Commenters nearly uniformly agreed that covered health care providers, health plans, and clearinghouses should not be prohibited from seeking authorization for treatment, payment, and health care operations. Some commenters stated that the prohibition against obtaining an authorization goes against professional ethics, undermines the patient-provider relationship, and is contrary to current industry practice.

Some commenters specifically noted the primacy of the doctor-patient relationship regarding consent. In general, commenters recommended that individually identifiable health information not be released by doctors without patient consent. A few commenters stated that prohibiting health care providers from obtaining consent could cause the patient to become suspicious and distrustful of the health care provider. Other commenters believed that clinicians have the responsibility for making sure that patients are fully informed about the consequences of releasing information. A few commented that the process of obtaining consent provided an opportunity for the patient and provider to negotiate the use and disclosure of patient information.

Commenters discussed how, when, and by whom consent should be sought. For example, some commenters viewed a visit between a health care provider and patient as the appropriate place for consent to be discussed and obtained. While others did not necessarily dispute the appropriateness of health care providers obtaining consent for uses and disclosures of protected health information from individuals, some said that it was appropriate for health plans to be permitted to obtain consent.

Response: In the NPRM we stated our concern that the blanket consents that individuals sign today provide these individuals with neither notice nor control over how their information is to be used. While we retain those concerns, we also understand that for many who participate in the health care system, the acts of providing and obtaining consent represent important values that these parties wish to retain. Many individuals argued that providing consent enhances their control; many advocates argued that the act of consent focuses patient attention on the transaction; and many health care providers argued that obtaining consent is part of ethical behavior.

The final rule amends our proposed approach and requires most covered health care providers to obtain a consent from their patients to use or disclose protected health information for treatment, payment, and health care operations. Providers who have

an indirect treatment relationship with the patient, as defined in § 164.501, cannot be expected to have an opportunity to obtain consent and may continue to rely on regulatory authorization for their uses and disclosures for these purposes.

As described in the comments, it is the relationship between the health care provider and the patient that is the basis for many decisions about uses and disclosures of protected health information. Much of the individually identifiable health information that is the subject of this rule is created when a patient interacts with a health care provider. By requiring covered providers to obtain consent for treatment, payment, and health care operations, the individual will have appropriate opportunity to consider the appropriate uses and disclosures of his or her protected health information. We also require that the consent contain a reference to the provider's notice, which contains a more detailed description of the provider's practices relating to uses and disclosures of protected health information. This combination provides the basis for an individual to have an informed conversation with his or her provider and to request restrictions.

It is our understanding that it is common practice for providers to obtain consent for this type of information-sharing today. Many providers and provider organizations stated that they are ethically obligated to obtain the patient's consent and that it is their practice to do so. A 1998 study by Merz, et al, published in the Journal of Law, Medicine and Ethics examined hospital consent forms regarding disclosure of medical information.[FN8] They found that 97% of all hospitals seek consent for the release of information for payment purposes; 45% seek consent for disclosure for utilization review, peer review, quality assurance, and/or prospective review; and 50% seek consent for disclosure to providers, other health care facilities, or others for continuity of care purposes. All of these activities fall within our definitions of treatment, payment, or health care operations.

In the final rule we have not required that health plans or health care clearinghouses obtain consent for their uses and disclosures of protected health information for treatment, payment, or health care operations. The rationale underlying the consent requirements for uses and disclosures by health care providers do not pertain to health plans and health care clearinghouses. First, current practice is varied, and there is little history of health plans obtaining ***82649** consent relating to their own information practices unless required to do so by some other law. This is reflected in the public comments, in which most health plans supported the regulatory authorization approach proposed in the NPRM. Further, unlike many health care providers, health plans did not maintain that they were ethically obligated to seek the consent of their patients for their use and disclosure activities. Finally, it is the unique relationship between an individual and his or her health care provider that provides the foundation for a meaningful consent process. Requiring that consent process between an individual and a health plan or clearinghouse, when no such unique relationship exists, we believe is not necessary.

Unlike their relationship with health care providers, individuals in most instances do not have a direct opportunity to engage in a discussion with a health plan or clearinghouse at the time that they enter into a relationship with those entities. Most individuals choose a health plan through their employer and often sign up through their employer without any direct contact with the health plan. We concluded that providing for a signed consent in such a circumstance would add little to the proposed approach, which would have required health plans to provide a detailed notice to their enrollees. In the final rule, we also clarify that an individual can request a restriction from a health plan or health care clearinghouse. Since individuals rarely if ever have any direct contact with clearinghouses, we concluded that requiring a signed consent would have virtually no effect beyond the provision of the notice and the opportunity to request restrictions.

We agree with the comments we received objecting to the provision prohibiting covered entities from obtaining consent from individuals. As discussed above, in the final rule we require covered health care providers with direct treatment relationships to obtain consent to use or disclose protected health information for treatment, payment, and health care operations. In addition, we have eliminated the provision prohibiting other covered entities from obtaining such consents. We note that the consents that covered entities are permitted to obtain relate to their own uses and disclosures of protected health information for treatment, payment, and health care operations and not to the practices of others. If a covered entity wants to obtain the individual's permission to receive protected health information from another covered entity, it must do so using an authorization under § 164.508.

"Consent" versus "Authorization"

Comment: In general, commenters did not distinguish between "consent" and "authorization." Commenters used both terms to refer to the individual's giving permission for the use and disclosure of protected health information by any entity.

Response: In the final rule we have made an important distinction between consent and authorization. Under the final rule, we refer to the process by which a covered entity seeks agreement from an individual regarding how it will use and disclose the individual's protected health information for treatment, payment, and health care operations as "consent." The provisions in the final rule relating to consent are largely contained in § 164.506. The process by which a covered entity seeks agreement from an individual to use or disclose protected health information for other purposes, or to authorize another covered entity to disclose protected health information to the requesting covered entity, are termed "authorizations" and the provisions relating to them are found in § 164.508.

Consent Requirements

Comment: Many commenters believed that consent might be problematic in that it could allow covered entities to refuse enrollment or services if the individual does not grant the consent. Some commenters proposed that covered entities be allowed to condition treatment, payment, or health care operations on whether or not an individual granted consent. Other commenters said that consent should be voluntary and not coerced.

Response: In the final rule (§ 164.506(b)(1)), we permit covered health care providers to condition treatment on the individual's consent to the covered provider's use or disclosure of protected health information to carry out treatment, payment, and health care operations. We recognize that it would be difficult, if not impossible, for health care providers to treat their patients and run their businesses without being able to use or disclose protected health information for these purposes. For example, a health care provider could not be reimbursed by a health plan unless the provider could share protected health information about the individual with the health plan. Under the final rule, if the individual refuses to grant consent for this disclosure, the health care provider may refuse to treat the individual. We encourage health care providers to exhaust other options, such as making alternative payment arrangements with the individual, before refusing to treat the individual on these grounds.

We also permit health plans to condition enrollment in the health plan on the individual's consent for the health plan to use and disclose protected health information to carry out treatment, payment, and health care operations (see § 164.506(b)(2)). The health plan must seek the consent in conjunction with the individual's enrollment in the plan for this provision to apply. For example, a health plan's application for enrollment may include a consent for the health plan to use or disclose protected health information to carry out treatment, payment, and/or health care operations. If the individual does not sign this consent, the health plan, under § 164.502(a)(1)(iii), is prohibited from using or disclosing protected health information about the individual for the purposes stated in the consent form. Because the health plan may not be able adequately to provide services to the individual without these uses and disclosures, we permit the health plan to refuse to enroll the individual if the consent is not signed.

Comment: Some commenters were concerned that the NPRM conflicted with state law regarding when covered entities would be required to obtain consent for uses and disclosures of protected health information.

Response: We have modified the provisions in the final rule to require certain health care providers to obtain consent for uses and disclosures for treatment, payment, and health care operations and to permit other covered entities to do so. A consent under this rule may be combined with other types of written legal permission from the individual, such as state-required consents for uses and disclosures of certain types of health information (e.g., information relating to HIV/AIDS or mental health). We also permit covered entities to seek authorization from the individual for another covered entity's use or disclosure of protected health information for these purposes, including if the covered entity is required to do so by other law. Though we do not believe any states currently require such authorizations, we wanted to avoid future conflicts. These changes should resolve the concerns raised by commenters regarding conflicts with state laws that require consent, authorization, or other types of written legal permission for uses and disclosures of protected health information. ***82650**

Comment: Some commenters noted that there would be circumstances when consent is impossible or impractical. A few commenters suggested that in such situations patient information be de-identified or reviewed by an objective third party to determine if consent is necessary.

Response: Covered health care providers with direct treatment relationships are required to obtain consent to use or disclose protected health information to carry out treatment, payment, and health care operations. In certain treatment situations where the provider is permitted or required to treat an individual without the individual's written consent to receive health care, the provider may use and disclose protected health information created or obtained in the course of that treatment without the individual's consent under this rule (see § 164.506(a)(3)). In these situations, the provider must attempt to obtain the individual's consent and, if the provider is unable to obtain consent, the provider must document the attempt and the reason consent could not be obtained. Together with the uses and disclosures permitted under §§ 164.510 and 164.512, the concerns raised regarding situations in which it is impossible or impractical for covered entities to obtain the individual's permission to use or disclose protected health information about the individual have been addressed.

Comment: An agency that provides care to individuals with mental retardation and developmental disabilities expressed concern that many of their consumers lack capacity to consent to the release of their records and may not have a surrogate readily available to provide consent on their behalf.

Response: Under § 164.506(a)(3), we provide exceptions to the consent requirement for certain treatment situations in which consent is difficult to obtain. In these situations, the covered provider must attempt to obtain consent and must document the reason why consent was not obtained. If these conditions are met, the provider may use and disclose the protected health information created or obtained during the treatment for treatment, payment, or health care operations purposes, without consent.

Comment: Many commenters were concerned that covered entities working together in an integrated health care system would each separately be required to obtain consent for use and disclosure of protected health information for treatment, payment, and health care operations. These commenters recommend that the rule permit covered entities that are part of the same integrated health care system to obtain a single consent allowing each of the covered entities to use and disclose protected health information in accordance with that consent form. Some commenters said that it would be confusing to patients and administratively burdensome to require separate consents for health care systems that include multiple covered entities.

Response: We agree with commenters' concerns. In § 164.506(f) of the final rule we permit covered entities that participate in an organized health care arrangement to obtain a single consent on behalf of the arrangement. See § 164.501 and the corresponding preamble discussion regarding organized health care arrangements. To obtain a joint consent, the covered entities must have a joint notice and must refer to the joint notice in the joint consent. See § 164.520(d) and the corresponding preamble discussion regarding joint notice. The joint consent must also identify the covered entities to which it applies so that individuals will know who is permitted to use and disclose information about them.

Comment: Many commenters stated that individuals own their medical records and, therefore, should have absolute control over them, including knowing by whom and for what purpose protected health information is used, disclosed, and maintained. Some commenters asserted that, according to existing law, a patient owns the medical records of which he is the subject.

Response: We disagree. In order to assert an ownership interest in a medical record, a patient must demonstrate some legitimate claim of entitlement to it under a state law that establishes property rights or under state contract law. Historically, medical records have been the property of the health care provider or medical facility that created them, and some state statutes directly provide that medical records are the property of a health care provider or a health care facility. The final rule is consistent with current state law that provides patients access to protected health information but not ownership of medical records. Furthermore, state laws that are more stringent than the rule, that is, state laws that provide a patient with greater access to protected health information, remain in effect. See discussion of “Preemption” above.

Electronically Stored Data

Comment: Some commenters stated that privacy concerns would be significantly reduced if patient information is not stored electronically. One commenter suggested that consent should be given for patient information to be stored electronically. One commenter believed that information stored in data systems should not be individually identifiable.

Response: We agree that storing and transmitting health information electronically creates concerns about the privacy of health information. We do not agree, however, that covered entities should be expected to maintain health information outside of an electronic system, particularly as health care providers and health plans extend their reliance on electronic transactions. We do not believe that it would be feasible to permit individuals to opt out of electronic transactions by withholding their consent. We note that individuals can ask providers and health plans whether or not they store information electronically, and can choose only providers who do not do so or who agree not to do so. We also do not believe that it is practical or efficient to require that electronic data bases contain only de-identified information. Electronic transactions have achieved tremendous savings in the health care system and electronic records have enabled significant improvements in the quality and coordination of health care. These improvements would not be possible with de-identified information.

Section 164.508—Uses and Disclosures for Which Authorization Is Required

Uses and Disclosures Requiring Authorization

Comment: We received many comments in general support of requiring authorization for the use or disclosure of protected health information. Some comments suggested, however, that we should define those uses and disclosures for which authorization is required and permit covered entities to make all other uses and disclosures without authorization.

Response: We retain the requirement for covered entities to obtain authorization for all uses and disclosures of protected health information that are not otherwise permitted or required under the rule without authorization. We define exceptions to the general rule requiring authorization for the use or disclosure of protected health information, rather than defining narrow circumstances in which authorization is required.

We believe this approach is consistent with well-established privacy principles, with other law, and with industry standards and ethical ***82651** guidelines. The July 1977 Report of the Privacy Protection Study Commission recommended that "each medical-care provider be considered to owe a duty of confidentiality to any individual who is the subject of a medical record it maintains, and that, therefore, no medical care provider should disclose, or be required to disclose, in individually identifiable form, any information about any such individual without the individual's explicit authorization, unless the disclosures would be" for specifically enumerated purposes such as treatment, audit or evaluation, research, public health, and law enforcement.[FN9] The Commission made similar recommendations with respect to insurance institutions.[FN10] The Privacy Act (5 U.S.C. 552a) prohibits government agencies from disclosing records except pursuant to the written request of or pursuant to a written consent of the individual to whom the record pertains, unless the disclosure is for certain specified purposes. The National Association of Insurance Commissioners' Health Information Privacy Model Act states, "A carrier shall not collect, use or disclose protected health information without a valid authorization from the subject of the protected health information, except as permitted by * * * this Act or as permitted or required by law or court order. Authorization for the disclosure of protected health information may be obtained for any purpose, provided that the authorization meets the requirements of this section." In its report "Best Principles for Health Privacy," the Health Privacy Working Group stated, "Personally identifiable health information should not be disclosed without patient authorization, except in limited circumstances' such as when required by law, for oversight, and for research.[FN11] The American Medical Association's Council on Ethical and Judicial Affairs has issued an opinion stating, "The physician should not reveal confidential communications or information without the express consent of the patient, unless required to do so by law [and] subject to certain exceptions which are ethically and legally justified because of overriding social considerations."[FN12] We build on these standards in this final rule.

Comment: Some comments suggested that, under the proposed rule, a covered entity could not use protected health information to solicit authorizations from individuals. For example, a covered entity could not use protected health information to generate a mailing list for sending an authorization for marketing purposes.

Response: We agree with this concern and clarify that covered entities are permitted to use protected health information in this manner without authorization as part of the management activities relating to implementation of and compliance with the requirements of this rule. See § 164.501 and the corresponding preamble regarding the definition of health care operations.

Comment: We received several comments suggesting that we not require written authorizations for disclosures to the individual or for disclosures initiated by the individual or the individual's legal representative.

Response: We agree with this concern and in the final rule we clarify that disclosures of protected health information to the individual who is the subject of the information do not require the individual's authorization. See § 164.502(a)(1). We do not intend to impose barriers between individuals and disclosures of protected health information to them.

When an individual requests that the covered entity disclose protected health information to a third party, however, the covered entity must obtain the individual's authorization, unless the third party is a personal representative of the individual with respect to such protected health information. See § 164.502(g). If under applicable law a person has authority to act on behalf of an individual in making decisions related to health care, except under limited circumstances, that person must be treated as the personal representative under this rule with respect to protected health information related to such representation. A legal representative is a personal representative under this rule if, under applicable law, such person is able to act on behalf of an individual in making decisions related to health care, with respect to the protected health information related to such decisions. For example, an attorney of an individual may or may not be a personal representative under the rule depending on the attorney's authority to act on behalf of the individual in decisions related to health care. If the attorney is the personal representative under the rule, he may obtain a copy of the protected health information relevant to such personal representation under the individual's right to access. If the attorney is not the personal representative under the rule, or if the attorney wants a copy of more protected health information than that which is relevant to his personal representation, the individual would have to authorize such disclosure.

Comment: Commenters expressed concern about whether a covered entity can rely on authorizations made by parents on behalf of their minor children once the child has reached the age of majority and recommended that covered entities be able to rely on the most recent, valid authorization, whether it was authorized by the parent or the minor.

Response: We agree. If an authorization is signed by a parent, who is the personal representative of the minor child at the time the authorization is signed, the covered entity may rely on the authorization for as long as it is a valid authorization, in accordance with § 164.508(b). A valid authorization remains valid until it expires or is revoked. This protects a covered entity's reasonable reliance on such authorization. The expiration date of the authorization may be the date the minor will reach the age of majority. In that case, the covered entity would be required to have the individual sign a new authorization form in order to use or disclose information covered in the expired authorization form.

Comment: Some commenters were concerned that covered entities working together in an integrated system would each be required to obtain authorization separately. These commenters suggested the rule should allow covered entities that are part of the same system to obtain a single authorization allowing each of the covered entities to use and disclose protected health information in accordance with that authorization.

Response: If the rule does not permit or require a covered entity to use or disclose protected health information without the individual's authorization, the covered entity must obtain the individual's authorization to make the use or disclosure. Multiple covered entities working together as an integrated delivery system or otherwise may satisfy this requirement in at least three ways. First, each covered entity may separately obtain an authorization directly from the individual who is the subject of the

protected health information to be used or disclosed. Second, one covered entity may obtain ***82652** a compound authorization in accordance with § 164.508(b)(3) that authorizes multiple covered entities to use and disclose protected health information. In accordance with § 164.508(c)(1)(ii), each covered entity, or class of covered entities, that is authorized to make the use or disclosure must be clearly identified. Third, if the requirements in § 164.504(d) are met, the integrated delivery system may elect to designate itself as a single affiliated covered entity. A valid authorization obtained by that single affiliated covered entity would satisfy the authorization requirements for each covered entity within the affiliated covered entity. Whichever option is used, because these authorizations are being requested by a covered entity for its own use or disclosure, the authorization must contain both the core elements in § 164.508(c) and the additional elements in § 164.508(d).

Sale, Rental, or Barter

Comment: Proposed § 164.508 listed examples of activities that would have required authorization, which included disclosure by sale, rental, or barter. Some commenters requested clarification that this provision is not intended to affect mergers, sale, or similar transactions dealing with entire companies or their individual divisions. A few commenters stated that covered entities should be allowed to sell protected health information, including claims data, as an asset of the covered entity.

Response: We clarify in the definition of health care operations that a covered entity may sell or transfer its assets, including protected health information, to a successor in interest that is or will become a covered entity. See § 164.501 and the corresponding preamble discussion regarding this change. We believe this change meets commenters' business needs without compromising individuals' privacy interests.

Comment: Some commenters supported the requirement for covered entities to obtain authorization for the sale, rental, or barter of protected health information. Some commenters argued that protected health information should never be bought or sold by anyone, even with the individual's authorization.

Response: We removed the reference to sale, rental, or barter in the final rule because we determined that the term was overly broad. For example, if a researcher reimbursed a provider for the cost of configuring health data to be disclosed under the research provisions at § 164.512(i), there may have been ambiguity that this was a sale and, therefore, required authorizations from the individuals who were the subjects of the information. We clarify in the final rule that if the use or disclosure is otherwise permitted or required under the rule without authorization, such authorization is not required simply because the disclosure is made by sale, rental, or barter.

Comment: Many commenters expressed concerns that their health information will be sold to pharmaceutical companies.

Response: Although we have removed the reference to sale, rental or barter, the final rule generally would not permit the sale of protected health information to a pharmaceutical company without the authorization of individuals who are the subjects of the information. In some cases, a covered entity could disclose protected health information to a pharmaceutical company for research purposes if the disclosure met the requirements of § 164.512(i).

Psychotherapy Notes

Comment: Public response to the concept of providing additional protections for psychotherapy notes was divided. Many individuals and most providers, particularly mental health practitioners, advocated requiring consent for use or disclosure of all or most protected health information, but particularly sensitive information such as mental health information, not necessarily limited to psychotherapy notes. Others thought there should be special protections for psychotherapy information based on the federal psychotherapist-patient privilege created by the U.S. Supreme Court in Jaffee v. Redmond and the need for an atmosphere of trust between therapist and patient that is required for effective psychotherapy. Several consumer groups recommended prohibiting disclosure of psychotherapy notes for payment purposes.

Some commenters, however, saw no need for special protections for psychotherapy communications and thought that the rules should apply the same protections for all individually identifiable information. Other commenters who advocated for no special protections based their opposition on the difficulty in drawing a distinction between physical and mental health and that special protections should be left to the states. Many health plans and employers did not support additional protections for psychotherapy notes because they stated they need access to this information to assess the adequacy of treatment, the severity of a patient's condition, the extent of a disability, or the ability to monitor the effectiveness of an individual's mental health care and eligibility for benefits. Other commenters, many from insurance companies, cited the need to have psychotherapy notes to detect fraud.

A few commenters said that it was not necessary to provide additional protections to psychotherapy notes because the "minimum necessary" provisions of the NPRM provide sufficient protections.

Response: In the final rule, a covered entity generally must obtain an authorization for disclosure of psychotherapy notes, or for use by a person other than the person who created the psychotherapy notes. This authorization is specific to psychotherapy notes and is in addition to the consent an individual may have given for the use or disclosure of other protected health information to carry out treatment, payment, and health care operations. This additional level of individual control provides greater protection than a general application of the "minimum necessary" rule. Nothing in this regulation weakens existing rules applicable to mental health information that provide more stringent protections. We do not intend to alter the holding in Jaffee v. Redmond.

Generally, we have not treated sensitive information differently from other protected health information; however, we have provided additional protections for psychotherapy notes because of Jaffee v. Redmond and the unique role of this type of information. There are few reasons why other health care entities should need access to psychotherapy notes, and in those cases, the individual is in the best position to determine if the notes should be disclosed. As we have defined them, psychotherapy notes are primarily of use to the mental health professional who wrote them, maintained separately from the medical record, and not involved in the documentation necessary to carry out treatment, payment, or health care operations. Since psychotherapy notes have been defined to exclude information that health plans would typically need to process a claim for benefits, special authorization for payment purposes should be rare. Unlike information shared with other health care providers for the purposes of treatment, psychotherapy notes are more detailed and subjective and are today subject to unique privacy and record retention practices. In fact, it is this separate existence and isolated use that allows us to grant the extra protection without causing an undue burden on the health care system. ***82653**

Comment: Many commenters suggested we prohibit disclosure of psychotherapy notes without authorization for uses and disclosures under proposed § 164.510 of the NPRM, or that protections should be extended to particular uses and disclosures, such as disclosures for public health, law enforcement, health oversight, and judicial and administrative proceedings. One of these commenters stated that the only purpose for which psychotherapy notes should be disclosed without authorization is for preventing or lessening a serious or imminent threat to health or safety (proposed § 154.510(k)). Another commenter stated that the rule should allow disclosure of psychotherapy notes without authorization for this purpose, or as required by law in cases of abuse or neglect.

Other commenters did not want these protections to be extended to certain national priority activities. They claimed that information relative to psychotherapy is essential to states' activities to protect the public from dangerous mentally ill offenders and abusers, to deliver services to individuals who are unable to authorize release of health care information, and for public health assessments. One commenter requested clarification of when psychotherapy notes could be released in emergency circumstances. Several commenters stated that psychotherapy notes should not be disclosed for public health purposes.

Response: We agree with the commenters who suggested extending protections of psychotherapy notes and have limited the purposes for which psychotherapy notes may be disclosed without authorization for purposes other than treatment, payment, or health care operations. The final rule requires covered entities to obtain authorization to use or disclose psychotherapy notes for purposes listed in § 164.512, with the following exceptions: An authorization is not required for use or disclosure of psychotherapy notes when the use or disclosure is required for enforcement of this rule, in accordance with § 164.502(a)(2)

(ii); when required by law, in accordance with § 164.512(a); when needed for oversight of the covered health care provider who created the psychotherapy notes, in accordance with § 164.512(d); when needed by a coroner or medical examiner, in accordance with § 164.512(g)(1); or when needed to avert a serious and imminent threat to health or safety, in accordance with § 164.512(j)(1)(i).

Comment: A commenter suggested that we follow the federal regulations governing confidentiality of alcohol and substance abuse records as a model for limited disclosure of psychotherapy notes for audits or evaluations. Under these regulations, a third party payor or a party providing financial assistance may access confidential records for auditing purposes if the party agrees in writing to keep the records secure and destroy any identifying information upon completion of the audit. (42 CFR part 2)

Response: We agree that the federal regulations concerning alcohol and drug abuse provide a good model for protection of information. However, according to our fact-finding discussions, audit or evaluation should not require access to psychotherapy notes. Protected health information kept in the medical record about an individual should be sufficient for these purposes. The final rule does not require authorization for use or disclosure of psychotherapy notes when needed for oversight of the covered health care provider who created the psychotherapy notes.

Comment: A provider organization urged that the disclosure of psychotherapy notes be strictly prohibited except to the extent needed in litigation brought by the client against the mental health professional on the grounds of professional malpractice or disclosure in violation of this section.

Response: We agree that psychotherapy notes should be available for the defense of the provider who created the notes when the individual who is the subject of the notes puts the contents of the notes at issue in a legal case. In the final rule, we allow the provider to disclose the notes to his or her lawyer for the purpose of preparing a defense. Any other disclosure related to judicial and administrative proceedings is governed by § 164.512(e).

Comment: One commenter requested that we prohibit mental health information that has been disclosed from being re-disclosed without patient authorization.

Response: Psychotherapy notes may only be disclosed pursuant to an authorization, except under limited circumstances. Covered entities must adhere to the terms of authorization and not disclose psychotherapy notes to persons other than those identified as intended recipients or for other purposes. A covered entity that receives psychotherapy notes must adhere to the terms of this rule—including obtaining an authorization for any further use or disclosure. We do not have the authority, however, to prohibit non-covered entities from re-disclosing psychotherapy notes or any other protected health information.

Comment: A provider organization argued for inclusion of language in the final rule that specifies that real or perceived "ownership" of the mental health record does not negate the requirement that patients must specifically authorize the disclosure of their psychotherapy notes. They cited a July 1999 National Mental Health Association survey, which found that for purposes of utilization review, every managed care plan policy reviewed "maintains the right to access the full medical record (including detailed psychotherapy notes) of any consumer covered under its benefit plan at its whim." At least one of the major managed health plans surveyed considered the patient record to be the property of the health plan and governed by the health plan's policies.

Response: Although a covered entity may own a mental health record, the ability to use or disclose an individual's information is limited by state law and this rule. Under this rule, a mental health plan would not have access to psychotherapy notes created by a covered provider unless the individual who is the subject of the notes authorized disclosure to the health plan.

Comment: Some commenters expressed concern regarding the burden created by having to obtain multiple authorizations and requested clarification as to whether separate authorization for use and disclosure of psychotherapy notes is required.

Response: For the reasons explained above, we retain in the final rule a requirement that a separate authorization must be obtained for most uses or disclosures of psychotherapy notes, including those for treatment, payment, and health care operations. The burden of such a requirement is extremely low, however, because under our definition of psychotherapy notes, the need for such authorization will be very rare.

Comment: One commenter stated that Medicare should not be able to require the disclosure of psychotherapy notes because it would destroy a practitioner's ability to treat patients effectively.

Response: We agree. As in the proposed rule, covered entities may not disclose psychotherapy notes for payment purposes without an authorization. If a specific provision of law requires the disclosure of these notes, a covered entity may make the disclosure under § 164.512(a). The final rule, however, does not require the disclosure of these notes to Medicare.

Comment: One commenter expressed concern that by filing a complaint an ***82654** individual would be required to reveal sensitive information to the public. Another commenter suggested that complaints regarding noncompliance in regard to psychotherapy notes should be made to a panel of mental health professionals designated by the Secretary. This commenter also proposed that all patient information would be maintained as privileged, would not be revealed to the public, and would be kept under seal after the case is reviewed and closed.

Response: We appreciate this concern and the Secretary will ensure that individually identifiable health information and other personal information contained in complaints will not be available to the public. This Department seeks to protect the privacy of individuals to the fullest extent possible, while permitting the exchange of records required to fulfill its administrative and program responsibilities. The Freedom of Information Act, 5 U.S.C. 552, and the HHS implementing regulation, 45 CFR part 5, protect records about individuals if the disclosure would constitute an unwarranted invasion of their personal privacy, as does the Privacy Act, 5 U.S.C. 552a. See the discussion of FOIA and the Privacy Act in the "Relationship to Other Federal Laws" section of the preamble. Information that the Secretary routinely withholds from the public in its current enforcement activities includes individual names, addresses, and medical information. Additionally, the Secretary attempts to guard against the release of information that might involve a violation of personal privacy by someone being able to "read between the lines" and piece together items that would constitute information that normally would be protected from release to the public. In implementing the privacy rule, the Secretary will continue this practice of protecting personal information.

It is not clear whether the commenter with regard to the use of mental health professionals believes that such professionals should be involved because they would be best able to keep psychotherapy notes confidential or because such professionals can best understand the meaning or relevance of such notes. We anticipate that we would not have to obtain a copy or review psychotherapy notes in investigating most complaints regarding noncompliance in regard to such notes. There may be some cases in which a quick review of the notes may be needed, such as when we need to identify that the information a covered entity disclosed was in fact psychotherapy notes. If we need to obtain a copy of psychotherapy notes, we will keep these notes confidential and secure. Investigative staff will be trained in privacy to ensure that they fully respect the confidentiality of personal information. In addition, while the content of these notes is generally not relevant to violations under this rule, we will secure the expertise of mental health professionals if needed in reviewing psychotherapy notes.

Comment: A mental health organization recommended prohibiting health plans and covered health care providers from disclosing psychotherapy notes to coroners or medical examiners.

Response: In general, we have severely limited disclosures of psychotherapy notes without the individual's authorization. One case where the information may prove invaluable, but authorization by the individual is impossible and authorization by a surrogate is potentially contraindicated, is in the investigation of the death of the individual. The final rule allows for disclosures to coroners or medical examiners in this limited case.

Comment: One commenter recommended prohibiting disclosure without authorization of psychotherapy notes to government health data systems.

Response: The decision to eliminate the general provision permitting disclosures to government health data systems addresses this comment.

Comment: Several commenters were concerned that in practice, a treatment team in a mental health facility shares information about a patient in order to care for the patient and that the provision requiring authorization for use and disclosure of psychotherapy notes would expose almost all privileged information to disclosure. They requested that we add a provision that any authorization or disclosure under that statute shall not constitute a waiver of the psychotherapist-patient privilege.

Response: Because of the restricted definition we have adopted for psychotherapy notes, we do not expect that members of a team will share such information. Information shared in order to care for the patient is, by definition, not protected as psychotherapy notes. With respect to waiving privilege, however, we believe that the consents and authorizations described in §§ 164.506 and 164.508 should not be construed as waivers of a patient's evidentiary privilege. See the discussions under § 164.506 and "Relationship to Other Laws," above.

Research Information Unrelated to Treatment

Definition of Research Information Unrelated to Treatment

Comment: The majority of commenters, including many researchers and health care providers, objected to the proposed definition of research information unrelated to treatment, asserting that the privacy rule should not distinguish research information unrelated to treatment from other forms of protected health information. Even those who supported the proposed distinction between research information related and unrelated to treatment suggested alternative definitions for research information unrelated to treatment.

A large number of commenters were concerned that the definition of research information unrelated to treatment was vague and unclear and, therefore, would be difficult or impossible to apply. These commenters asserted that in many instances it would not be feasible to ascertain whether research information bore some relation to treatment. In addition, several commenters asserted that the need for distinguishing research information unrelated to treatment from other forms of protected health information was not necessary because the proposed rule's general restrictions for the use and disclosure of protected health information and the existing protections for research information were sufficiently strong.

Of the commenters who supported the proposed distinction between research information related and unrelated to treatment, very few supported the proposed definition of research unrelated to treatment. A few commenters recommended that the definition incorporate a good faith provision and apply only to health care providers, because they thought it was unlikely that a health plan or health care clearinghouse would be conducting research. One commenter recommended defining research information unrelated to treatment as information which does not directly affect the treatment of the individual patient. As a means of clarifying and standardizing the application of this definition, one commenter also asserted that the definition should be based on whether the research information was for publication. In addition, one commenter specifically objected to the provision of the proposed definition that would have required that research information unrelated to treatment be information "with respect to which the covered entity has not requested payment from ***82655** a third party payor." This commenter asserted that patient protection should not be dependent on whether a health plan will pay for certain care.

Response: We agree with the commenters who found the proposed definition of research information unrelated to treatment to be impractical and infeasible to apply and have eliminated this definition and its related provisions in the final rule. Although we share concerns raised by some commenters that research information generated from research studies that involve the delivery of treatment to individual subjects may need additional privacy protection, we agree with the commenters who asserted that there is not always a clear distinction between research information that is related to treatment and research information that

is not. We found that the alternative definitions proposed by commenters did not alleviate the serious concerns raised by the majority of comments received on this definition.

Instead, in the final rule, we require covered entities that create protected health information for the purpose, in whole or in part, of research that includes treatment of individuals to include additional elements in authorizations they request for the use or disclosure of that protected health information. As discussed in § 164.508(f), these research-related authorizations must include a description of the extent to which some or all of the protected health information created for the research will also be used or disclosed for purposes of treatment, payment, and health care operations. For example, if the covered entity intends to seek reimbursement from the individual's health plan for the routine costs of care associated with the research protocol, it must explain in the authorization the types of information that it will provide to the health plan for this purpose. This information, and the circumstances under which disclosures will be made for treatment, payment, and health care operations, may be more limited than the information and circumstances described in the covered entity's general notice of information practices and are binding on the covered entity.

Under this approach, the covered entity that creates protected health information for research has discretion to determine whether there is a subset of research information that will have fewer allowable disclosures without authorization, and prospective research subjects will be informed about how research information about them would be used and disclosed should they agree to participate in the research study. We believe this provision in the final rule provides covered entities that participate in research necessary flexibility to enhance privacy protections for research information and provides prospective research subjects with needed information to determine whether their privacy interests would be adequately protected before agreeing to participate in a research study that involves the delivery of health care.

The intent of this provision is to permit covered entities that participate in research to bind themselves to a more limited scope of uses and disclosures for all or identified subsets of research information generated from research that involves the delivery of treatment than it may apply to other protected health information. In designing their authorizations, we expect covered entities to be mindful of the often highly sensitive nature of research information and the impact of individuals' privacy concerns on their willingness to participate in research. For example, a covered entity conducting a study which involves the evaluation of a new drug, as well as an assessment of a new un-validated genetic marker of a particular disease, could choose to stipulate in the research authorization that the genetic information generated from this study will not be disclosed without authorization for some of the public policy purposes that would otherwise be permitted by the rule under §§ 164.510 and 164.512 and by the covered entity's notice. A covered entity may not, however, include a limitation affecting its right to make a use or disclosure that is either required by law or is necessary to avert a serious and imminent threat to health or safety.

The final rule also permits the covered entity to combine the research authorization under § 164.508(f) with the consent to participate in research, such as the informed consent document as stipulated under the Common Rule or the Food and Drug Administration's human subjects regulations.

Enhance Privacy Protections for Research Information

Comment: A number of commenters argued that research information unrelated to treatment should have fewer allowable disclosures without authorization than those that would have been permitted by the proposed rule. The commenters who made this argument included those commenters who recommended that the privacy rule not cover the information we proposed to constitute research information unrelated to treatment, as well as those who asserted that the rule should cover such information. These commenters agreed with the concern expressed in the proposed rule that patients would be reluctant to participate in research if they feared that research information could be disclosed without their permission or used against them. They argued that fewer allowable disclosures should be permitted for research information because the clinical utility of the research information is most often unknown, and thus, it is unsuitable for use in clinical decision making. Others also argued that it is critical to the conduct of clinical research that researchers be able to provide individual research subjects, and the public at large, the greatest possible assurance that their privacy and the confidentiality of any individually identifiable research information will be protected from disclosure.

Several commenters further recommended that only the following uses and disclosures be permitted for research information unrelated to treatment without authorization: (1) For the oversight of the researcher or the research study; (2) for safety and efficacy reporting required by FDA; (3) for public health; (4) for emergency circumstances; or (5) for another research study. Other commenters recommended that the final rule explicitly prohibit law enforcement officials from gaining access to research records.

In addition, several commenters asserted that the rule should be revised to ensure that once protected health information was classified as research information unrelated to treatment, it could not be re-classified as something else at a later date. These commenters believed that if this additional protection were not added, this information would be vulnerable to disclosure in the future, if the information were later to gain scientific validity. They argued that individuals may rely on this higher degree of confidentiality when consenting to the collection of the information in the first instance, and that confidentiality should not be betrayed in the future just because the utility of the information has changed.

Response: We agree with commenters who argued that special protections may be appropriate for research information in order to provide research subjects with assurances that their decision to participate in research will not result in harm stemming from the misuse of the research information. We are aware that some researchers currently retain separate research records and medical records as a means of providing more stringent privacy protections for the research record. The final rule permits ***82656** covered entities that participate in research to continue to provide more stringent privacy protections for the research record, and the Secretary strongly encourages this practice to protect research participants from being harmed by the misuse of their research information.

As discussed above, in the final rule, we eliminate the special rules for this proposed definition of research information unrelated to treatment and its related provisions, so the comments regarding its application are moot.

Comment: Some commenters recommended that the final rule prohibit a covered entity from conditioning treatment, enrollment in a health plan, or payment on a requirement that the individual authorize the use or disclosure of information we proposed to constitute research information unrelated to treatment.

Response: Our decision to eliminate the definition of research information unrelated to treatment and its related provisions in the final rule renders this comment moot.

Comment: A few commenters opposed distinguishing between research information related to treatment and research information unrelated to treatment, arguing that such a distinction could actually weaken the protection afforded to clinically-related health information that is collected in clinical trials. These commenters asserted that Certificates of Confidentiality shield researchers from being compelled to disclose individually identifiable health information relating to biomedical or behavioral research information that an investigator considers sensitive.

Response: Our decision to eliminate the definition of research information unrelated to treatment and its related provisions in the final rule renders this comment moot. We would note that nothing in the final rule overrides Certificates of Confidentiality, which protect against the compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research as provided by the Public Health Service Act section 301(d), 42 U.S.C. 241(d).

Privacy Protections for Research Information Too Stringent

Comment: Many of the commenters who opposed the proposed definition of research information unrelated to treatment and its related provisions believed that the proposed rule would have required authorization before research information unrelated to treatment could have been used or disclosed for any of the public policy purposes outlined in proposed § 164.510, and that this restriction would have significantly hindered many important activities. Many of these commenters specifically opposed this

provision, arguing that the distinction would undermine and impede research by requiring patient authorization before research information unrelated to treatment could be used or disclosed for research.

Furthermore, some commenters recommended that the disclosure of research information should be governed by an informed consent agreement already in place as part of a clinical protocol, or its disclosure should be considered by an institutional review board or privacy board.

Response: Our decision to eliminate the definition of research information unrelated to treatment and its related provisions in the final rule renders the first two comments moot.

We disagree with the comment that suggests that existing provisions under the Common Rule are sufficient to protect the privacy interests of individuals who are subjects in research that involves the delivery of treatment. As discussed in the NPRM, not all research is subject to the Common Rule. In addition, we are not convinced that existing procedures adequately inform individuals about how their information will be used as part of the informed consent process. In the final rule, we provide for additional disclosure to subjects of research that involves the delivery of treatment as part of the research authorization under § 164.508(f). We also clarify that the research authorization could be combined with the consent to participate in research, such as the informed consent document as stipulated under the Common Rule or the Food and Drug Administration's human subjects regulations. The Common Rule (§_.116(a)(5)) requires that "informed consent" include "a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained." We believe that the research authorization requirements of § 164.508(f) complement the Common Rule's requirement for informed consent.

The Secretary's Authority

Comment: Several commenters, many from the research community, asserted that the coverage of "research information unrelated to treatment" was beyond the Department's legal authority since HIPAA did not give the Secretary authority to regulate researchers. These commenters argued that the research records held by researchers who are performing clinical trials and who keep separate research records should not be subject to the final rule. These commenters strongly disagreed that a health provider-researcher cannot carry out two distinct functions while performing research and providing clinical care to research subjects and, thus, asserted that research information unrelated to treatment that is kept separate from the medical record, would not be covered by the privacy rule.

Response: We do not agree the Secretary lacks the authority to adopt standards relating to research information, including research information unrelated to treatment. HIPAA provides authority for the Secretary to set standards for the use and disclosure of individually identifiable health information created or received by covered entities. For the reasons commenters identified for why it was not practical or feasible to divide research information into two categories—research information related to treatment and research information unrelated to treatment—we also determined that for a single research study that includes the treatment of research subjects, it is not practical or feasible to divide a researcher into two categories—a researcher who provides treatment and a researcher who does not provide treatment to research subjects. When a researcher is interacting with research subjects for a research study that involves the delivery of health care to subjects, it is not always clear to either the researcher or the research subject whether a particular research activity will generate research information that will be pertinent to the health care of the research subject. Therefore, we clarify that a researcher may also be a health care provider if that researcher provides health care, e.g., provides treatment to subjects in a research study, and otherwise meets the definition of a health care provider, regardless of whether there is a component of the research study that is unrelated to the health care of the research subjects. This researcher/health care provider is then a covered entity with regard to her provider activities if she conducts standard transactions.

Valid Authorizations

Comment: In proposed § 164.508(b)(1), we specified that an authorization containing the applicable required elements "must be accepted by the covered entity." A few comments requested clarification of this requirement. ***82657**

Response: We agree with the commenters that the proposed provision was ambiguous and we remove it from the final rule. We note that nothing in the rule requires covered entities to act on authorizations that they receive, even if those authorizations are valid. A covered entity presented with an authorization is permitted to make the disclosure authorized, but is not required to do so.

We want to be clear, however, that covered entities will be in compliance with this rule if they use or disclose protected health information pursuant to an authorization that meets the requirements of § 164.508. We have made changes in § 164.508(b)(1) to clarify this point. First, we specify that an authorization containing the applicable required elements is a valid authorization. A covered entity may not reject as invalid an authorization containing such elements. Second, we clarify that a valid authorization may contain elements or information in addition to the required elements, as long as the additional elements are not inconsistent with the required elements.

Comment: A few comments requested that we provide a model authorization or examples of wording meeting the "plain language" requirement. One commenter requested changes to the language in the model authorization to avoid confusion when used in conjunction with an insurer's authorization form for application for life or disability income insurance. Many other comments, however, found fault with the proposed model authorization form.

Response: Because of the myriad of types of forms that could meet these requirements and the desire to encourage covered entities to develop forms that meet their specific needs, we do not include a model authorization form in the final rule. We intend to issue additional guidance about authorization forms prior to the compliance date. We also encourage standard-setting organizations to develop model forms meeting the requirements of this rule.

Defective Authorizations

Comment: Some commenters suggested we insert a "good-faith reliance" or "substantial compliance" standard into the authorization requirements. Commenters suggested that covered entities should be permitted to rely on an authorization as long as the individual has signed and dated the document. They stated that individuals may not fill out portions of a form that they feel are irrelevant or for which they do not have an answer. They argued that requiring covered entities to follow up with each individual to complete the form will cause unwarranted delays. In addition, commenters were concerned that large covered entities might act in good faith on a completed authorization, only to find out that a component of the entity "knew" some of the information on the form to be false or that the authorization had been revoked. These commenters did not feel that covered entities should be held in violation of the rule in such situations.

Response: We retain the provision as proposed and include one additional element: the authorization is invalid if it is combined with other documents in violation of the standards for compound authorizations. We also clarify that an authorization is invalid if material information on the form is known to be false. The elements we require to be included in the authorization are intended to ensure that individuals knowingly and willingly authorize the use or disclosure of protected health information about them. If these elements are missing or incomplete, the covered entity cannot know which protected health information to use or disclose to whom and cannot be confident that the individual intends for the use or disclosure to occur.

We have attempted to make the standards for defective authorizations as unambiguous as possible. In most cases, the covered entity will know whether the authorization is defective by looking at the form itself. Otherwise, the covered entity must know that the authorization has been revoked, that material information on the form is false, or that the expiration date or event has occurred. If the covered entity does not know these things and the authorization is otherwise satisfactory on its face, the covered entity is permitted to make the use or disclosure in compliance with this rule.

We have added two provisions to make it easier for covered entities to "know" when an authorization has been revoked. First, under § 164.508(b)(5), the revocation must be made in writing. Second, under § 164.508(c)(1)(v), authorizations must include

instructions for how the individual may revoke the authorization. Written revocations submitted in the manner appropriate for the covered entity should ease covered entities' compliance burden.

Compound Authorizations

Comment: Many commenters raised concerns about the specificity of the authorization requirement. Some comments recommended that we permit covered entities to include multiple uses and disclosures in a single authorization and allow individuals to authorize or not authorize specific uses and disclosures in the authorization. Other commenters asked whether a single authorization is sufficient for multiple uses or disclosures for the same purpose, for multiple uses and disclosures for related purposes, and for uses and disclosures of different types of information for the same purpose. Some comments from health care providers noted that specific authorizations would aid their compliance with requests.

Response: As a general rule, we prohibit covered entities from combining an authorization for the use or disclosure of protected health information with any other document. For example, an authorization may not be combined with a consent to receive treatment or a consent to assign payment of benefits to a provider. We intend the authorizations required under this rule to be voluntary for individuals, and, therefore, they need to be separate from other forms of consent that may be a condition of treatment or payment or that may otherwise be coerced.

We do, however, permit covered entities to combine authorizations for uses and disclosures for multiple purposes into a single authorization. The only limitations are that an authorization for the use or disclosure of psychotherapy notes may not be combined with an authorization for the use or disclosure of other types of protected health information and that an authorization that is a condition of treatment, payment, enrollment, or eligibility may not be combined with any other authorization.

In § 164.508(b)(3), we also permit covered entities to combine an authorization for the use or disclosure of protected health information created for purposes of research including treatment of individuals with certain other documents.

We note that covered entities may only make uses or disclosures pursuant to an authorization that are consistent with the terms of the authorization. Therefore, if an individual agrees to one of the disclosures described in the compound authorization but not another, the covered entity must comply with the individual's decision. For example, if a covered entity asks an individual to sign an authorization to disclose protected health information for both marketing and fundraising purposes, but the individual only agrees to the fundraising disclosure, the ***82658** covered entity is not permitted to make the marketing disclosure.

Prohibition on Conditioning Treatment, Payment, Eligibility, or Enrollment

Comment: Many commenters supported the NPRM's prohibition of covered entities from conditioning treatment or payment on the individual's authorization of uses and disclosures. Some commenters requested clarification that employment can be conditioned on an authorization. Some commenters recommended that we eliminate the requirement for covered entities to state on the authorization form that the authorization is not a condition of treatment or payment. Some commenters suggested that we prohibit the provision of anything of value, including employment, from being conditioned on receipt of an authorization.

In addition, many commenters argued that patients should not be coerced into signing authorizations for a wide variety of purposes as a condition of obtaining insurance coverage. Some health plans, however, requested clarification that health plan enrollment and eligibility can be conditioned on an authorization.

Response: We proposed to prohibit covered entities from conditioning treatment, payment, or enrollment in a health plan on an authorization for the use or disclosure of psychotherapy notes (see proposed § 164.508(a)(3)(iii)). We proposed to prohibit covered entities from conditioning treatment or payment on authorization for the use or disclosure of any other protected health information (see proposed § 164.508(a)(2)(iii)).

We resolve this inconsistency by clarifying in § 164.508(b)(4) that, with certain exceptions, a covered entity may not condition the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits on an authorization for the use or disclosure of any protected health information, including psychotherapy notes. We intend to minimize the potential for covered entities to coerce individuals into signing authorizations for the use or disclosure of protected health information when such information is not essential to carrying out the relationship between the individual and the covered entity.

Pursuant to that goal, we have created limited exceptions to the prohibition. First, a covered health care provider may condition research-related treatment of an individual on obtaining the individual's authorization to use or disclose protected health information created for the research. Second, except with respect to psychotherapy notes, a health plan may condition the individual's enrollment or eligibility in the health plan on obtaining an authorization for the use or disclosure of protected health information for making enrollment or eligibility determinations relating to the individual or for its underwriting or risk rating determinations. Third, a health plan may condition payment of a claim for specified benefits on obtaining an authorization under § 164.508(e) for disclosure to the plan of protected health information necessary to determine payment of the claim. Fourth, a covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party (such as fitness-for-duty exams and physicals necessary to obtain life insurance coverage) on obtaining an authorization for the disclosure of the protected health information. We recognize that covered entities need protected health information in order to carry out these functions and provide services to the individual; therefore, we allow authorization for the disclosure of the protected health information to be a condition of obtaining the services.

We believe that we have prohibited covered entities from conditioning the services they provide to individuals on obtaining an authorization for uses and disclosures that are not essential to those services. Due to our limited authority, however, we cannot entirely prevent individuals from being coerced into signing these forms. We do not, for example, have the authority to prohibit an employer from requiring its employees to sign an authorization as a condition of employment. Similarly, a program such as the Job Corps may make such an authorization a condition of enrollment in the Job Corps program. While the Job Corps may include a health care component, the non-covered component of the Job Corps may require as a condition of enrollment that the individual authorize the health care component to disclose protected health information to the non-covered component. See § 164.504(b). However, we note that other nondiscrimination laws may limit the ability to condition these authorizations as well.

Comment: A Medicaid fraud control association stated that many states require or permit state Medicaid agencies to obtain an authorization for the use and disclosure of protected health information for payment purposes as a condition of enrolling an individual as a Medicaid recipient. The commenter, therefore, urged an exception to the prohibition on conditioning enrollment on obtaining an authorization.

Response: As explained above, under § 164.506(a)(4), health plans and other covered entities may seek the individual's consent for the covered entity's use and disclosure of protected health information to carry out treatment, payment, or health care operations. If the consent is sought in conjunction with enrollment, the health plan may condition enrollment in the plan on obtaining the individual's consent.

Under § 164.506(a)(5), we specify that a consent obtained by one covered entity is not effective to permit another covered entity to use or disclose protected health information for payment purposes. If state law requires a Medicaid agency to obtain the individual's authorization for providers to disclose protected health information to the Medicaid agency for payment purposes, the agency may do so under § 164.508(e). This authorization must not be a condition of enrollment or eligibility, but may be a condition of payment of a claim for specified benefits if the disclosure is necessary to determine payment of the claim.

Revocation of Authorizations

Comment: Many commenters supported the right to revoke an authorization. Some comments, however, suggested that we require authorizations to remain valid for a minimum period of time, such as one year or the duration of the individual's enrollment in a health plan.

Response: We retain the right for individuals to revoke an authorization at any time, with certain exceptions. We believe this right is essential to ensuring that the authorization is voluntary. If an individual determines that an authorized use or disclosure is no longer in her best interest, she should be able to withdraw the authorization and prevent any further uses or disclosures.

Comment: Several commenters suggested that we not permit individuals to revoke an authorization if the revocation would prevent an investigation of material misrepresentation or fraud. Other commenters similarly suggested that we not permit individuals to revoke an authorization prior to a claim for benefits if the insurance was issued in reliance on the authorization.

Response: To address this concern, we include an additional exception to the right to revoke an authorization. Individuals do not have the right to revoke an authorization that was obtained as a condition of insurance coverage during any contestability ***82659** period under other law. For example, if a life insurer obtains the individual's authorization for the use or disclosure of protected health information to determine eligibility or premiums under the policy, the individual does not have the right to revoke the authorization during any period of time in which the life insurer can contest a claim for benefits under the policy in accordance with state law. If an individual were able to revoke the authorization after enrollment but prior to making a claim, the insurer would be forced to pay claims without having the necessary information to determine whether the benefit is due. We believe the existing exception for covered entities that have acted in reliance on the authorization is insufficient to address this concern because it is another person, not the covered entity, that has acted in reliance on the authorization. In the life insurance example, it is the life insurer that has taken action (i.e., issued the policy) in reliance on the authorization. The life insurer is not a covered entity, therefore the covered entity exception is inapplicable.

Comment: Some comments suggested that a covered entity that had compiled, but not yet disclosed, protected health information would have already taken action in reliance on the authorization and could therefore disclose the information even if the individual revoked the authorization.

Response: We intend for covered entities to refrain from further using or disclosing protected health information to the maximum extent possible once an authorization is revoked. The exception exists only to the extent the covered entity has taken action in reliance on the authorization. If the covered entity has not yet used or disclosed the protected health information, it must refrain from doing so, pursuant to the revocation. If, however, the covered entity has already disclosed the information, it is not required to retrieve the information.

Comment: One comment suggested that the rule allow protected health information to be only rented, not sold, because there can be no right to revoke authorization for disclosure of protected health information that has been sold.

Response: We believe this limitation would be an unwarranted abrogation of covered entities' business practices and outside the scope of our authority. We believe individuals should have the right to authorize any uses or disclosures they feel are appropriate. We have attempted to create authorization requirements that make the individual's decisions as clear and voluntary as possible.

Comment: One commenter expressed concern as to whether the proposed rule's standard to protect the protected health information about a deceased individual for two years would interfere with the payment of death benefit claims. The commenter asked that the regulation permit the beneficiary or payee under a life insurance policy to authorize disclosure of protected health information pertaining to the cause of death of a decedent or policyholder. Specifically, the commenter explained that when substantiating a claim a beneficiary, such as a fiancee or friend, may be unable to obtain the authorization required to release information to the insurer, particularly if, for example, the decedent's estate does not require probate or if the beneficiary is not on good terms with the decedent's next of kin. Further, the commenter stated that particularly in cases where the policyholder dies within two years of the policy's issuance (within the policy's contestable period) and the cause of death is uncertain, the insurer's inability to access relevant protected health information would significantly interfere with claim payments and increase administrative costs.

Response: We do not believe this will be a problem under the final regulation, because we create an exception to the right to revoke an authorization if the authorization was obtained as a condition of obtaining insurance coverage and other applicable law provides the insurer that obtained the authorization with the right to contest a claim under the policy. Thus, if a policyholder dies within the two year contestability period, the authorization the insurer obtained from the policyholder prior to death could not be revoked during the contestability period.

Core Elements and Requirements

Comment: Many commenters raised concerns about the required elements for a valid authorization. They argued that the requirements were overly burdensome and that covered entities should have greater flexibility to craft authorizations that meet their business needs. Other commenters supported the required elements as proposed because the elements help to ensure that individuals make meaningful, informed choices about the use and disclosure of protected health information about them.

Response: As in the proposed rule, we define specific elements that must be included in any authorization. We draw on established laws and guidelines for these requirements. For example, the July 1977 Report of the Privacy Protection Study Commission recommended that authorizations obtained by insurance institutions include plain language, the date of authorization, and identification of the entities authorized to disclose information, the nature of the information to be disclosed, the entities authorized to receive information, the purpose(s) for which the information may be used by the recipients, and an expiration date.[FN13] The Commission made similar recommendations concerning the content of authorizations obtained by health care providers.[FN14] The National Association of Insurance Commissioners' Health Information Privacy Model Act requires authorizations to be in writing and include a description of the types of protected health information to be used or disclosed, the name and address of the person to whom the information is to be disclosed, the purpose of the authorization, the signature of the individual or the individual's representative, and a statement that the individual may revoke the authorization at any time, subject to the rights of any person that acted in reliance on the authorization prior to revocation and provided the revocation is in writing, dated, and signed. Standards of the American Society for Testing and Materials recommend that authorizations identify the subject of the protected health information to be disclosed; the name of the person or institution that is to release the information; the name of each individual or institution that is to receive the information; the purpose or need for the information; the information to be disclosed; the specific date, event, or condition upon which the authorization will expire, unless revoked earlier; and the signature and date signed. They also recommend the authorization include a statement that the authorization can be revoked or amended, but not retroactive to a release made in reliance on the authorization.[FN15]

Comment: Some commenters requested clarification that authorizations “initiated by the individual” include authorizations initiated by the individual's representative. ***82660**

Response: In the final rule, we do not classify authorizations as those initiated by the individual versus those initiated by a covered entity. Instead, we establish a core set of elements and requirements that apply to all authorizations and require certain additional elements for particular types of authorizations initiated by covered entities.

Comment: Some commenters urged us to permit authorizations that designate a class of entities, rather than specifically named entities, that are authorized to use or disclose protected health information. Commenters made similar recommendations with respect to the authorized recipients. Commenters suggested these changes to prevent covered entities from having to seek, and individuals from having to sign, multiple authorizations for the same purpose.

Response: We agree. Under § 164.508(c)(1), we require authorizations to identify both the person(s) authorized to use or disclose the protected health information and the person(s) authorized to receive protected health information. In both cases, we permit the authorization to identify either a specific person or a class of persons.

Comment: Many commenters requested clarification that covered entities may rely on electronic authorizations, including electronic signatures.

Response: All authorizations must be in writing and signed. We intend e-mail and electronic documents to qualify as written documents. Electronic signatures are sufficient, provided they meet standards to be adopted under HIPAA. In addition, we do not intend to interfere with the application of the Electronic Signature in Global and National Commerce Act.

Comment: Some commenters requested that we permit covered entities to use and disclose protected health information pursuant to verbal authorizations.

Response: To ensure compliance and mutual understanding between covered entities and individuals, we require all authorizations to be in writing.

Comment: Some commenters asked whether covered entities can rely on copies of authorizations rather than the original. Other comments asked whether covered entities can rely on the assurances of a third party, such as a government entity, that a valid authorization has been obtained to use or disclose protected health information. These commenters suggested that such procedures would promote the timely provision of benefits for programs that require the collection of protected health information from multiple sources, such as determinations of eligibility for disability benefits.

Response: Covered entities must obtain the individual's authorization to use or disclose protected health information for any purpose not otherwise permitted or required under this rule. They may obtain this authorization directly from the individual or from a third party, such as a government agency, on the individual's behalf. In accordance with the requirements of § 164.530(j), the covered entity must retain a written record of authorization forms signed by the individual. Covered entities must, therefore, obtain the authorization in writing. They may not rely on assurances from others that a proper authorization exists. They may, however, rely on copies of authorizations if doing so is consistent with other law.

Comment: We requested comments on reasonable steps that a covered entity could take to be assured that the individual who requests the disclosure is whom she or he purports to be. Some commenters stated that it would be extremely difficult to verify the identity of the person signing the authorization, particularly when the authorization is not obtained in person. Other comments recommended requiring authorizations to be notarized.

Response: To reduce burden on covered entities, we are not requiring verification of the identities of individuals signing authorization forms or notarization of the forms.

Comment: A few commenters asked for clarification regarding the circumstances in which a covered entity may consider a non-response as an authorization.

Response: Non-responses to requests for authorizations cannot be considered authorizations. Authorizations must be signed and have the other elements of a valid authorization described above.

Comment: Most commenters generally supported the requirement for an expiration date on the authorization. Commenters recommended expiration dates from 6 months to 3 years and/or proposed that the expiration be tied to an event such as duration of enrollment or when an individual changes health plans. Others requested no expiration requirement for some or all authorizations.

Response: We have clarified that an authorization may include an expiration date in the form of a specific date, a specific time period, or an event directly related to the individual or the purpose of the authorization. For example, a valid authorization could expire upon the individual's disenrollment from a health plan or upon termination of a research project. We prohibit an authorization from having an indeterminate expiration date.

These changes were intended to address situations in which a specific date for the termination of the purpose for the authorization is difficult to determine. An example may be a research study where it may be difficult to predetermine the length of the project.

Comment: A few commenters requested that the named insured be permitted to sign an authorization on behalf of dependents.

Response: We disagree with the commenter that a named insured should always be able to authorize uses and disclosures for other individuals in the family. Many dependents under group health plans have their own rights under this rule, and we do not assume that one member of a family has the authority to authorize uses or disclosures of the protected health information of other family members.

A named insured may sign a valid authorization for an individual if the named insured is a personal representative for the individual in accordance with § 164.502(g). The determination of whether an individual is a personal representative under this rule is based on other applicable law that determines when a person can act on behalf of an individual in making decisions related to health care. This rule limits a person's rights and authorities as a personal representative to only the protected health information relevant to the matter for which he or she is a personal representative under other law. For example, a parent may be a personal representative of a child for most health care treatment and payment decisions under state law. In that case, a parent, who is a named insured for her minor child, would be able to provide authorization with respect to most protected health information about her dependent child. However, a wife who is the named insured for her husband who is a dependent under a health insurance policy may not be a personal representative for her husband under other law or may be a personal representative only for limited purposes, such as for making decisions regarding payment of disputed claims. In this case, she may have limited authority to access protected health information related to the payment of disputed claims, but would not have the authority to authorize that her husband's information be used for ***82661** marketing purposes, absent any other authority to act for her husband. See § 164.502(g) for more information regarding personal representatives.

Comment: One commenter suggested that authorizations should be dated on the day they are signed.

Response: We agree and have retained this requirement in the final rule.

Additional Elements and Requirements for Authorizations Requested by the Covered Entity for Its Own Uses and Disclosures

Comment: Some commenters suggested that we should not require different elements in authorizations initiated by the covered entity versus authorizations initiated by the individual. The commenters argued the standards were unnecessary, confusing, and burdensome.

Response: The proposed authorization requirements are intended to ensure that an individual's authorization is truly voluntary. The additional elements required for authorizations initiated by the covered entity for its own uses and disclosures or for receipt of protected health information from other covered entities to carry out treatment, payment, or health care operations address concerns that are unique to these forms of authorization. (See above regarding requirements for research authorizations under § 164.508(f).)

First, when applicable, these authorizations must state that the covered entity will not condition treatment, payment, eligibility, or enrollment on the individual's providing authorization for the requested use or disclosure. This statement is not appropriate for authorizations initiated by the individual or another person who does not have the ability to withhold services if the individual does not authorize the use or disclosure.

Second, the authorization must state that the individual may refuse to sign the authorization. This statement is intended to signal to the individual that the authorization is voluntary and may not be accurate if the authorization is obtained by a person other than a covered entity.

Third, these authorizations must describe the purpose of the use or disclosure. We do not include this element in the core requirements because we understand there may be times when the individual does not want the covered entity maintaining the

protected health information to know the purpose for the use or disclosure. For example, an individual contemplating litigation may not want the covered entity to know that litigation is the purpose of the disclosure. If the covered entity is initiating the authorization for its own use or disclosure, however, the individual and the covered entity maintaining the protected health information should have a mutual understanding of the purpose of the use or disclosure. Similarly, when a covered entity is requesting authorization for a disclosure by another covered entity that may have already obtained the individual's consent for the disclosure, the individual and covered entity that maintains the protected health information should be aware of this potential conflict.

There are two additional requirements for authorizations requested by a covered entity for its own use or disclosure of protected health information it maintains. First, we require the covered entity to describe the individual's right to inspect or copy the protected health information to be used or disclosed. Individuals may want to review the information to be used or disclosed before signing the authorization and should be reminded of their ability to do so. This requirement is not appropriate for authorizations for a covered entity to receive protected health information from another covered entity, however, because the covered entity requesting the authorization is not the covered entity that maintains the protected health information and cannot, therefore, grant or describe the individual's right to access the information.

If applicable, we also require a covered entity that requests an authorization for its own use or disclosure to state that the use or disclosure of the protected health information will result in direct or indirect remuneration to the entity. Individuals should be aware of any conflicts of interest or financial incentives on the part of the covered entity requesting the use or disclosure. These statements are not appropriate, however, in relation to uses and disclosures to carry out treatment, payment, and health care operations. Uses and disclosures for these purposes will often involve remuneration by the nature of the use or disclosure, not due to any conflict of interest on the part of either covered entity.

We note that authorizations requested by a covered entity include authorizations requested by the covered entity's business associate on the covered entity's behalf. Authorizations requested by a business associate on the covered entity's behalf and that authorize the use or disclosure of protected health information by the covered entity or the business associate must meet the requirements in § 164.508(d). Similarly, authorizations requested by a business associate on behalf of a covered entity to accomplish the disclosure of protected health information to that business associate or covered entity as described in § 164.508(e) must meet the requirements of that provision.

We disagree that these elements are unnecessary, confusing, or burdensome. We require them to ensure that the individual has a complete understanding of what he or she is agreeing to permit.

Comment: Many commenters suggested we include in the regulation text a provision stated in the preamble that entities and their business partners must limit their uses and disclosures to the purpose(s) specified by the individual in the authorization.

Response: We agree. In accordance with § 164.508(a)(1), covered entities may only use or disclose protected health information consistent with the authorization. In accordance with § 164.504(e)(2), a business associate may not make any uses or disclosures that the covered entity couldn't make.

Comment: Some comments suggested that authorizations should identify the source and amount of financial gain, if any, resulting from the proposed disclosure. Others suggested that the proposed financial gain requirements were too burdensome and would decrease trust between patients and providers. Commenters recommended that the requirement either should be eliminated or should only require covered entities, when applicable, to state that direct and foreseeable financial gain to the covered entity will result. Others requested clarification of how the requirement for covered entities to disclose financial gain relates to the criminal penalties that accrue for offenses committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm. Some commenters advocated use of the term “financial compensation” rather than “financial gain” to avoid confusion with in-kind compensation rules. Some comments additionally suggested excluding marketing uses and disclosures from the requirements regarding financial gain.

Response: We agree that clarification is warranted. In § 164.508(d)(1)(iv) of the final rule, we require a covered entity that asks an individual to sign an authorization for the covered entity's use or disclosure of protected health information and that will receive direct ***82662** or indirect remuneration from a third party for the use or disclosure, to state that fact in the authorization. Remuneration from a third party includes payments such as a fixed price per disclosure, compensation for the costs of compiling and sending the information to be disclosed, and, with respect to marketing communications, a percentage of any sales generated by the marketing communication. For example, a device manufacturer may offer to pay a fixed price per name and address of individuals with a particular diagnosis, so that the device manufacturer can market its new device to people with the diagnosis. The device manufacturer may also offer the covered entity a percentage of the profits from any sales generated by the marketing materials sent. If a covered entity seeks an authorization to make such a disclosure, the authorization must state that the remuneration will occur. We believe individuals should have the opportunity to weigh the covered entity's potential conflict of interest when deciding to authorize the covered entity's use or disclosure of protected health information. We believe that the term "remuneration from a third party" clarifies our intent to describe a direct, tangible exchange, rather than the mere fact that parties intend to profit from their enterprises.

Comment: One commenter suggested we require covered entities to request authorizations in a manner that does not in itself disclose sensitive information.

Response: We agree that covered entities should make reasonable efforts to avoid unintentional disclosures. In § 164.530(c)(2), we require covered entities to have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

Comment: Some commenters requested clarification that covered entities are permitted to seek authorization at the time of enrollment or when individuals otherwise first interact with covered entities. Similarly, commenters requested clarification that covered entities may disclose protected health information created after the date the authorization was signed but prior to the expiration date of the authorization. These commenters were concerned that otherwise multiple authorizations would be required to accomplish a single purpose. Other comments suggested that we prohibit prospective authorizations (i.e., authorizations requested prior to the creation of the protected health information to be disclosed under the authorization) because it is not possible for individuals to make informed decisions about these authorizations.

Response: We confirm that covered entities may act on authorizations signed in advance of the creation of the protected health information to be released. We note, however, that all of the required elements must be completed, including a description of the protected health information to be used or disclosed pursuant to the authorization. This description must identify the information in a specific and meaningful fashion so that the individual can make an informed decision as to whether to sign the authorization.

Comment: Some commenters suggested that the final rule prohibit financial incentives, such as premium discounts, designed to encourage individuals to sign authorizations.

Response: We do not prohibit or require financial incentives for authorizations. We have attempted to ensure that authorizations are entered into voluntary. If a covered entity chooses to offer a financial incentive for the individual to sign the authorization, and the individual chooses to accept it, they are free to do so.

Section 164.510—Uses and Disclosures Requiring an Opportunity for the Individual to Agree or to Object

Section 164.510(a)—Use and Disclosure for Facility Directories

Comment: Many hospital organizations opposed the NPRM's proposed opt-in approach to disclosure of directory information. These groups noted the preamble's statement that most patients welcomed the convenience of having their name, location, and general condition included in the patient directory. They said that requiring hospitals to obtain authorization before including patient information in the directory would cause harm to many patients' needs in an effort to serve the needs of the small number

of patients who may not want their information to be included. Specifically, they argued that the proposed approach ultimately could have the effect of making it difficult or impossible for clergy, family members, and florists to locate patients for legitimate purposes. In making this argument, commenters pointed to problems that occurred after enactment of privacy legislation in the State of Maine in 1999. The legislation, which never was officially implemented, was interpreted by hospitals to prohibit disclosure of patient information to directories without written consent. As a result, when hospitals began complying with the law based on their interpretation, family members and clergy had difficulty locating patients in the hospital.

Response: We share commenters' concern about the need to ensure that family members and clergy who have a legitimate need to locate patients are not prevented from doing so by excessively stringent restrictions on disclosure of protected health information to health care facilities' directories. Accordingly, the final rule takes an opt-out approach, stating that health care institutions may include the name, general condition, religious affiliation, and location of a patient within the facility in the facility's directory unless the patient explicitly objects to the use or disclosure of protected health information for directory purposes. To ensure that this opt-out can be exercised, the final rule requires facilities to notify individuals of their right not to be included in the directory and to give them the opportunity to opt out. The final rule indicates that the notice and opt-out may be oral. The final rule that allows health care facilities to disclose to clergy the four types of protected health information specified above without requiring the clergy to ask for the individual by name will allow the clergy to identify the members of his or her faith who are in the facility, thus ensuring that this rule will not significantly interfere with the exercise of religion, including the clergy's traditional religious mission to provide services to individuals.

Comment: A small number of commenters recommended requiring written authorization for all disclosures of protected health information for directory purposes. These commenters believed that the NPRM's proposed provision allowing oral agreement would not provide sufficient privacy protection; that it did not sufficiently hold providers accountable for complying with patient wishes; and that it could create liability issues for providers.

Response: The final rule does not require written authorization for disclosure of protected health information for directory purposes. We believe that requiring written authorization in these cases would increase substantially the administrative burdens and costs for covered health care providers and could lead to significant inconvenience for families and others attempting to locate individuals in health care institutions. Experience from the State of Maine suggests that requiring written authorization before patient information may be included in facility directories ***82663** can be disruptive for providers, families, clergy, and others.

Comment: Domestic violence organizations raised concerns that including information about domestic violence victims in health care facilities' directories could result in further harm to victims. The NPRM addressed the issue of potential danger to patients by stating that when patients were incapacitated, covered health care providers could exercise discretion —consistent with good medical practice and prior expression of patient preference—regarding whether to disclose protected health information for directory purposes. Several commenters recommended prohibiting providers from including information in a health care facility's directory about incapacitated individuals when the provider reasonably believed that the injuries to the individual could have been caused by domestic violence. These groups believed that such a prohibition was necessary to prevent abusers from locating and causing further harm to domestic violence patients.

Response: We share commenters' concerns about protecting victims of domestic violence from further abuse. We are also concerned, however, that imposing an affirmative duty on institutions not to disclose information any time injuries to the individual could have been the result of domestic violence would place too high a burden on health care facilities, essentially requiring them to rule out domestic violence as a potential cause of the injuries before disclosing to family members that an incapacitated person is in the institution.

We do believe, however, that it is appropriate to require covered health care providers to consider whether including the individual's name and location in the directory could lead to serious harm. As in the preamble to the NPRM, in the preamble to the final rule, we encourage covered health care providers to consider several factors when deciding whether to include an

incapacitated patient's information in a health care facility's directory. One of these factors is whether disclosing an individual's presence in the facility could reasonably cause harm or danger to the individual (for example, if it appeared that an unconscious patient had been abused and disclosing that the individual is in the facility could give the attacker sufficient information to seek out the person and repeat the abuse). Under the final rule, when the opportunity to object to uses and disclosures for a facility's directory cannot practicably be provided due to an individual's incapacity or an emergency treatment circumstance, covered health care providers may use or disclose some or all of the protected health information that the rule allows to be included in the directory, if the disclosure is: (1) consistent with the individual's prior expressed preference, if known to the covered health care provider; and (2) in the individual's best interest, as determined by the covered health care provider in the exercise of professional judgement. The rule allows covered health care providers making decisions about incapacitated patients to include some portions of the patient's information (such as name) but not other information (such as location in the facility) to protect patient interests.

Section 164.510(b)—Uses and Disclosures for Involvement in the Individual's Care and Notification Purposes

Comment: A number of comments supported the NPRM's proposed approach, which would have allowed covered entities to disclose protected health information to the individual's next of kin, family members, or other close personal friends when the individual verbally agreed to the disclosure. These commenters agreed that the presumption should favor disclosures to the next of kin, and they believed that health care providers should encourage individuals to share genetic information and information about transmittable diseases with family members at risk. Others agreed with the general approach but suggested the individual's agreement be noted in the medical record. These commenters also supported the NPRM's proposed reliance on good professional practices and ethics to determine when disclosures should be made to the next of kin when the individual's agreement could not practicably be obtained.

A few commenters recommended that the individual's agreement be in writing for the protection of the covered entity and to facilitate the monitoring of compliance with the individual's wishes. These commenters were concerned that, absent the individual's written agreement, the covered entity would become embroiled in intra-family disputes concerning the disclosures. Others argued that the individual's authorization should be obtained for all disclosures, even to the next of kin.

One commenter favored disclosures to family members and others unless the individual actively objected, as long as the disclosure was consistent with sound professional practice. Others believed that no agreement by the individual was necessary unless sensitive medical information would be disclosed or unless the health care provider was aware of the individual's prior objection. These commenters recommended that good professional practice and ethics determine when disclosures were appropriate and that disclosure should relate only to the individual's current treatment. A health care provider organization said that the ethical and legal obligations of the medical professional alone should control in this area, although it believed the proposed rule was generally consistent with these obligations.

Response: The diversity of comments regarding the proposal on disclosures to family members, next of kin, and other persons, reflects a wide range of current practice and individual expectations. We believe that the NPRM struck the proper balance between the competing interests of individual privacy and the need that covered health care providers may have, in some cases, to have routine, informal conversations with an individual's family and friends regarding the individual's treatment.

We do not agree with the comments stating that all such disclosures should be made only with consent or with the individual's written authorization. The rule does not prohibit obtaining the agreement of the individual in writing; however, we believe that imposing a requirement for consent or written authorization in all cases for disclosures to individuals involved in a person's care would be unduly burdensome for all parties. In the final rule, we clarify the circumstances in which such disclosures are permissible. The rule allows covered entities to disclose to family members, other relatives, close personal friends of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care. In addition, the final rule allows covered entities to use or disclose protected health information to notify, or assist in the notification of (including identifying or locating) a family member, a personal representative of the individual, or another person responsible for the care of the

individual, of the individual's location, general condition, or death. The final rule includes separate provisions for situations in which the individual is present and for when the individual is not present at the time of disclosure. When the individual is present and can make his or her own decisions, a covered entity may disclose protected health information only if the covered entity: (1) Obtains the ***82664** individual's agreement to disclose to the third parties involved in the individual's care; (2) provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or (3) reasonably infers from the circumstances, based on the exercise of professional judgement, that the individual does not object to the disclosure. The final rule continues to permit disclosures in circumstances when the individual is not present or when the opportunity to agree or object to the use or disclosure cannot practicably be provided due to the individual's incapacity or an emergency circumstance. In such instances, covered entities may, in the exercise of professional judgement, determine whether the disclosure is in the individual's best interests and if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care.

As discussed in the preamble for this section, we do not intend to disrupt most covered entities' current practices with respect to informing family members and others with whom a patient has a close personal relationship about a patient's specific health condition when a patient is incapacitated due to a medical emergency and the family member or close personal friend comes to the covered entity to ask about the patient's condition. To the extent that disclosures to family members and others in these situations currently are allowed under state law and covered entities' own rules, § 164.510(b) allows covered entities to continue making them in these situations, consistent with the exercise of professional judgement as to the patient's best interest. As indicated in the preamble above, this section is not intended to provide a loophole for avoiding the rule's other requirements, and it is not intended to allow disclosures to a broad range of individuals, such as journalists who may be curious about a celebrity's health status.

Comments: A few comments supported the NPRM approach because it permitted the current practice of allowing someone other than the patient to pick up prescriptions at pharmacies. One commenter noted that this practice occurs with respect to 25-40% of the prescriptions dispensed by community retail pharmacies. These commenters strongly supported the proposal's reliance on the professional judgement of pharmacists in allowing others to pick up prescriptions for bedridden or otherwise incapacitated patients, noting that in most cases it would be impracticable to verify that the person was acting with the individual's permission. Two commenters requested that the rule specifically allow this practice. One comment opposed the practice of giving prescriptions to another person without the individual's authorization, because a prescription implicitly could disclose medical information about the individual.

Response: As stated in the NPRM, we intended for this provision to authorize pharmacies to dispense prescriptions to family or friends who are sent by the individual to the pharmacy to pick up the prescription. We believe that stringent consent or verification requirements would place an unreasonable burden on numerous transactions. In addition, such requirements would be contrary to the expectations and preferences of all parties to these transactions. Although prescriptions are protected health information under the rule, we believe that the risk to individual privacy in allowing this practice to continue is minimal. We agree with the suggestion that the final rule should state explicitly that pharmacies have the authority to operate in this manner. Therefore, we have added a sentence to § 164.510(b)(3) allowing covered entities to use professional judgement and experience with common practice to make reasonable inferences of an individual's best interest in allowing a person to act on the individual's behalf to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information. In such situations, as when making disclosures of protected health information about an individual who is not present or is unable to agree to such disclosures, covered entities should disclose only information which directly relates to the person's involvement in the individual's current health care. Thus, when dispensing a prescription to a friend who is picking it up on the patient's behalf, the pharmacist should not disclose unrelated health information about medications that the patient has taken in the past which could prove embarrassing to the patient.

Comment: We received a few comments that misunderstood the provision as addressing disclosures related to deceased individuals.

Response: We understand that use of the term next of kin in this section may cause confusion. To promote clarity in the final rule, we eliminate the term "next of kin," as well as the term's proposed definition. In the final rule, we address comments on next of kin and the deceased in the section on disclosure of protected health information about deceased individuals in § 164.512(g).

Comments: A number of commenters expressed concern for the interaction of the proposed section with state laws. Some of these comments interpreted the NPRM's use of the term next of kin as referring to individuals with health care power of attorney and thus they believed that the proposed rule's approach to next of kin was inappropriately informal and in conflict with state law. Others noted that some state laws did not allow health care information to be disclosed to family or friends without consent or other authorization. One commenter said that case law may be evolving toward imposing a more affirmative duty on health care practitioners to inform next of kin in a variety of circumstances. One commenter noted that state laws may not define clearly who is considered to be the next of kin.

Response: The intent of this provision was not to interfere with or change current practice regarding health care powers of attorney or the designation of other personal representatives. Such designations are formal, legal actions which give others the ability to exercise the rights of or make treatment decisions related to individuals. While persons with health care powers of attorney could have access to protected health information under the personal representatives provision (§ 164.502(g)), and covered entities may disclose to such persons under this provision, such disclosures do not give these individuals substantive authority to act for or on behalf of the individual with respect to health care decisions. State law requirements regarding health care powers of attorney continue to apply.

The comments suggesting that state laws may not allow the disclosures otherwise permitted by this provision or, conversely, that they may impose a more affirmative duty, did not provide any specifics with which to judge the affect of such laws. In general, however, state laws that are more protective of an individual's privacy interests than the rule by prohibiting a disclosure of protected health information continue to apply. The rule's provisions regarding disclosure of protected health information to family or friends of the individual are permissive only, enabling covered entities to abide by more stringent state laws without violating our rules. Furthermore, if the state law creates an affirmative and binding legal obligation on the covered entity to make disclosures to family or other persons under specific circumstances, the final rule allows covered entities to comply ***82665** with these legal obligations. See § 164.512(a).

Comments: A number of commenters supported the proposal to limit disclosures to family or friends to the protected health information that is directly relevant to that person's involvement in the individual's health care. Some comments suggested that this standard apply to all disclosures to family or friends, even when the individual has agreed to or not objected to the disclosure. One commenter objected to the proposal, stating that it would be too difficult to administer. According to this comment, it is accepted practice for health care providers to communicate with family and friends about an individual's condition, regardless of whether the person is responsible for or otherwise involved in the individual's care.

Other comments expressed concern for disclosures related to particular types of information. For example, two commenters recommended that psychotherapy notes not be disclosed without patient authorization. One commenter suggested that certain sensitive medical information associated with social stigma not be disclosed to family members or others without patient consent.

Response: We agree with commenters who advocated limiting permissible disclosures to relatives and close personal friends to information consistent with a person's involvement in the individual's care. Under the final rule, we clarify the NPRM provision to state that covered entities may disclose protected health information to family members, relatives, or close personal friends of an individual or any other person identified by the individual, to the extent that the information directly relates to the person's involvement in the individual's current health care. It is not intended to allow disclosure of past medical history that is not relevant to the individual's current condition. In addition, as discussed above, we do not intend to disrupt covered entities' current practices with respect to disclosing specific information about a patient's condition to family members or others when the individual is incapacitated due to a medical emergency and the family member or other individual comes to the covered

entity seeking specific information about the patient's condition. For example, this section allows a hospital to disclose to a family member the fact that a patient had a heart attack, and to provide updated information to the family member about the patient's progress and prognosis during his or her period of incapacity.

We agree with the recommendation to require written authorization for a disclosure of psychotherapy notes to family, close personal friends, or others involved in the individual's care. As discussed below, the final rule allows disclosure of psychotherapy notes without authorization in a few limited circumstances; disclosure to individuals involved in a person's care is not among those circumstances. See § 164.508 for a further discussion of the final rule's provisions regarding disclosure of psychotherapy notes.

We do not agree, however, with the suggestion to treat some medical information as more sensitive than others. In most cases, individuals will have the opportunity to prohibit or limit such disclosures. For situations in which an individual is unable to do so, covered entities may, in the exercise of professional judgement, determine whether the disclosure is in the individual's best interests and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care.

Comment: One commenter suggested that this provision should allow disclosure of protected health information to the clergy and to the Red Cross. The commenter noted that clergy have ethical obligations to ensure confidentiality and that the Red Cross often notifies the next of kin regarding an individual's condition in certain circumstances. Another commenter recommended allowing disclosures to law enforcement for the purpose of contacting the next of kin of individuals who have been injured or killed. One commenter sought clarification that “close personal friend” was intended to include domestic partners and same-sex couples in committed relationships.

Response: As discussed above, § 164.510(a) allows covered health care providers to disclose to clergy protected health information from a health care facility's directory. Under § 164.510(b), an individual may identify any person, including clergy, as involved in his or her care. This approach provides more flexibility than the proposed rule would have provided.

As discussed in the preamble of the final rule, this provision allows disclosures to domestic partners and others in same-sex relationships when such individuals are involved in an individual's care or are the point of contact for notification in a disaster. We do not intend to change current practices with respect to involvement of others in an individual's treatment decisions; informal information-sharing among persons involved; or the sharing of protected health information during a disaster. As noted above, a power of attorney or other legal relationship to an individual is not necessary for these informal discussions about the individual for the purpose of assisting in or providing a service related to the individual's care.

We agree with the comments noting that the Red Cross and other organizations may play an important role in locating and communicating with the family about individuals injured or killed in an accident or disaster situation. Therefore, the final rule includes new language, in § 164.510(b)(4), which allows covered entities to use or disclose protected health information to a public or private entity authorized by law or its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities to notify, or assist in the notification of (including identifying or locating) a family member, an individual's personal representative, or another person responsible for the individual's care regarding the individual's location, general condition, or death. The Red Cross is an example of a private entity that may obtain protected health information pursuant to these provisions. We recognize the role of the Red Cross and similar organizations in disaster relief efforts, and we encourage cooperation with these entities in notification efforts and other means of assistance.

Comment: One commenter recommended stating that individuals who are mentally retarded and unable to agree to disclosures under this provision do not, thereby, lose their access to further medical treatment. This commenter also proposed stating that mentally retarded individuals who are able to provide agreement have the right to control the disclosure of their protected health information. The commenter expressed concern that the parent, relative, or other person acting in loco parentis may not have the individual's best interest in mind in seeking or authorizing for the individual the disclosure of protected health information.

Response: The final rule regulates only uses and disclosures of protected health information, not the delivery of health care. Under the final rule's section on personal representatives (§ 164.502(g)), a person with authority to make decisions about the health care of an individual, under applicable law, may make decisions about the protected health information of that individual, to the extent that the protected health information is relevant to such person's representation. ***82666**

In the final rule, § 164.510(b) may apply to permit disclosures to a person other than a personal representative. Under § 164.510(b), when an individual is present and has the capacity to make his or her own decisions, a covered entity may disclose protected health information only if the covered entity: (1) Obtains the individual's agreement to disclose protected health information to the third parties involved in the individual's care; (2) provides the individual with an opportunity to object to such disclosure, and the individual does not express an objection; or (3) reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure. These conditions apply to disclosure of protected health information about individuals with mental retardation as well as to disclosures about all other individuals. Thus we do not believe it is necessary to include in this section of the final rule any language specifically on persons with mental retardation.

Comments: A few commenters recommended that disclosures made in good faith to the family or friends of the individual not be subject to sanctions by the Secretary, even if the covered entity had not fully complied with the requirements of this provision. One commenter believed that a fear of sanction would make covered entities overly cautious, such that they would not disclose protected health information to domestic partners or others not recognized by law as next of kin. Another commenter recommended that sanctions not be imposed if the covered entity has proper policies in place and has trained its staff appropriately. According to this commenter, the lack of documentation of disclosures in a particular case or medical record should not subject the entity to sanctions if the information was disclosed in good faith.

Response: We generally agree with commenters regarding disclosure in good faith pursuant to this provision. As discussed above, the final rule expands the scope of individuals to whom covered entities may disclose protected health information pursuant to this section. In addition, we delete the term next of kin, to avoid the appearance of requiring any legal determination of a person's relationship in situations involving informal disclosures. Similarly, consistent with the informal nature of disclosures pursuant to this section, we do not require covered entities to document such disclosures. If a covered entity imposes its own documentation requirements and a particular covered health care provider does not follow the entity's documentation requirements, the disclosure is not a violation of this rule.

Comments: The majority of comments on this provision were from individuals and organizations concerned about domestic violence. Most of these commenters wanted assurance that domestic violence would be a consideration in any disclosure to the spouse or relatives of an individual whom the covered entity suspected to be a victim of domestic violence or abuse. In particular, these commenters recommended that disclosures not be made to family members suspected of being the abuser if to do so would further endanger the individual. Commenters believed that this limitation was particularly important when the individual was unconscious or otherwise unable to object to the disclosures.

Response: We agree with the comments that victims of domestic violence and other forms of abuse need special consideration in order to avoid further harm, and we provide for discretion of a covered entity to determine that protected health information not be disclosed pursuant to § 164.510(b). Section 164.510(b) of the final rule, disclosures to family or friends involved in the individual's care, states that when an individual is unable to agree or object to the disclosure due to incapacity or another emergency situation, a covered entity must determine based on the exercise of professional judgment whether it is in the individual's best interest to disclose the information. As stated in the preamble, we intend for this exercise of professional judgment in the individual's best interest to account for the potential for harm to the individual in cases involving domestic violence. These circumstances are unique and are best decided by a covered entity, in the exercise of professional judgment, in each situation rather than by a blanket rule.

Section 164.512—Uses and Disclosures for Which Consent, Authorization, or Opportunity to Agree or Object Is Not Required

Section 164.512(a)—Uses and Disclosures Required by Law

Comment: Numerous commenters addressed directly or by implication the question of whether the provision permitting uses and disclosures of protected health information if required by other law was necessary. Other commenters generally endorsed the need for such a provision. One such commenter approved of the provision as a needed fail-safe mechanism should the enumeration of permissible uses and disclosures of protected health information in the NPRM prove to be incomplete. Other commenters cited specific statutes which required access to protected health information, arguing that such a provision was necessary to ensure that these legally mandated disclosures would continue to be permitted. For example, some commenters argued for continued access to protected health information to investigate and remedy abuse and neglect as currently required by the Developmental Disabilities Assistance and Bill of Rights, 42 U.S.C. 6042, and the Protection and Advocacy for Mentally Ill Individuals Act, 42 U.S.C. 10801.

Some comments urged deletion of the provision for uses and disclosures required by other law. This concern appeared to be based on a generalized concern that the provision fostered government intrusion into individual medical information.

Finally, a number of commenters also urged that the required by law provision be deleted. These commenters argued that the proposed provision would have undermined the intent of the statute to preempt state laws which were less protective of individual privacy. As stated in these comments, the provision for uses and disclosures required by other law was "broadly written and could apply to a variety of state laws that are contrary to the proposed rule and less protective of privacy. (Indeed, a law requiring disclosure is the least protective of privacy since it allows for no discretion.) The breadth of this provision greatly exceeds the exceptions to preemption contained in HIPAA."

Response: We agree with the comments that proposed § 164.510(n) was necessary to harmonize the rule with existing state and federal laws mandating uses and disclosures of protected health information. Therefore, in the final rule, the provision permitting uses and disclosures as required by other law is retained. To accommodate other reorganization of the final rule, this provision has been designated as § 164.512(a).

We do not agree with the comments expressing concern for increased governmental intrusion into individual privacy under this provision. The final rule does not create any new duty or obligation to disclose protected health information. Rather, it permits covered entities to use or disclose protected health information when they are required by law to do so. ***82667**

We likewise disagree with the characterization of the proposed provision as inconsistent with or contrary to the preemption standards in the statute or Part 160 of the rule. As described in the NPRM, we intend this provision to preserve access to information considered important enough by state or federal authorities to require its disclosure by law.

The importance of these required uses or disclosures is evidenced by the legislative or other public process necessary for the government to create a legally binding obligation on a covered entity. Furthermore, such required uses and disclosures arise in a myriad of other areas of law, ranging from topics addressing national security (uses and disclosures to obtain security clearances), to public health (reporting of communicable diseases), to law enforcement (disclosures of gun shot wounds). Required uses and disclosures also may address broad national concerns or particular regional or state concerns. It is not possible, or appropriate, for HHS to reassess the legitimacy of or the need for each of these mandates in each of their specialized contexts. In some cases where particular concerns have been raised by legal mandates in other laws, we allow disclosure as required by law, and we establish additional requirements to protect privacy (for example, informing the individual as required in § 164.512(c)) when covered entities make a legally mandated disclosure.

We also disagree with commenters who suggest that the approach in the final rule is contrary to the preemption provisions in HIPAA. HIPAA provides HHS with broad discretion in fashioning privacy protections. Recognizing the legitimacy of existing

legal requirements is certainly within the Secretary's discretion. Additionally, given the variety of these laws, the varied contexts in which they arise, and their significance in ensuring that important public policies are achieved, we do not believe that Congress intended to preempt each such law unless HHS specifically recognized the law or purpose in the regulation.

Comment: A number of commenters urged that the provision permitting uses and disclosures required by other law be amended by deleting the last sentence which stated: “This paragraph does not apply to uses or disclosures that are covered by paragraphs (b) through (m) of this section.” Some commenters sought deletion of this sentence to avoid any inadvertent preemption of mandatory reporting laws, and requested clarification of the effect on specific statutes.

The majority of the commenters focused their concerns on the potential conflict between mandatory reporting laws to law enforcement and the limitations imposed by proposed § 164.510(f), on uses and disclosures to law enforcement. For example, the comments raised concerns that mandatory reporting to law enforcement of injuries resulting from violent acts and abuse require the health care provider to initiate such reports to local law enforcement or other state agencies, while the NPRM would have allowed such reporting on victims of crimes only in response to specific law enforcement requests for information. Similarly, mandatory reports of violence-related injuries may implicate suspected perpetrators, as well as victims, and compliance with such laws could be blocked by the proposed requirement that disclosures about suspects was similarly limited to a response to law enforcement inquiries for the specific purpose of identifying the suspect. The NPRM also would have limited the type of protected health information that could have been disclosed about a suspect or fugitive.

In general, commenters sought to resolve this overlap by removing the condition that the required-by-other-law provision applied only when no other national priority purpose addressed the particular use or disclosure. The suggested change would permit the covered entity to comply with legally mandated uses and disclosures as long as the relevant requirements of that law were met. Alternatively, other commenters suggested that the restrictions on disclosures to law enforcement be lifted to permit full compliance with laws requiring reporting for these purposes.

Finally, some comments sought clarification of when a use or disclosure was “covered by paragraphs (b) through (m).” These commenters were confused as to whether a particular use or disclosure had to be specifically addressed by another provision of the rule or simply within the scope of the one of the national priority purposes specified by proposed paragraphs (b) through (m).

Response: We agree with the commenters that the provision as proposed would have inadvertently interfered with many state and federal laws mandating the reporting to law enforcement or others of protected health information.

In response to these comments, we have modified the final rule to clarify how this section interacts with the other provisions in the rule.

Comment: A number of commenters sought expanded authority to use and disclosure protected health information when permitted by other law, not just when required by law. These comments specified a number of significant duties or potential societal benefits from disclosures currently permitted or authorized by law, and they expressed concern should these beneficial uses and disclosures no longer be allowed if not specifically recognized by the rule. For example, one commenter listed 25 disclosures of health records that are currently permitted, but not required, by state law. This commenter was concerned that many of these authorized uses and disclosures would not be covered by any of the national priority purposes specified in the NPRM, and, therefore, would not be a permissible use or disclosure under the rule. To preserve these important uses and disclosures, the comments recommended that provision be made for any use or disclosure which is authorized or permitted by other law.

Response: We do not agree with the comments that seek general authority to use and disclose protected health information as permitted, but not required, by other law. The uses and disclosures permitted in the final rule reflect those purposes and circumstances which we believe are of sufficient national importance or relevance to the needs of the health care system to warrant the use or disclosure of protected health information in the absence of either the individual's express authorization or

a legal duty to make such use or disclosure. In permitting specific uses and disclosures that are not required by law, we have considered the individual privacy interests at stake in each area and crafted conditions or limitations in each identified area as appropriate to balance the competing public purposes and individual privacy needs. A general rule authorizing any use or disclosure that is permitted, but not required, by other law would undermine the careful balancing in the final rule.

In making this judgment, we have distinguished between laws that mandate uses or disclosures and laws that merely permit them. In the former case, jurisdictions have determined that public policy purposes cannot be achieved absent the use of certain protected health information, and we have chosen in general not to disturb their judgments. On the other hand, where jurisdictions have determined that certain protected health information is not necessary to achieve ***82668** a public policy purpose, and only have permitted its use or disclosure, we do not believe that those judgments reflect an interest in use or disclosure strong enough to override the Congressional goal of protecting privacy rights.

Moreover, the comments failed to present any compelling circumstance to warrant such a general provision. Despite commenters' concerns to the contrary, most of the beneficial uses and disclosures that the commenters referenced to support a general provision were, in fact, uses or disclosures already permissible under the rule. For example, the general statutory authorities relied on by one state health agency to investigate disease outbreaks or to comply with health data-gathering guidelines for reporting to certain federal agencies are permissible disclosures to public health agencies.

Finally, in the final rule, we add new provisions to § 164.512 to address three examples raised by commenters of uses and disclosures that are authorized or permitted by law, but may not be required by law. First, commenters expressed concern for the states that provide for voluntary reporting to law enforcement or state protective services of domestic violence or of abuse, neglect or exploitation of the elderly or other vulnerable adults. As discussed below, a new section, § 164.512(c), has been added to the final rule to specifically address uses and disclosures of protected health information in cases of abuse, neglect, or domestic violence. Second, commenters were concerned about state or federal laws that permitted coordination and cooperation with organizations or entities involved in cadaveric organ, eye, or tissue donation and transplantation. In the final rule, we add a new section, § 164.512(h), to permit disclosures to facilitate such donation and transplantation functions. Third, a number of commenters expressed concern for uses and disclosure permitted by law in certain custodial settings, such as those involving correctional or detention facilities. In the final rule, we add a new subsection to the section on uses and disclosures for specialized government functions, § 164.512(k), to identify custodial settings in which special rules are necessary and to specify the additional uses and disclosures of the protected health information of inmates or detainees which are necessary in such facilities.

Comment: A number of commenters asked for clarification of the term “law” and the phrase “required by law” for purposes of the provision permitting uses or disclosures that are required by law. Some of the commenters noted that “state law” was a defined term in Part 160 of the NPRM and that the terms should be used consistently. Other commenters were concerned about differentiating between laws that required a use or disclosure and those that merely authorize or permit a use or disclosure. A number of commenters recommended that the final rule include a definitive list of the laws that mandate a use or disclosure of protected health information.

Response: In the final rule, we clarify that, consistent with the “state law” definition in § 160.202, “law” is intended to be read broadly to include the full array of binding legal authority, such as constitutions, statutes, rules, regulations, common law, or other governmental actions having the effect of law. However, for the purposes of § 164.512(a), law is not limited to state action; rather, it encompasses federal, state or local actions with legally binding effect, as well as those by territorial and tribal governments.

For more detail on the meaning of “required by law,” see § 164.501. Only where the law imposes a duty on the health care professional to report would the disclosure be considered to be required by law.

The final rule does not include a definitive list of the laws that contain legal mandates for disclosures of protected health information. In light of the breadth of the term "law" and number of federal, state, local, and territorial or tribal authorities that may engage in the promulgation of binding legal authority, it would be impossible to compile and maintain such a list. Covered entities have an independent duty to be aware of their legal obligations to federal, state, local and territorial or tribal authorities. The rule's approach is simply intended to avoid any obstruction to the health plan or covered health care provider's ability to comply with its existing legal obligations.

Comment: A number of commenters recommended that the rule compel covered entities to use or disclose protected health information as required by law. They expressed concern that covered entities could refuse or delay compliance with legally mandated disclosures by misplaced reliance on a rule that permits, but does not require, a use or disclosure required by other law.

Response: We do not agree that the final rule should require covered entities to comply with uses or disclosures of protected health information mandated by law. The purpose of this rule is to protect privacy, and to allow those disclosures consistent with sound public policy. Consistent with this purpose, we mandate disclosure only to the individual who is the subject of the information, and for purposes of enforcing the rule. Where a law imposes a legal duty on the covered entity to use or disclose protected health information, it is sufficient that the privacy rule permit the covered entity to comply with such law. The enforcement of that legal duty, however, is a matter for that other law.

Section 164.512(b)—Uses and Disclosures for Public Health Activities

Comment: Several non-profit entities commented that medical records research by nonprofit entities to ensure public health goals, such as disease-specific registries, would not have been covered by this provision. These organizations collect information without relying on a government agency or law. Commenters asserted that such activities are essential and must continue. They generally supported the provisions allowing the collection of individually identifiable health information without authorization for registries. One stated that both governmental and non-governmental cancer registries should be exempt from the regulation. They stated that "such entities, by their very nature, collect health information for legitimate public health and research purposes." Another, however, addressed its comments only to "disclosure to non-government entities operating such system as required or authorized by law."

Response: We acknowledge that such entities may be engaged in disease-specific or other data collection activities that provide a benefit to their members and others affected by a particular malady and that they contribute to the public health and scientific database on low incidence or little known conditions. However, in the absence of some nexus to a government public health authority or other underlying legal authority, it is unclear upon what basis covered entities can determine which registries or collections are "legitimate" and how the confidentiality of the registry information will be protected. Commenters did not suggest methods for "validating" these private registry programs, and no such methods currently exist at the federal level. It is unknown whether any states have such a program. Broadening the exemption could provide a loophole for private data collections for inappropriate ***82669** purposes or uses under a "public health" mask.

In this rule, we do not seek to make judgments as to the legitimacy of private entities' disease-specific registries or of private data collection endeavors. Rather, we establish the general terms and conditions for disclosure and use of protected health information. Under the final rule, covered entities may obtain authorization to disclose protected health information to private entities seeking to establish registries or other databases; they may disclose protected health information as required by law; or they may disclose protected health information to such entities if they meet the conditions of one of the provisions of §§ 164.510 or 164.512. We believe that the circumstances under which covered entities may disclose protected health information to private entities should be limited to specified national priority purposes, as reflected through the FDA requirements or directives listed in § 164.512(b)(iii), and to enable recalls, repairs, or replacements of products regulated by the FDA. Disclosures by covered health care providers who are workforce members of an employer or are conducting evaluations relating to work-related injuries or illnesses or workplace surveillance also may disclose protected health information to employers of findings of such evaluations that are necessary for the employer to comply with requirements under OSHA and related laws.

Comment: Several commenters said that the NPRM did not indicate how to distinguish between public health data collections and government health data systems. They suggested eliminating proposed § 164.510(g) on disclosures and uses for government health data systems, because they believed that such disclosures and uses were adequately covered by proposed § 164.510(b) on public health.

Response: As discussed below, we agree with the commenters who suggested that the proposed provision that would have permitted disclosures to government health data bases was overly broad, and we remove it from the final rule. We reviewed the important purposes for which some commenters said government agencies needed protected health information, and we believe that most of those needs can be met through the other categories of permitted uses and disclosures without authorization allowed under the final rule, including provisions permitting covered entities to disclose information (subject to certain limitations) to government agencies for public health, health oversight, law enforcement, and otherwise as required by law. For example, the final rule continues to allow collection of protected health information without authorization to monitor trends in the spread of infectious disease, morbidity and mortality.

Comment: Several commenters recommended expanding the scope of disclosures permissible under proposed § 164.510(b)(1)(iii), which would have allowed covered entities to disclose protected health information to private entities that could demonstrate that they were acting to comply with requirements, or at the direction, of a public health authority. These commenters said that they needed to collect individually identifiable health information in the process of drug and device development, approval, and post-market surveillance—activities that are related to, and necessary for, the FDA regulatory process. However, they noted that the specific data collections involved were not required by FDA regulations. Some commenters said that they often devised their own data collection methods, and that health care providers disclosed information to companies voluntarily for activities such as post-marketing surveillance and efficacy surveys. Commenters said they used this information to comply with FDA requirements such as reporting adverse events, filing other reports, or recordkeeping. Commenters indicated that the FDA encouraged but did not require them to establish other data collection mechanisms, such as pregnancy registries that track maternal exposure to drugs and the outcomes.

Accordingly, several commenters recommended modifying proposed § 164.510(b) to allow covered entities to disclose protected health information without authorization to manufacturers registered with the FDA to manufacture, distribute, or sell a prescription drug, device, or biological product, in connection with post-marketing safety and efficacy surveillance or for the entity to obtain information about the drug, device, or product or its use. One commenter suggested including in the regulation an illustrative list of examples of FDA-related requirements, and stating in the preamble that all activities taken in furtherance of compliance with FDA regulations are "public health activities."

Response: We recognize that the FDA conducts or oversees many activities that are critical to help ensure the safety or effectiveness of the many products it regulates. These activities include, for example, reporting of adverse events, product defects and problems; product tracking; and post-marketing surveillance. In addition, we believe that removing defective or harmful products from the market is a critical national priority and is an important tool in FDA efforts to promote the safety and efficacy of the products it regulates. We understand that in most cases, the FDA lacks statutory authority to require product recalls. We also recognize that the FDA typically does not conduct recalls, repairs, or product replacement surveillance directly, but rather, that it relies on the private entities it regulates to collect data, notify patients when applicable, repair and replace products, and undertake other activities to promote the safety and effectiveness of FDA-regulated products.

We believe, however, that modifying the NPRM to allow disclosure of protected health information to private entities as part of any data-gathering activity related to a drug, device, or biological product or its use, or for any activity that is consistent with, or that appears to promote objectives specified, in FDA regulation would represent an inappropriately broad exception to the general requirement to obtain authorization prior to disclosure. Such a change could allow, for example, drug companies to collect protected health information without authorization to use for the purpose of marketing pharmaceuticals. We do not agree that all activities taken to promote compliance with FDA regulations represent public health activities as that term is defined in this rule. In addition, we believe it would not be appropriate to include in the regulation text an "illustrative list"

of requirements "related to" the FDA. The regulation text and preamble list the FDA-related activities for which we believe disclosure of protected health information to private entities without authorization is warranted.

We believe it is appropriate to allow disclosure of protected health information without authorization to private entities only: For purposes that the FDA has, in effect, identified as national priorities by issuing regulations or express directions requiring such disclosure; or if such disclosure is necessary for a product recall. For example, we believe it is appropriate to allow covered health care providers to disclose to a medical device manufacturer recalling defective heart valves the names and last known addresses of patients in whom the provider implanted the valves. Thus, in the final rule, we allow covered entities to disclose protected health information to entities subject to FDA jurisdiction for the following activities: To report adverse events (or similar reports with ***82670** respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations, if the disclosure is made to the person required or directed to report such information to the FDA; to track products if the disclosure is made to a person required or directed by the FDA to track the product; to enable product recalls, repairs, or replacement (including locating and notifying individuals who have received products of product recalls, withdrawals, or other problems); or to conduct post-marketing surveillance to comply with requirements or at the direction of the FDA. The preamble above provides further detail on the meaning of some of the terms in this list. Covered entities may disclose protected health information to entities for activities other than those described above only as required by law; with authorization; or if permissible under another section of this rule.

We understand that many private registries, such as pregnancy registries, currently obtain patient authorization for data collection. We believe the approach of § 164.512(b) strikes an appropriate balance between the objective of promoting patient privacy and control over their health information and the objective of allowing private entities to collect data that ultimately may have important public health benefits.

Comment: One commenter remarked that our proposal may impede fetal/infant mortality and child fatality reviews.

Response: The final rule permits a covered entity to disclose protected health information to a public health authority authorized by law to conduct public health activities, including the collection of data relevant to death or disease, in accordance with § 164.512(b). Such activities may also meet the definition of "health care operations." We therefore do not believe this rule impedes these activities.

Comment: Several comments requested that the final regulation clarify that employers be permitted to use and/or disclose protected health information pursuant to the requirements of the Occupational Safety and Health Act and its accompanying regulations ("OSHA"). A few comments asserted that the regulation should not only permit employers to use and disclose protected health information without first obtaining an authorization consistent with OSHA requirements, but also permit them to use and disclose protected health information if the use or disclosure is consistent with the spirit of OSHA. One commenter supported the permissibility of these types of uses and disclosures, but warned that the regulation should not grant employers unfettered access to the entire medical record of employees for the purpose of meeting OSHA requirements. Other commenters noted that OSHA not only requires disclosures to the Occupational Safety and Health Administration, but also to third parties, such as employers and employee representatives. Thus, this comment asked HHS to clarify that disclosures to third parties required by OSHA are also permissible under the regulation.

Response: Employers as such are not covered entities under HIPAA and we generally do not have authority over their actions. When an employer has a health care component, such as an on-site medical clinic, and the components meets the requirements of a covered health care provider, health plan or health care clearinghouse, the uses and disclosures of protected health information by the health care component, including disclosures to the larger employer entity, are covered by this rule and must comply with its provisions.

A covered entity, including a covered health care provider, may disclose protected health information to OSHA under § 164.512(a), if the disclosure is required by law, or if the disclosure is a discretionary one for public health activities, under

§ 164.512(b). Employers may also request employees to provide authorization for the employer to obtain protected health information from covered entities to conduct analyses of work-related health issues. See § 164.508.

We also permit covered health care providers who provide health care as a workforce member of an employer or at the request of an employer to disclose protected health information to the employer concerning work-related injuries or illnesses or workplace medical surveillance in situations where the employer has a duty to keep records on or act on such information under the OSHA or similar laws. We added this provision to ensure that employers are able to obtain the information that they need to meet federal and state laws designed to promote safer and healthier workplaces. These laws are vital to protecting the health and safety of workers and we permit specified covered health care providers to disclose protected health information as necessary to carry out these purposes.

Comment: A few comments suggested that the final regulation clarify how it would interact with existing and pending OSHA requirements. One of these comments requested that the Secretary delay the effective date of the regulation until reviews of existing requirements are complete.

Response: As noted in the "Relationship to Other Federal Laws" section of the preamble, we are not undertaking a complete review of all existing laws with which covered entities might have to comply. Instead we have described a general framework under which such laws may be evaluated. We believe that adopting national standards to protect the privacy of individually identifiable health information is an urgent national priority. We do not believe that it is appropriate to delay the effective date of this regulation.

Comment: One commenter asserted that the proposed regulation conflicted with the OSHA regulation requirement that when a designated representative (to whom the employee has already provided a written authorization to obtain access) requests a release form for access to employee medical records, the form must include the purpose for which the disclosure is sought, which the proposed privacy regulation does not require.

Response: We do not agree that this difference creates a conflict for covered entities. If an employer seeks to obtain a valid authorization under § 164.508, it may add a purpose statement to the authorization so that it complies with OSHA's requirements and is a valid authorization under § 164.508 upon which a covered entity may rely to make a disclosure of protected health information to the employer.

Comment: One commenter stated that access to workplace medical records by the occupational medical physicians is fundamental to workplace and community health and safety. Access is necessary whether it is a single location or multiple sites of the same company, such as production facilities of a national company located throughout the country.

Response: We permit covered health care providers who provide health care as a workforce member of an employer or at the request of an employer to disclose protected health information to the employer concerning work-related injuries or illnesses or workplace medical surveillance, as described in this paragraph. Information obtained by an employer under this paragraph would be available for it to use, consistent with other laws and regulations, as it chooses and throughout the national company. We do not regulate uses or disclosures of individually identifiable health ***82671** information by employers acting as employers.

Section 164.512(c)—Disclosures About Victims of Abuse, Neglect, or Domestic Violence

The NPRM did not include a paragraph specifically addressing covered entities' disclosures of protected health information regarding victims of abuse, neglect, or domestic violence. Rather, the NPRM addressed disclosures about child abuse pursuant to proposed § 164.510(b), which would have allowed covered entities to report child abuse to a public health authority or to another appropriate authority authorized by law to receive reports of child abuse or neglect. We respond to comments regarding victims of domestic violence or abuse throughout the final rule where relevant. (See responses to comments on §§ 164.502(g), 164.510(b), 164.512(f)(3), 164.522, and 164.524.)

Comment: Several commenters urged us to require that victims of domestic violence be notified about requests for or disclosures of protected health information about them, so that victims could take safety precautions.

Response: We agree that, in balancing the burdens on covered entities from such a notification requirement against the benefits to be gained, victims of domestic abuse merit heightened concern. For this reason, we generally require covered entities to inform the individual when they disclose protected health information to authorized government authorities. As the Family Violence Prevention Fund has noted in its Health Privacy Principles for Protecting Victims of Domestic Violence (October 2000), victims of domestic violence and abuse sometimes are subject to retaliatory violence. By informing a victim of abuse or domestic violence of a disclosure to law enforcement or other authorities, covered entities give victims the opportunity to take appropriate safety precautions. See the above preamble discussion of § 164.512(c) for more detail about the requirements for disclosing protected health information about victims of domestic violence.

Comment: Some commenters argued that a consent requirement should apply at a minimum to disclosures involving victims of crime or victims of domestic violence.

Response: We agree, and we modify the proposed rule to require covered entities to obtain an individual's agreement prior to disclosing protected health information in most instances involving victims of a crime or of abuse, neglect, or domestic violence. See the above preamble discussions of § 164.512(c), on disclosures about victims of abuse, neglect, or domestic violence, and § 164.512(f)(3), on disclosures to law enforcement about crime victims.

Section 164.512(d)—Uses and Disclosures for Health Oversight Activities

Comment: A couple of commenters supported the NPRM's approach to health oversight. Several other commenters generally supported the NPRM's approach to disclosure of protected health information for national priority purposes, and they recommended some clarification regarding disclosure for health oversight. Two commenters recommended clarifying in the final rule that disclosure is allowed to all federal, state, and local agencies that use protected health information to carry out legally mandated responsibilities.

Response: The final rule permits disclosures to public agencies that meet the definition of a health oversight agency and for oversight of the particular areas described in the statute. Section 164.512(a) of the final rule permits disclosures that are required by law. As discussed in the responses to comments of § 164.512(a), we do not in the final rule permit disclosures merely authorized by other laws that do not fit within the other public policy purposes recognized by the rule.

Comment: One commenter recommended clarifying in the final rule that covered entities are not required to establish business partner contracts with health oversight agencies or public health authorities to release individually identifiable information to them for purposes exempt from HIPAA and sanctioned by state law.

Response: The final rule does not require covered entities to establish business associate contracts with health oversight agencies when they disclose protected health information to these agencies for oversight purposes.

Comment: Two commenters recommended clarifying in the regulation text that the health oversight section does not create a new right of access to protected health information.

Response: We agree and include such a statement in the preamble of § 164.512(d) of the final rule.

Comment: Several commenters were concerned that the proposed oversight section allowed but did not require disclosure of protected health information to health oversight agencies for oversight activities.

Response: This rule's purpose is to protect the privacy of individually identifiable health information. Except to enforce the rule and to establish individuals' right to access their own protected health information (see § 164.502(a)(2)), we do not require

disclosure of protected health information to any person or entity. We allow such disclosure for situations in which other laws require disclosure.

Comment: Some commenters were concerned that the NPRM would have allowed health oversight agencies to re-use and redisclose protected health information to other entities, and they were particularly concerned about re-disclosure to and re-use by law enforcement agencies. One commenter believed that government agencies would use the label of health oversight to gain access to protected health information from covered entities—thereby avoiding the procedural requirements of the law enforcement section (proposed § 164.510(f)) and subsequently would turn over information to law enforcement officials. Thus, these groups were concerned that the potential for oversight access to protected health information under the rule to become the "back door" to law enforcement access to such information.

Based on their concerns, these commenters recommended establishing a general prohibition on the re-use and re-disclosure of protected health information obtained by health oversight agencies in actions against individuals. One health plan expressed general concern about re-disclosure among all of the public agencies covered in the proposed § 164.510. It recommended building safeguards into the rule to prevent information gathered for one purpose (for example, public health) from being used for another purpose (such as health oversight).

Many of the commenters concerned about re-disclosure of protected health information obtained for oversight purposes said that if the Secretary lacked statutory authority to regulate oversight agencies' re-disclosure of protected health information and the re-use of this information by other agencies covered in proposed § 164.510, the President should issue an Executive Order barring such re-disclosure and re-use. One of these groups specified that the Executive Order should bar re-use and re-disclosure of protected health information in actions against individuals.

In contrast, some commenters advocated information-sharing between law enforcement and oversight agencies. Most of these commenters recognized that the NPRM would have allowed re-use and re-disclosure of protected health information from oversight to law ***82672** enforcement agencies, and they supported this approach.

Response: We believe that the language we have added to the rule, at § 164.512(d)(2) and the corresponding explanation in the preamble, to clarify the boundary between disclosures for health oversight and for law enforcement purposes should partially address the concern expressed by some that oversight agencies will be the back door for access by law enforcement. In situations when the individual is the subject of an investigation or activity and the investigation or activity is not related to health care fraud, the requirements for disclosure to law enforcement must be met, and an oversight agency cannot request the information under its more general oversight authority.

We acknowledge, however, that there will be instances under the rule when a health oversight agency (or a law enforcement agency in its oversight capacity) that has obtained protected health information appropriately will be able to redisclose the information to a law enforcement agency for law enforcement purposes. Under HIPAA, we have the authority to restrict re-disclosure of protected health information only by covered entities. Re-disclosures by public agencies such as oversight agencies are not within the purview of this rule. We support the enactment of comprehensive privacy legislation that would govern such public agencies' re-use and re-disclosure of this information. Furthermore, in an effort to prevent health oversight provisions from becoming the back door to law enforcement access to protected health information, the President is issuing an Executive Order that places strict limitations on the use of protected health information gathered in the course of an oversight investigation for law enforcement activities. For example, such use will be subject to review by the Deputy Attorney General.

Comment: Several commenters recommended modifying the proposed oversight section to require health oversight officials to justify and document their need for identifiable information.

Response: We encourage covered entities to work with health oversight agencies to determine the scope of information needed for health oversight inquiries. However, we believe that requiring covered entities to obtain extensive documentation of health

oversight information needs could compromise health oversight agencies' ability to complete investigations, particularly when an oversight agency is investigating the covered entity from which it is seeking information.

Comment: Several commenters believed that health oversight activities could be conducted without access to individually identifiable health information. Some of these groups recommended requiring information provided to health oversight agencies to be de-identified to the extent possible.

Response: We encourage health oversight agencies to use de-identified information whenever possible to complete their investigations. We recognize, however, that in some cases, health oversight agencies need identifiable information to complete their investigations. For example, as noted in the preamble to the NPRM, to determine whether a hospital has engaged in fraudulent billing practices, it may be necessary to examine billing records for a set of individual cases. Similarly, to determine whether a health plan is complying with federal or state health care quality standards, it may be necessary to examine individually identifiable health information in comparison with such standards. Thus, to allow health oversight agencies to conduct the activities that are central to their mission, the final rule does not require covered entities to de-identify protected health information before disclosing it to health oversight organizations.

Comment: One commenter recommended requiring whistleblowers, pursuant to proposed § 164.518(a)(4) of the NPRM, to raise the issue of a possible violation of law with the affected covered entity before disclosing such information to an oversight agency, attorney, or law enforcement official.

Response: We believe that such a requirement would be inappropriate, because it would create the potential for covered entities that are the subject of whistleblowing to take action to evade law enforcement and oversight action.

Comment: One commenter recommended providing an exemption from the proposed rule's requirements for accounting for disclosures when such disclosures were for health oversight purposes.

Response: We recognize that in some cases, informing individuals that their protected health information has been disclosed to a law enforcement official or to a health oversight agency could compromise the ability of law enforcement and oversight officials to perform their duties appropriately. Therefore, in the final rule, we retain the approach of proposed § 164.515 of the NPRM. Section 164.528(a)(2) of the final rule states that an individual's right to receive an accounting of disclosures to a health oversight agency, law enforcement official, or for national security or intelligence purposes may be temporarily suspended for the time specified by the agency or official. As described in § 164.528(a)(2), for such a suspension to occur, the agency or official must provide the affected covered entity with a written request stating that an accounting to the individual would be reasonably likely to impede the agency's activity. The request must specify the time for which the suspension is required. We believe that providing a permanent exemption to the right to accounting for disclosures for health oversight purposes would fail to ensure that individuals are sufficiently informed about the extent of disclosures of their protected health information.

Comment: One commenter recommended making disclosures to health oversight agencies subject to a modified version of the NPRM's proposed three-part test governing disclosure of protected health information to law enforcement pursuant to an administrative request (as described in proposed § 164.510(f)(1)).

Response: We disagree that it would be appropriate to apply the procedural requirements for law enforcement to health oversight. We apply more extensive procedural requirements to law enforcement disclosures than to disclosures for health oversight because we believe that law enforcement investigations more often involve situations in which the individual is the subject of the investigation (and thus could suffer adverse consequences), and we believe that it is appropriate to provide greater protection to individuals in such cases. Health oversight involves investigations of institutions that use health information as part of business functions, or of individuals whose health information has been used to obtain a public benefit. These circumstances justify broader access to information.

Overlap Between Law Enforcement and Oversight

Comment: Some commenters expressed concern that the NPRM's provisions permitting disclosures for health oversight and disclosures for law enforcement overlapped, and that the overlap could create confusion among covered entities, members of the public, and government agencies. The commenters identified particular factors that could lead to confusion, including that (1) the phrase "criminal, civil, or administrative proceeding" appeared in the definitions of both law enforcement ***82673** and oversight; (2) the examples of oversight agencies listed in the preamble included a number of organizations that also conduct law enforcement activities; (3) the NPRM addressed the issue of disclosures to investigate health care fraud in the law enforcement section (§ 164.510(f)(5)), yet health care fraud investigations are central to the mission of some health care oversight agencies; (4) the NPRM established more stringent rules for disclosure of protected health information pursuant to an administrative subpoena issued for law enforcement than for disclosure pursuant to an oversight agency's administrative subpoena; and (5) the preamble, but not the NPRM regulation text, indicated that agencies conducting both oversight and law enforcement activities would be subject to the oversight requirements when conducting oversight activities.

Some commenters said that covered entities would be confused by the overlap between law enforcement and oversight and that this concern would lead to litigation over which rules should apply when an entity engaged in more than one of the activities listed under the exceptions in proposed § 164.510. Other commenters believed that covered entities could manipulate the NPRM's ambiguities in their favor, claim that the more stringent law enforcement disclosure rules always should apply, and thereby delay investigations. A few comments suggested that the confusion could be clarified by making the regulation text consistent with the preamble, by stating that when agencies conducting both law enforcement and oversight seek protected health information as part of their oversight activities, the oversight rules would apply.

Response: We agree that the boundary between disclosures for health oversight and disclosures for law enforcement proposed in the NPRM could have been more clear. Because many investigations, particularly investigations involving public benefit programs, have both health oversight and law enforcement aspects to them, and because the same agencies often perform both functions, drawing any distinction between the two functions is necessarily difficult. For example, traditional law enforcement agencies, such as the Federal Bureau of Investigation, have a significant role in health oversight. At the same time, traditional health oversight agencies, such as federal Offices of Inspectors General, often participate in criminal investigations.

To clarify the boundary between law enforcement and oversight for purposes of complying with this rule, we add new language in the final rule, at § 164.512(d)(2). This section indicates that health oversight activities do not include an investigation or activity in which the individual is the subject of the investigation or activity and the investigation or activity does not arise out of and is not directly related to health care fraud. In this rule, we describe investigations involving suspected health care fraud as investigations related to: (1) The receipt of health care; (2) a claim for public benefits related to health; or (3) qualification for, or receipt of public benefits or services where a patient's health is integral to the claim for public benefits or services. In such cases, where the individual is the subject of the investigation and the investigation does not relate to health care fraud, identified as investigations regarding issues (a) through (c), the rules regarding disclosure for law enforcement purposes (see § 164.512(f)) apply.

Where the individual is not the subject of the activity or investigation, or where the investigation or activity relates to health care fraud, a covered entity may make a disclosure pursuant to § 164.512(d)(1), allowing uses and disclosures for health oversight activities. For example, when the U.S. Department of Labor's Pension and Welfare Benefits Administration (PWBA) needs to analyze protected health information about health plan enrollees in order to conduct an audit or investigation of the health plan (i.e., the enrollees are not subjects of the investigation) to investigate potential fraud by the health plan, the health plan may disclose protected health information to the PWBA under the health oversight rules.

To clarify further that health oversight disclosure rules apply generally in health care fraud investigations (subject to the exception described above), in the final rule, we eliminate proposed § 164.510(f)(5)(i), which would have established requirements for disclosure related to health fraud for law enforcement purposes. All disclosures of protected health information that would have been permitted under proposed § 164.510(f)(5)(i) are permitted under § 164.512(d).

We also recognize that sections 201 and 202 of HIPAA, which established a federal Fraud and Abuse Control Program and the Medicare Integrity Program, identified health care fraud-fighting as a critical national priority. Accordingly, under the final rule, in joint law enforcement/oversight investigations involving suspected health care fraud, the health oversight disclosures apply, even if the individual also is the subject of the investigation.

We also recognize that in some cases, health oversight agencies may conduct joint investigations with other oversight agencies involved in investigating claims for benefits unrelated to health. For example, in some cases, a state Medicaid agency may be working with officials of the Food Stamps program to investigate suspected fraud involving Medicaid and Food Stamps. While this issue was not raised specifically in the comments, we add new language (§ 164.512(d)(3)) to provide guidance to covered entities in such situations. Specifically, we clarify that if a health oversight investigation is conducted in conjunction with an oversight activity related to a claim for benefits unrelated to health, the joint activity or investigation is considered health oversight for purposes of the rule, and the covered entities may disclose protected health information pursuant to the health oversight provisions.

Comment: An individual commenter recommended requiring authorization for disclosure of patient records in fraud investigations, unless the individual was the subject or target of the investigation. This commenter recommended requiring a search warrant for cases in which the individual was the subject and stating that fraud investigators should have access to the minimum necessary patient information.

Response: As described above, we recognize that in some cases, activities include elements of both law enforcement and health oversight. Because we consider both of these activities to be critical national priorities, we do not require covered entities to obtain authorization for disclosure of protected health information to law enforcement or health oversight agencies—including those oversight activities related to health care fraud. We believe that investigations involving health care fraud represent health oversight rather than law enforcement. Accordingly, as indicated above, we remove proposed § 164.510(f)(5)(i) from the law enforcement section of the proposed rule and clarify that all disclosures of protected health information for health oversight are permissible without authorization. As discussed in greater detail in § 164.514, the final rule's minimum necessary standard applies to disclosures under § 164.512 unless the disclosure is required by law under § 164.512(a). ***82674**

Comment: A large number of commenters expressed concern about the potential for health oversight agencies to become, in effect, the “back door” for law enforcement access to such information. The commenters suggested that health oversight agencies could use their relatively unencumbered access to protected health information to circumvent the more stringent process requirements that otherwise would apply to disclosures for law enforcement purposes. These commenters urged us to prohibit health oversight agencies from re-disclosing protected health information to law enforcement.

Response: As indicated above, we do not intend for the rule's permissive approach to health oversight or the absence of specific documentation to permit the government to gather large amounts of protected health information for purposes unrelated to health oversight as defined in the rule, and we do not intend for these oversight provisions to serve as a “back door” for law enforcement access to protected health information. While we do not have the statutory authority to regulate law enforcement and oversight agencies' re-use and re-disclosure of protected health information, we strongly support enactment of comprehensive privacy legislation that would govern public agencies' re-use and re-disclosure of this information. Furthermore, in an effort to prevent health oversight provisions from becoming the back door to law enforcement access to protected health information, the President is issuing an Executive Order that places strict limitations on the use of protected health information gathered in the course of an oversight investigation for law enforcement activities.

Comment: One commenter asked us to allow the requesting agency to decide whether a particular request for protected health information was for law enforcement or oversight purposes.

Response: As described above, we clarify the overlap between law enforcement disclosures and health oversight disclosures based on the privacy and liberty interests of the individual (whether the individual also is the subject of the official inquiry) and the nature of the public interest (whether the inquiry relates to health care fraud or to another potential violation of law). We believe it is more appropriate to establish these criteria than to leave the decision to the discretion of an agency that has a stake in the outcome of the investigation.

Section 164.512(e)—Disclosures for Judicial and Administrative Proceedings

Comment: A few commenters suggested that the final rule not permit disclosures without an authorization for judicial and administrative proceedings.

Response: We disagree. Protected health information is necessary for a variety of reasons in judicial and administrative proceedings. Often it may be critical evidence that may or may not be about a party. Requiring an authorization for all such disclosures would severely impede the review of legal and administrative claims. Thus, we have tried to balance the need for the information with the individual's privacy. We believe the approach described above provides individuals with the opportunity to object to disclosures and provides a mechanism through which their privacy interests are taken into account.

Comment: A few commenters sought clarification about the interaction between permissible disclosures for judicial and administrative proceedings, law enforcement, and health oversight.

Response: In the final rule, we state that the provision permitting disclosures without an authorization for judicial and administrative proceedings does not supersede other provisions in § 164.512 that would otherwise permit or restrict the use or disclosure of protected health information. Additionally, in the descriptive preamble of § 164.512, we provide further explanation of how these provisions relate to one another.

Comments: Many commenters urged the Secretary to revise the rule to state that it does not preempt or supersede existing rules and statutes governing judicial proceedings, including rules of evidence, procedure, and discovery. One commenter asserted that dishonest health care providers and others should not be able to withhold their records by arguing that state subpoena and criminal discovery statutes compelling disclosure are preempted by the privacy regulation. Other commenters maintained that there is no need to replace providers' current practice, which typically requires either a signed authorization from the patient or a subpoena to release medical information.

Response: These comments are similar to many of the more general preemption comments we received. For a full discussion of the Secretary's response on preemption issues, see part 160—subpart B.

Comment: One commenter stated that the proposed rule creates a conflict with existing rules and statutes governing judicial proceedings, including rules of evidence and discovery. This commenter stated that the rule runs afoul of state judicial procedures for enforcement of subpoenas that require judicial involvement only when a party seeks to enforce a subpoena.

Response: We disagree with this comment. The final rule permits covered entities to disclose protected health information for any judicial or administrative procedure in response to a subpoena, discovery request, or other lawful process if the covered entity has received satisfactory assurances that the party seeking the disclosure has made reasonable efforts to ensure that the individual has been given notice of the request or has made reasonable efforts to secure a qualified protective order from a court or administrative tribunal. A covered entity may disclose protected health information in response to a subpoena, discovery request, or other lawful process without a satisfactory assurance if it has made reasonable efforts to provide the individual with such notice or to seek a qualified protected order itself. These rules do not require covered entities or parties seeking the disclosure of protected health information to involve the judiciary; they may choose the notification option rather than seeking a qualified protective order.

Many states have already enacted laws that incorporate these concepts. In California, for instance, an individual must be given ten days notice that his or her medical records are being subpoenaed from a health care provider and state law requires that the party seeking the records furnishes the health care provider with proof that the notice was given to the individual. In Montana, a party seeking discovery or compulsory process of medical records must give notice to the individual at least ten days in advance of serving the request on a health care provider, Service of the request must be accompanied by written certification that the procedure has been followed. In Rhode Island, an individual must be given notice that his or her medical records are being subpoenaed and notice of his or her right to object. The party serving the subpoena on the health care provider must provide written certification to the provider that: (1) This procedure has been followed, (2) twenty days have passed from the date of service, and (3) no challenge has been made to the disclosure or the court has ordered disclosure after resolution of a legal court challenge. In Washington, an individual must be given at least fourteen days from the date of service of notice that his or her health information is the subject of a ***82675** discovery request or compulsory process to obtain a protective order. The notice must identify the health care provider from whom the information is sought, specify the health care information that is sought, and the date by which a protective order must be obtained in order to prevent the provider from disclosing the information.

Comment: A few commenters expressed concern that the rule would place unnecessary additional burdens on health care providers because when they receive a request for disclosure in connection with an administrative or judicial procedure, they would have to determine whether the litigant's health was at issue before they made the disclosure. A number of commenters complained that this requirement would make it too easy for litigants to obtain protected health information. One commenter argued that litigants should not be able to circumvent state evidentiary rules that would otherwise govern disclosure of protected health information simply upon counsel's statement that the other party's medical condition or history is at issue.

Other commenters, however, urged that disclosure without authorization should be permitted whenever a patient places his or her medical condition or history at issue and recommended requiring the request for information to include a certification to this effect. Only if another party to litigation has raised a medical question, do these commenters believe a court order should be required. Similarly, one commenter supported a general requirement that disclosure without authorization be permitted only with a court order unless the patient has placed his or her physical or mental condition at issue.

Response: We agree with the concerns expressed by several commenters about this provision and have eliminated this requirement from the final rule.

Comment: A number of commenters stated that the proposed rule should be modified to permit disclosure without authorization pursuant to a lawful subpoena. One commenter argued that the provision would limit the scope of the Inspector General's subpoena power for judicial and administrative proceedings to information concerning a litigant whose health condition or history is at issue, and would impose a requirement that the Inspector General provide a written certification to that effect. Other commenters stated that the proposed rule would seriously impair the ability of state agencies to conduct administrative hearings on physician licensing and disciplinary matters. These commenters stated that current practice is to obtain information using subpoenas.

Other commenters argued that disclosure of protected health information for judicial and administrative proceedings should require a court order and/or judicial review unless the subject of the information consents to disclosure. These commenters believed that an attorney's certification should not be considered sufficient authority to override an individual's privacy, and that the proposed rule made it too easy for a party to litigation to obtain information about the other party.

Response: As a general matter, we agree with these comments. As noted, the final rule deletes the provision that would permit a covered entity to disclose protected health information pursuant to an attorney's certification that the individual is a party to the litigation and has put his or her medical condition at issue. Under the final rule, covered entities may disclose protected health information in response to a court or administrative order, provided that only the protected health information expressly authorized by the order is disclosed. Covered entities may also disclose protected health information in response to a subpoena, discovery request, or other lawful process without a court order, but only if the covered entity receives satisfactory assurances

that the party seeking disclosure has made reasonable efforts to ensure that the individual has been notified of the request or that reasonable efforts have been made by the party seeking the information to secure a qualified protective order. Additionally, a covered entity may disclose protected health information in response to a subpoena, discovery request, or other lawful process without a satisfactory assurance if it makes reasonable efforts to provide the individual with such notice or to seek a qualified protected order itself.

We also note that the final rule specifically provides that nothing in Subchapter C should be construed to diminish the authority of any Inspector General, including authority provided in the Inspector General Act of 1978.

Comment: A number of commenters expressed concern that the proposed rule would not permit covered entities to introduce material evidence in proceedings in which, for example, the provisions of an insurance contract are at issue, or when a billing or payment issue is presented. They noted that although the litigant may be the owner of an insurance policy, he or she may not be the insured individual to whom the health information pertains. In addition, they stated that the medical condition or history of a deceased person may be at issue when the deceased person is not a party.

Response: We disagree. Under the final rule, a covered entity may disclose protected health information without an authorization pursuant to a court or administrative order. It may also disclose protected health information with an authorization for judicial or administrative proceedings in response to a subpoena, discovery request, or other lawful process without a court order, if the party seeking the disclosure provides the covered entity with satisfactory assurances that it has made reasonable efforts to ensure that the individual has been notified of the request or to seek a qualified protective order. Additionally, a covered entity may disclose protected health information in response to a subpoena, discovery request, or other lawful process without a satisfactory assurance if it makes reasonable efforts to provide the individual with such notice or to seek a qualified protected order itself. Therefore, a party may obtain the information even if the subject of the information is not a party to the litigation or deceased.

Comment: A few commenters argued that disclosure of protected health information should be limited only to those cases in which the individual has consented or a court order has been issued compelling disclosure.

Response: The Secretary believes that such an approach would impose an unreasonable burden on covered entities and the judicial system and that greater flexibility is necessary to assure that the judicial and administrative systems function smoothly. We understand that even those states that have enacted specific statutes to protect the privacy of health information have not imposed requirements as strict as these commenters would suggest.

Comment: Many commenters asked that the final rule require the notification of the disclosure be provided to the individual whose health information is subject to disclosure prior to the disclosure as part of a judicial or administrative proceeding. Most of these commenters also asked that the rule require that the individual who is the subject of a disclosure be given an opportunity to object to the disclosure. A few commenters suggested that patients be given ten days to object before requested information may be disclosed and recommend that the rule require the requester to provide a certification that notice has been provided and that ten days have passed ***82676** with no objection from the subject of the information. Some commenters suggested that if a subpoena for disclosure is not accompanied by a court order, the covered entities be prohibited from disclosing protected health information unless the individual has been given notice and an opportunity to object. Another commenter recommended requiring, in most circumstances, notice and an opportunity to object before a court order is issued and requiring the requestor of information to provide a signed document attesting the date of notification and forbid disclosure until ten days after notice is given.

Response: We agree that in some cases the provision of notice with an opportunity to object to the disclosure is appropriate. Thus, in the final rule we provide that a covered entity may disclose protected health information in response to a subpoena, discovery request or other lawful process that is not accompanied by a court order if it receives satisfactory assurance from the party seeking the request that the requesting party has made a good faith attempt to provide written notice to the individual that includes sufficient information about the litigation or proceeding to permit the individual to raise an objection to the court or

administrative tribunal and that the time for the individual to raise objections has elapsed (and that none were filed or all have been resolved). Covered entities may make reasonable efforts to provide such notice as well.

In certain instances, however, the final rule permits covered entities to disclose protected health information for judicial and administrative proceedings without notice to the individual if the party seeking the request has made reasonable efforts to seek a qualified protective order, as described in the rule. A covered entity may also make reasonable efforts to seek a qualified protective order in order to make the disclosure. Additionally, a covered entity may disclose protected health information for judicial and administrative proceedings in response to an order of a court or administrative tribunal provided that the disclosure is limited to only that information that is expressly authorized by the order. The Secretary believes notice is not necessary in these instances because a court or administrative tribunal is in the best position to evaluate the merits of the arguments of the party seeking disclosure and the party who seeks to block it before it issues the order and that imposing further procedural obstacles before a covered entity may honor that disclosure request is unnecessary.

Comment: Many commenters urged the Secretary to require specific criteria for court and administrative orders. Many of these commenters proposed that a provision be added to the rule that would require court and administrative orders to safeguard the disclosure and use of protected health information. These commenters urged that the information sought must be relevant and material, as specific and narrowly drawn as reasonably practicable, and only disclosed if de-identified information could not reasonably be used.

Response: The Secretary's authority is limited to covered entities. Therefore, we do not impose requirements on courts and administrative tribunals. However, we note that the final rule limits the permitted disclosures by covered entities in court or administrative proceedings to only that information which is specified in the order from a court or an administrative body should provide a degree of protection for individuals from unnecessary disclosure.

Comment: Several commenters asked that the “minimum necessary” standard not apply to disclosures made pursuant to a court order because individuals could then use the rule to contest the scope of discovery requests. However, many other commenters recommended that the rule permit disclosure only of information “reasonably necessary” to respond to a subpoena. These commenters raised concerns with applying the “minimum necessary” standard in judicial and administrative proceedings, but did not believe the holder of protected health information should have blanket authority to disclose all protected health information. Some of the commenters urged that disclosure of any information about third parties that may be included in the medical records of another person— for example, the HIV status of a partner—be prohibited. Finally, some commenters disagreed with the proposed rule because it did not require covered entities to evaluate the validity of subpoenas and discovery requests to determine whether these requests ask for the “minimum necessary” or “reasonably necessary” amount of information.

Response: Under the final rule, if the disclosure is pursuant to an order of a court or administrative tribunal, covered entities may disclose only the protected health information expressly authorized by the order. In these instances, a covered entity is not required to make a determination whether or not the order might otherwise meet the minimum necessary requirement.

If the disclosure is pursuant to a satisfactory assurance from the party seeking the disclosure, at least a good faith attempt has been made to notify the individual in writing of the disclosure before it is made or the parties have sought a qualified protective order that prohibits them from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which the information was requested and that the information will be returned to the covered entity or destroyed at the end of the litigation or the proceeding. Alternatively, the covered entity may seek such notice or qualified protective order itself. This approach provides the individual with protections and places the burden on the parties to resolve their differences about the appropriateness and scope of disclosure as part of the judicial or administrative procedure itself before the order is issued, rather than requiring the covered entity to get involved in evaluating the merits of the dispute in order to determine whether or not the particular request is appropriate or too broad. In these cases, the covered entity must disclose only the protected health information that is the minimum amount necessary to achieve the purpose for which the information is sought.

We share the concern of the commenters that covered entities should redact any information about third parties before disclosing an individual's protected health information. During the fact-finding stage of our consideration of revisions to the proposed rule, we discussed this issue with representatives of covered entities. Currently, information about third parties is sometimes redacted by medical records personnel responding to requests for information. In particular, information regarding HIV status is treated with special sensitivity by these professionals. Although we considered including a special provision in the final rule prohibiting such disclosure, we decided that the revisions made to the proposed rule would provide sufficient protection. By restricting disclosure of protected health information to only that information specified in a court or administrative order or released pursuant to other types of lawful process only if the individual had notice and an opportunity to object or if the information was subject to a protective order, individuals who are concerned about disclosure of information concerning third parties will have the opportunity to raise that ***82677** issue prior to the request for disclosure being presented to the covered entity. We are reluctant to put the covered entity in the position of having to resolve disputes concerning the type of information that may be disclosed when that dispute should more appropriately be settled through the judicial or administrative procedure itself.

Comment: One commenter asked that the final regulation clarify that a court order is not required when disclosure would otherwise be permitted under the rule. This commenter noted that the preamble states that the requirement for a court order would not apply if the disclosure would otherwise be permitted under the rule. For example, disclosures of protected health information pursuant to administrative, civil, and criminal proceedings relating to “health oversight” are permitted, even if no court or administrative orders have been issued. However, the commenter was concerned that this principle only appeared in the preamble and not in the rule itself.

Response: Section 164.512(e)(4) of the final regulation contains this clarification.

Comment: One commenter was concerned that the rule is unclear as to whether governmental entities are given a special right to “use” protected health information that private parties do not have under the proposed regulation or whether governmental entities that seek or use protected health information are treated the same as private parties in their use of such information. This commenter urged that we clarify our intent regarding the use of protected health information by governmental entities.

Response: Generally governmental entities are treated the same as private entities under the rule. In a few clearly defined cases, a special rule applies. For instance, under § 164.504(e)(3), when a covered entity and its business associate are both governmental entities, they may enter into a memorandum of understanding or adopt a regulation with the force and effect of law that incorporates the requirements of a business associate contract, rather than having to negotiate a business associate contract itself.

Comment: One commenter recommended that final rule state that information developed as part of a quality improvement or medical error reduction program may not be disclosed under this provision. The commenter explained that peer review information developed to identify and correct systemic problems in delivery of care must be protected from disclosure to allow a full discussion of the root causes of such events so they may be identified and addressed. According to the commenter, this is consistent with peer review protections afforded this information by the states.

Response: The question of whether or not such information should be protected is currently the subject of debate in Congress and in the states. It would be premature for us to adopt a position on this issue until a clear consensus emerges. Under the final rule, no special protection against disclosure is provided for peer review information of the type the commenter describes. However, unless the request for disclosure fits within one of the categories of permitted or required disclosures under the regulation, it may not be disclosed. For instance, if disclosure of peer review information is required by another law (such as Medicare or a state law), covered entities subject to that law may disclose protected health information consistent with the law.

Comment: One commenter stated that the requirements of this section are in conflict with Medicare contractor current practices, as defined by the HCFA Office of General Counsel and suggested that the final rule include more specific guidelines.

Response: Because the commenter failed to indicate the nature of these conflicts, we are unable to respond.

Comment: One commenter stated that the rule should require rather than permit disclosure pursuant to court orders.

Response: Under the statutory framework adopted by Congress in HIPAA, a presumption is established that the data contained in an individual's medical record belongs to the individual and must be protected from disclosure to third parties. The only instance in which covered entities holding that information must disclose it is if the individual requests access to the information himself or herself. In the final rule (as in the proposed rule), covered entities may use or disclose protected health information under certain enumerated circumstances, but are not required to do so. We do not believe that this basic principle should be compromised merely because a court order has been issued. Consistent with this principle, we provide covered entities with the flexibility to deal with circumstances in which the covered entity may have valid reasons for declining to release the protected health information without violating this regulation.

Comment: One commenter noted that in some states, public health records are not subject to discovery, and that the proposed rule would not permit disclosure of protected health information pursuant to court order or subpoena if the disclosure is not allowed by state law. The commenter requested clarification as to whether a subpoena in a federal civil action would require disclosure if a state law prohibiting the release of public health records existed.

Response: As explained above, the final rule permits, but does not require, disclosure of protected health information pursuant to a court order. Under the applicable preemption provisions of HIPAA, state laws relating to the privacy of medical information that are more stringent than the federal rules are not preempted. To the extent that an applicable state law precludes disclosure of protected health information that would otherwise be permitted under the final rule, state law governs.

Comment: A number of commenters expressed concern that the proposed rule would negatively impact state and federal benefits programs, particularly social security and workers' compensation. One commenter requested that the final rule remove any possible ambiguity about application of the rule to the Social Security Administration's (SSA) evidence requests by permitting disclosure to all administrative level of benefit programs. In addition, several commenters stated that requiring SSA or states to provide the covered entity holding the protected health information with an individual's consent before it could disclose the information would create a huge administrative and paperwork burden with no added value to the individual. In addition, several other commenters indicated that states that make disability determinations for SSA also support special accommodation for SSA's determination process. They expressed concern that providers will narrowly interpret the HIPAA requirements, resulting in significant increases in processing time and program costs for obtaining medical evidence (especially purchased consultative examinations when evidence of record cannot be obtained). A few commenters were especially concerned about the impact on states and SSA if the final rule were to eliminate the NPRM's provision for a broad consent for “all evidence from all sources.”

Some commenters also note that it would be inappropriate for a provider to make a minimum necessary determination in response to a request from SSA because the provider usually will not know the legal parameters of SSA's programs, or have access to the ***82678** individual's other sources of evidence. In addition, one commenter urged the Secretary to be sensitive to these concerns about delay and other negative impacts on the timely determination of disability by SSA for mentally impaired individuals.

Response: Under the final rule, covered entities may disclose protected health information pursuant to an administrative order so the flow of protected health information from covered entities to SSA and the states should not be disrupted.

Although some commenters urged that special rules should be included for state and federal agencies that need protected health information, the Secretary rejects that suggestion because, wherever possible, the public and the private sectors should operate under the same rules regarding the disclosure of health information. To the extent the activities of SSA constitute an actual administrative tribunal, covered entities must follow the requirements of § 164.512(e), if they wish to disclose protected health information to SSA in those circumstances. Not all administrative inquiries are administrative tribunals, however. If SSA's

request for protected health information comes within another category of permissible exemptions, a covered entity, following the requirements of the applicable section, may disclose the information to SSA. For example, if SSA seeks information for purposes of health oversight, a covered entity that wishes to disclose the information to SSA may do so under § 164.512(d) and not § 164.512(e). If the disclosure does not come within one of the other permissible disclosures would a covered entity need to meet the requirements of § 164.512(e). If the SSA request does not come within another permissible disclosure, the agency will be treated like anyone else under the rules.

The Secretary recognizes that even under current circumstances, professional medical records personnel do not always respond unquestioningly to an agency's request for health information. During the fact finding process, professionals charged with managing provider response to requests for protected health information indicated to us that when an agency's request for protected health information is over broad, the medical records professional will contact the agency and negotiate a more limited request. In balancing the interests of individuals against the need of governmental entities to receive protected health information, we think that applying the minimum necessary standard is appropriate and that covered entities should be responsible for ensuring that they disclose only that protected health information that is necessary to achieve the purpose for which the information is sought.

Comment: In a similar vein, one commenter expressed concern that the proposed rule would adversely affect the informal administrative process usually followed in processing workers' compensation claims. Using formal discovery is not always possible, because some programs do not permit it. The commenter urged that the final rule must permit administrative agencies, employers, and workers' compensation carriers to use less formal means to obtain relevant medical evidence while the matter is pending before the agency. This commenter asked that the rule be revised to permit covered entities to disclose protected health information without authorization for purposes of federal or state benefits determinations at all levels of processing, from the initial application through continuing disability reviews.

Response: If the disclosure is required by a law relating to workers' compensation, a covered entity may disclose protected health information as authorized by and to the extent necessary to comply with that law under § 164.512(l). If the request for protected health information in connection with a workers' compensation claim is part of an administrative proceeding, a covered entity must meet the requirements set forth in § 164.512(e), and discussed above, before disclosing the information. As noted, one permissible manner by which a covered entity may disclose protected health information under § 164.512(e) is if the party seeking the disclosure makes reasonable efforts to provide notice to the individual as required by this provision. Under this method, the less formal process noted by the commenter would not be disturbed. Covered entity may disclose protected health information in response to other types of requests only as permitted by this regulation.

Section 164.512(f)—Disclosures for Law Enforcement Purposes

General Comments on Proposed § 164.510(f)

Comment: Some commenters argued that current law enforcement use of protected health information was legitimate and important. These commenters cited examples of investigations and prosecutions for which protected health information is needed, from white collar insurance fraud to violent assault, to provide incriminating evidence or to exonerate a suspect, to determine what charges are warranted and for bail decisions. For example, one commenter argued that disclosure of protected health information for law enforcement purposes should be exempt from the rule, because the proposed regulation would hamper Drug Enforcement Administration investigations. A few commenters argued that effective law enforcement requires early access to as much information as possible, to rule out suspects, assess severity of criminal acts, and for other purposes. A few commenters noted the difficulties criminal investigators and prosecutors face when fighting complex criminal schemes. In general, these commenters argued that all disclosures of protected health information to law enforcement should be allowed, or for elimination of the process requirements proposed in § 164.510(f)(1).

Response: The importance and legitimacy of law enforcement activities are beyond question, and they are not at issue in this regulation. We permit disclosure of protected health information to law enforcement officials without authorization in

some situations precisely because of the importance of these activities to public safety. At the same time, individuals' privacy interests also are important and legitimate. As with all the other disclosures of protected health information permitted under this regulation, the rules we impose attempt to balance competing and legitimate interests.

Comment: Law enforcement representatives stated that law enforcement agencies had a good track record of protecting patient privacy and that additional restrictions on their access and use of information were not warranted. Some commenters argued that no new limitations on law enforcement access to protected health information were necessary, because sufficient safeguards exist in state and federal laws to prevent inappropriate disclosure of protected health information by law enforcement.

Response: Disclosure of protected health information by law enforcement is not at issue in this regulation. Law enforcement access to protected health information in the first instance, absent any re-disclosure by law enforcement, impinges on individuals' privacy interests and must therefore be justified by a public purpose that outweighs individuals' privacy interests.

We do not agree that sufficient safeguards already exist in this area. We are not aware of, and the comments did ***82679** not provide, evidence of a minimum set of protections for individuals relating to access by law enforcement to their protected health information. Federal and state laws in this area vary considerably, as they do for other areas addressed in this final rule. The need for standards in this area is no less critical than in the other areas addressed by this rule.

Comment: Many commenters argued that no disclosures of protected health information should be made to law enforcement (absent authorization) without a warrant issued by a judicial officer after a finding of probable cause. Others argued that a warrant or subpoena should be required prior to disclosure of protected health information unless the disclosure is for the purposes of identifying a suspect, fugitive, material witness, or missing persons, as described in proposed § 164.510(f)(2). Some commenters argued that judicial review prior to release of protected health information to law enforcement should be required absent the exigent and urgent circumstances identified in the NPRM in § 164.510(f)(3) and (5), or absent "a compelling need" or similar circumstances.

Response: In the final rule, we attempt to match the level of procedural protection for privacy required by this rule with the nature of the law enforcement need for access, the existence of other procedural protections, and individuals' privacy interests. Where other rules already impose procedural protections, this rule generally relies on those protections rather than imposing new ones. Thus, where access to protected health information is granted after review by an independent judicial officer (such as a court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer), no further requirements are necessary. Similarly, because information disclosed to a grand jury is vital to law enforcement purposes and is covered by secrecy protection, this rule allows disclosure with no further process.

We set somewhat stricter standards for disclosure of protected health information pursuant to administrative process, such as administrative subpoenas, summonses, and civil or authorized investigative demands. In these cases, the level of existing procedural protections is lower than for judicially-approved or grand jury disclosures. We therefore require a greater showing, specifically, the three-part test described in § 164.512(f)(1)(ii), before the covered entity is permitted to release protected health information. Where the information to be disclosed is about the victim of a crime, privacy interests are heightened and we require the victim's agreement prior to disclosure in most instances.

In the limited circumstances where law enforcement interests are heightened, we allow disclosure of protected health information without prior legal process or agreement, but we impose procedural protections such as limits on the information that may lawfully be disclosed, limits on the circumstances in which the information may be disclosed, and requirements for verifying the identity and authority of the person requesting the disclosures. For example, in some cases law enforcement officials may seek limited but focused information needed to obtain a warrant. A witness to a shooting may know the time of the incident and the fact that the perpetrator was shot in the left arm, but not the identity of the perpetrator. Law enforcement would then have a legitimate need to ask local emergency rooms whether anyone had presented with a bullet wound to the left arm near the time of the incident. Law enforcement may not have sufficient information to obtain a warrant, but instead would

be seeking such information. In such cases, when only limited identifying information is disclosed and the purpose is solely to ascertain the identity of a person, the invasion of privacy would be outweighed by the public interest. For such circumstances, we allow disclosure of protected health information in response to a law enforcement inquiry where law enforcement is seeking to identify a suspect, fugitive, material witness, or missing person, but allow only disclosure of a limited list of information.

Similarly, it is in the public interest to allow covered entities to take appropriate steps to protect the integrity and safety of their operations. Therefore, we permit covered entities on their own initiative to disclose to law enforcement officials protected health information for this purpose. However, we limit such disclosures to protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

We shape the rule's provisions with respect to law enforcement according to the limited scope of our regulatory authority under HIPAA, which applies only to the covered entities and not to law enforcement officials. We believe the rule sets the correct standards for when an exception to the rule of non-disclosure is appropriate for law enforcement purposes. There may be advantages, however, to legislation that applies the appropriate standards directly to judicial officers, prosecutors in grand juries, and to those making administrative or other requests for protected health information, rather than to covered entities. These advantages could include measures to hold officials accountable if they seek or receive protected health information contrary to the legal standard. In Congressional consideration of law enforcement access, there have also been useful discussions of other topics, such as limits on re-use of protected health information gathered in the course of health oversight activities. The limitations on our regulatory authority provide additional reason to support comprehensive medical privacy legislation.

Comment: A few commenters cited existing sanctions for law enforcement officials who violate the rights of individuals in obtaining evidence, ranging from suppression of that evidence to monetary penalties, and argued that such sanctions are sufficient to protect patients' privacy interests.

Response: After-the-fact sanctions are important, but they are effective only when coupled with laws that establish the ground rules for appropriate behavior. That is, a sanction applies only where some other rule has been violated. This regulation sets such basic ground rules. Further, under the HIPAA statutory authority, we cannot impose sanctions on law enforcement officials or require suppression of evidence. We must therefore rely on rules that regulate disclosure of protected health information by covered entities in the first instance.

Comment: Several commenters argued that disclosure of protected health information under § 164.510(f) should be mandatory, not just permitted. Others argued that we should mandate disclosure of protected health information in response to Inspector General subpoenas. A few commenters argued that we should require all covered entities to include disclosure of protected health information to law enforcement in their required notice of privacy practices.

Response: The purpose of this regulation is to protect individuals' privacy interests, consistent with other important public activities. Other laws set the rules governing those public activities, including when health information is necessary for their effective operation. See discussion of § 164.512(a). ***82680**

Comment: Some commenters questioned whether the Secretary had statutory authority to directly or indirectly impose new procedural or substantive requirements on otherwise lawful legal process issued under existing federal and state rules. They argued that, while the provisions are imposed on “covered entities,” the rule would result in law enforcement officials being compelled to modify current practices to harmonize them with the requirements this rule imposes on covered entities. A number of state law enforcement agencies argued that the rule would place new burdens on state administrative subpoenas and requests that are intrusive in state functions. At least one commenter argued that the requirement for prior process places unreasonable restrictions on the right of the states to regulate law enforcement activities.

Response: This rule regulates the ability of health care clearinghouses, health plans, and covered health care providers to use and disclose health information. It does not regulate the behavior of law enforcement officials or the courts, nor does it prevent

states from regulating law enforcement officials. All regulations have some effects on entities that are not directly regulated. We have considered those effects in this instance and have determined that the provisions of the rule are necessary to protect the privacy of individuals.

Comment: One commenter argued that state licensing boards should be exempt from restrictions placed on law enforcement officials, because state licensing and law enforcement are different activities.

Response: Each state's law determines what authorities are granted to state licensing boards. Because state laws differ in this regard, we cannot make a blanket determination that state licensing officials are or are not law enforcement officials under this regulation. We note, however, that the oversight of licensed providers generally is included as a health oversight activity at § 164.512(d).

Relationship to Existing Rules and Practices

Comment: Many commenters expressed concern that the proposed rule would have expanded current law enforcement access to protected health information. Many commenters said that the NPRM would have weakened their current privacy practices with respect to law enforcement access to health records. For example, some of the commenters arguing that a warrant or subpoena should be required prior to disclosure of protected health information unless the disclosure is for the purposes of identifying a suspect, fugitive, material witness, or missing persons, did so because they believed that such a rule would be consistent with current state law practices.

Response: This regulation does not expand current law enforcement access to protected health information. We do not mandate any disclosures of protected health information to law enforcement officials, nor do we make lawful any disclosures of protected health information which are unlawful under other rules and regulations. Similarly, this regulation does not describe a set of "best practices." Nothing in this regulation should cause a covered entity to change practices that are more protective of privacy than the floor of protections provided in this regulation.

This regulation sets forth the minimum practices which a covered entity must undertake in order to avoid sanctions under the HIPAA. We expect and encourage covered entities to exercise their judgment and professional ethics in using and disclosing health information, and to continue any current practices that provide privacy protections greater than those mandated in this regulation.

Comment: Many commenters asserted that, today, consent or judicial review always is required prior to release of protected health information to law enforcement; therefore, they said that the proposed rule would have lessened existing privacy protections.

Response: In many situations today, law enforcement officials lawfully obtain health information absent any prior legal process and absent exigent circumstances. The comments we received on the NPRM, both from law enforcement and consumer advocacy groups, describe many such situations. Moreover, this rule sets forth minimum privacy protections and does not preempt more stringent, pre-existing standards.

Comment: Some commenters argued that health records should be entitled to at least as much protection as cable subscription records and video rental records.

Response: We agree. The Secretary, in presenting her initial recommendations on the protection of health information to the Congress in 1997, stated that, "When Congress looked at the privacy threats to our credit records, our video records, and our motor vehicle records, it acted quickly to protect them. It is time to do the same with our health care records' (Testimony of Donna E. Shalala, Secretary, U. S. Department of Health and Human Services, before the Senate Committee on Labor & Human Resources, September 11, 1997). However, the limited jurisdiction conferred on us by the HIPAA does not allow us to impose such restrictions on law enforcement officials or the courts.

Comment: At least one commenter argued that the regulation should allow current routine uses for law enforcement under the Privacy Act.

Response: This issue is discussed in the "Relationship to Other Federal Laws" preamble discussion of the Privacy Act.

Comment: A few commenters expressed concern that people will 8be less likely to provide protected health information for public health purposes if they fear the information could be used for law enforcement purposes.

Response: This regulation does not affect law enforcement access to records held by public health authorities, nor does it expand current law enforcement access to records held by covered entities. These agencies are for the most part not covered entities under HIPAA. Therefore, this regulation should not reduce current cooperation with public health efforts.

Relationship to Other Provisions of This Regulation

Comment: Several commenters pointed out an unintended interaction between proposed §§ 164.510(f) and 164.510(n). Because proposed § 164.510(n), allowing disclosures mandated by other laws, applied only if the disclosure would not fall into one of the categories of disclosures provided for in § 164.510 (b)-(m), disclosures of protected health information mandated for law enforcement purposes by other law would have been preempted.

Response: We agree, and in the final rule we address this unintended interaction. It is not our intent to preempt these laws. To clarify the interaction between these provisions, in the final rule we have specifically added language to the paragraph addressing disclosures for law enforcement that permits covered entities to comply with legal mandates, and have included a specific cross reference in the provision of the final rule that permits covered entities to make other disclosures required by law. See § 164.512(a).

Comment: Several commenters argued that, when a victim of abuse or of a crime has requested restrictions on disclosure, the restrictions should be communicated to any law enforcement officials who receive that protected health information.

Response: We do not have the authority to regulate law enforcement ***82681** use and disclosure of protected health information, and therefore we could not enforce any such restrictions communicated to law enforcement officials. For this reason, we determined that the benefits to be gained from requiring communication of restrictions would not outweigh the burdens such a requirement would place on covered entities. We expect that professional ethics will guide health care providers' communications to law enforcement officials about the welfare of victims of abuse or other crime.

Comment: Some commenters argued against imposing the "minimum necessary" requirement on disclosure of protected health information to law enforcement officials. Some law enforcement commenters expressed concern that the "minimum necessary" test could be "manipulated" by a covered entity that wished to withhold relevant evidence. A number of covered entities complained that they were ill-equipped to substitute their judgment for that of law enforcement for what was the minimum amount necessary, and they also argued that the burden of determining the "minimum necessary'information should be transferred to law enforcement agencies. Some commenters argued that imposing such "uninformed" discretion on covered entities would delay or thwart legitimate investigations, and would result in withholding information that might exculpate an individual or might be necessary to present a defendant's case. One comment suggested that covered entities have "immunity" for providing too much information to law enforcement.

Response: The "minimum necessary" standard is discussed at § 164.514.

Comment: A few commenters asked us to clarify when a disclosure is for a "Judicial or Administrative Proceeding" and when it is for "Law Enforcement" purposes.

Response: In the final rule we have clarified that § 164.512(e) relating to disclosures for judicial or administrative proceedings does not supersede the authority of a covered entity to make disclosures under other provisions of the rule.

Use of Protected Health Information After Disclosure to Law Enforcement

Comment: Many commenters recommended that we restrict law enforcement officials' re-use and re-disclosure of protected health information. Some commenters asked us to impose such restrictions, while other commenters noted that the need for such restrictions underscores the need for legislation. Another argued for judicial review prior to release of protected health information to law enforcement because this regulation cannot limit further uses or disclosures of protected health information once it is in the hands of law enforcement agencies.

Response: We agree that there are advantages to legislation that imposes appropriate restrictions directly on the re-use and re-disclosure of protected health information by many persons who may lawfully receive protected health information under this regulation, but whom we cannot regulate under the HIPAA legislative authority, including law enforcement agencies.

Comment: A few commenters expressed concern that protected health information about persons who are not suspects may be used in court and thereby become public knowledge. These commenters urged us to take steps to minimize or prevent such protected health information from becoming part of the public record.

Response: We agree that individuals should be protected from unnecessary public disclosure of health information about them. However, we do not have the statutory authority in this regulation to require courts to impose protective orders. To the extent possible within the HIPAA statutory authority, we address this problem in § 164.512(e), Judicial and Administrative Proceedings.

Comment: Some commenters argued that evidence obtained in violation of the regulation should be inadmissible at trial.

Response: In this regulation, we do not have the authority to regulate the courts. We can neither require nor prohibit courts from excluding evidence obtain in violation of this regulation.

Comments Regarding Proposed § 164.510(f)(1), Disclosures to Law Enforcement Pursuant to Process

Comments Supporting or Opposing a Requirement of Consent or Court Order

Comment: Some commenters argued that a rule that required a court order for every instance that law enforcement sought protected health information would impose substantial financial and administrative burdens on federal and state law enforcement and courts. Other commenters argued that imposing a new requirement of prior judicial process would compromise the time-sensitive nature of many investigations.

Response: We do not impose such a requirement in this regulation.

Comment: Many commenters argued that proposed § 164.510(f)(1) would have given law enforcement officials the choice of obtaining records with or without a court order, and that law enforcement "will choose the least restrictive means of obtaining records, those that do not require review by a judge or a prosecutor." Several commenters argued that this provision would have provided the illusion of barriers—but no real barriers—to law enforcement access to protected health information. A few argued that this provision would have allowed law enforcement to regulate itself.

Response: We agree with commenters that, in some cases, a law enforcement official may have discretion to seek health information under more than one legal avenue. Allowing a choice in these circumstances does not mean an absence of real limits. Where law enforcement officials choose to obtain protected health information through administrative process, they must meet the three-part test required by this regulation.

Comment: At least one commenter argued for judicial review prior to disclosure of health information because the rule will become the "de facto" standard for release of protected health information.

Response: We do not intend for this regulation to become the "de facto" standard for release of protected health information. Nothing in this regulation limits the ability of states and other governmental authorities to impose stricter requirements on law enforcement access to protected health information. Similarly, we do not limit the ability of covered entities to adopt stricter policies for disclosure of protected health information not mandated by other laws.

Comment: A few commenters expressed concern that proposed § 164.510(f)(1) would have overburdened the judicial system.

Response: The comments did not provide any factual basis for evaluating this concern.

Comment: Some commenters argued that, while a court order should be required, the standard of proof should be something other than "probable cause." For example, one commenter argued that the court should apply the three-part test proposed in § 164.510(f)(1)(i)(C). Another commenter suggested a three-part test: The information is necessary, the need cannot be met with non-identifiable information, and the need of law enforcement outweighs the privacy interest of the patient. Some commenters suggested that we impose a "clear and convincing" standard. Another suggested that we require clear and convincing evidence that: (1) The ***82682** information sought is relevant and material to a legitimate criminal investigation; (2) the request is as specific and narrow as is reasonably practicable; (3) de-identified information, for example coded records, could not reasonably be used; (4) on balance, the need for the information outweighs the potential harm to the individuals and to patient care generally; and (5) safeguards appropriate to the situation have been considered and imposed. This comment also suggested the following as such appropriate safeguard: granting only the right to inspect and take notes; allowing copying of only certain portions of records; prohibiting removing records from the premises; placing limits on subsequent use and disclosure; and requiring return or destruction of the information at the earliest possible time.) Others said the court order should impose a "minimum necessary" standard.

Response: We have not revised the regulation in response to comments suggesting that we impose additional standards relating to disclosures to comply with court orders. Unlike administrative subpoenas, where there is no independent review of the order, court orders are issued by an independent judicial officer, and we believe that covered entities should be permitted under this rule to comply with them. Court orders are issued in a wide variety of cases, and we do not know what hardships might arise by imposing standards that would require judicial officers to make specific findings related to privacy.

Comment: At least one commenter argued that the proposed rule would have placed too much burden on covered entities to evaluate whether to release information in response to a court order. This comment suggested that the regulation allow disclosure to attorneys for assessment of what the covered entity should release in response to a court order.

Response: This regulation does not change current requirements on or rights of covered entities with respect to court orders for the release of health information. Where such disclosures are required today, they continue to be required under this rule. Where other law allows a covered entity to challenge a court order today, this rule will not reduce the ability of a covered entity to mount such a challenge. Under § 164.514, a covered entity will be permitted to rely on the face of a court order to meet this rule's requirements for verification of the legal authority of the request for information. A covered entity may disclose protected health information to its attorneys as needed, to perform health care operations, including to assess the covered entity's appropriate response to court orders. See definition of "health care operations" under § 164.501.

Comment: Many commenters argued that the regulation should prohibit disclosures of protected health information to law enforcement absent patient consent.

Response: We disagree with the comment. Requiring consent prior to any release of protected health information to a law enforcement official would unduly jeopardize public safety. Law enforcement officials need protected health information for their investigations in a variety of circumstances. The medical condition of a defendant could be relevant to whether a crime was committed, or to the seriousness of a crime. The medical condition of a witness could be relevant to the reliability of that witness. Health information may be needed from emergency rooms to locate a fleeing prison escapee or criminal suspect who was injured and is believed to have stopped to seek medical care.

These and other uses of medical information are in the public interest. Requiring the authorization of the subject prior to disclosure could make apprehension or conviction of some criminals difficult or impossible. In many instances, it would not be possible to obtain such consent, for example because the subject of the information could not be located in time (or at all). In other instances, the covered entity may not wish to undertake the burden of obtaining the consent. Rather than an across-the-board consent requirement, to protect individuals' privacy interests while also promoting public safety, we impose a set of procedural safeguards (described in more detail elsewhere in this regulation) that covered entities must ensure are met before disclosing protected health information to law enforcement officials.

In most instances, such procedural safeguards consist of some prior legal process, such as a warrant, grand jury subpoena, or an administrative subpoena that meets a three-part test for protecting privacy interests. When the information to be disclosed is about the victim of a crime, privacy interests are heightened and we require the victim's agreement prior to disclosure in most instances. In the limited circumstances where law enforcement interests are heightened and we allow disclosure of protected health information without prior legal process or agreement, the procedural protections include limits on the information that may lawfully be disclosed, the circumstances in which the information may be disclosed, and requirements for verifying the identity and authority of the person requesting the disclosures.

We also allow disclosure of protected health information to law enforcement officials without consent when other law mandates the disclosures. When such other law exists, another public entity has made the determination that law enforcement interests outweigh the individual's privacy interests in the situations described in that other law, and we do not upset that determination in this regulation.

Comment: Several commenters recommended requiring that individuals receive notice and opportunity to contest the validity of legal process under which their protected health information will be disclosed, prior to disclosure of their records to law enforcement. Some of these commenters recommended adding this requirement to provisions proposed in the NPRM, while others recommended establishing this requirement as part of a new requirement for a judicial warrant prior to all disclosures of protected health information to law enforcement. At least one of these commenters proposed an exception to such a notice requirement where notice might lead to destruction of the records.

Response: Above we discuss the reasons why we believe it is inappropriate to require consent or a judicial order prior to any release of protected health information to law enforcement. Many of those reasons apply here, and they lead us not to impose such a notice requirement.

Comment: A few commenters believed that the proposed requirements in § 164.510(f)(1) would hinder investigations under the Civil Rights for Institutionalized Persons Act (CRIPA).

Response: We did not intend that provision to apply to investigations under CRIPA, and we clarify in the final rule that covered entities may disclose protected health information for such investigations under the health oversight provisions of this regulation (see § 164.512(d) for further detail).

Comments Suggesting Changes to the Proposed Three-Part Test

Comment: Many commenters argued for changes to the proposed three-part test that would make the test more difficult to meet. Many of these urged greater, but unspecified, restrictions. Others argued that the proposed test was too stringent, and

that it would have hampered criminal investigations and prosecutions. Some argued that it ***82683** was too difficult for law enforcement to be specific at the beginning of an investigation. Some argued that there was no need to change current practices, and they asked for elimination of the three-part test because it was "more stringent" than current practices and would make protected health information more difficult to obtain for law enforcement purposes. These commenters urged elimination of the three-part test so that administrative bodies could continue current practices without additional restrictions. Some of these argued for elimination of the three-part test for all administrative subpoenas; others argued for elimination of the three-part test for administrative subpoenas from various Inspectors General offices. A few commenters argued that the provisions in proposed § 164.510(f)(1) should be eliminated because they would have burdened criminal investigations and prosecutions but would have served "no useful public purpose."

Response: We designed the proposed three-part test to require proof that the government's interest in the health information was sufficiently important and sufficiently focused to overcome the individual's privacy interest. If the test were weakened or eliminated, the individual's privacy interest would be insufficiently protected. At the same time, if the test were significantly more difficult to meet, law enforcement's ability to protect the public interest could be unduly compromised.

Comment: At least one comment argued that, in the absence of a judicial order, protected health information should be released only pursuant to specific statutory authority.

Response: It is impossible to predict all the facts and circumstances, for today and into the future, in which law enforcement's interest in health information outweigh individuals' privacy interests. Recognizing this, states and other governments have not acted to list all the instances in which health information should be available to law enforcement officials. Rather, they specify some such instances, and rely on statutory, constitutional, and other limitations to place boundaries on the activities of law enforcement officials. Since the statutory authority to which the commenter refers does not often exist, many uses of protected health information that are in the public interest (described above in more detail) would not be possible under such an approach.

Comment: At least one commenter, an administrative agency, expressed concern that the proposed rule would have required its subpoenas to be approved by a judicial officer.

Response: This rule does not require judicial approval of administrative subpoenas. Administrative agencies can avoid the need for judicial review under this regulation by issuing subpoenas for protected health information only where the three-part test has been met.

Comment: Some commenters suggested alternative requirements for law enforcement access to protected health information. A few suggested replacing the three-part test with a requirement that the request for protected health information from law enforcement be in writing and signed by a supervisory official, and/or that the request "provide enough information about their needs to allow application of the minimum purpose rule."

Response: A rule requiring only that the request for information be in writing and signed fails to impose appropriate substantive standards for release of health information. A rule requiring only sufficient information for the covered entity to make a "minimum necessary" determination would leave these decisions entirely to covered entities' discretion. We believe that protection of individuals' privacy interests must start with a minimum floor of protections applicable to all. We believe that while covered entities may be free to provide additional protections (within the limits of the law), they should not have the ability to allow unjustified access to health information.

Comment: Some commenters argued that the requirement for an unspecified "finding" for a court order should be removed from the proposed rule, because it would have been confusing and would have provided no guidance to a court as to what finding would be sufficient.

Response: We agree that the requirement would have been confusing, and we delete this language from the final regulation.

Comment: A few commenters argued that the proposed three-part test should not be applied where existing federal or state law established a standard for issuing administrative process.

Response: It is the content of such a standard, not its mere existence, that determines whether the standard strikes an appropriate balance between individuals' privacy interests and the public interest in effective law enforcement activities. We assume that current authorities to issue administrative subpoena are all subject to some standards. When an existing standard provides at least as much protection as the three-part test imposed by this regulation, the existing standard is not disturbed by this rule. When, however, an existing standard for issuing administrative process provides less protection, this rule imposes new requirements.

Comment: Some covered entities said that they should not have been asked to determine whether the proposed three-part test has been met. Some argued that they were ill-equipped to make a judgment on whether an administrative subpoena actually met the three-part test, or that it was unfair to place the burden of making such determinations on covered entities. Some argued that the burden should have been on law enforcement, and that it was inappropriate to shift the burden to covered entities. Other commenters argued that the proposal would have given too much discretion to the record holders to withhold evidence without having sufficient expertise or information on which to make such judgments. At least one comment said that this aspect of the proposal would have caused delay and expense in the detection and prevention of health care fraud. The commenter believed that this delay and expense could be prevented by shifting to law enforcement and health care oversight the responsibility to determine whether standards have been met.

At least one commenter recommended eliminating the three-part test for disclosures of protected health information by small providers.

Some commenters argued that allowing covered entities to rely on law enforcement representation that the three-part test has been met would render the test meaningless.

Response: Because the statute does not bring law enforcement officials within the scope of this regulation, the rule must rely on covered entities to implement standards that protect individuals' privacy interests, including the three-part test for disclosure pursuant to administrative subpoenas. To reduce the burden on covered entities, we do not require a covered entity to second-guess representations by law enforcement officials that the three part test has been met. Rather, we allow covered entities to disclose protected health information to law enforcement when the subpoena or other administrative request indicates on its face that the three-part test has been met, or where a separate document so indicates. Because we allow such reliance, we do not believe that it is necessary or appropriate to reduce privacy protections for individuals who obtain care from small health care providers. ***82684**

Comment: Some commenters ask for modification of the three-part test to include a balancing of the interests of law enforcement and the privacy of the individual, pointing to such provisions in the Leahy-Kennedy bill.

Response: We agree with the comment that the balancing of these interests is important in this circumstance. We designed the regulation's three-part test to accomplish that result.

Comment: At least one commenter recommended that “relevant and material” be changed to “relevant,” because “relevant” is a term at the core of civil discovery rules and is thus well understood, and because it would be difficult to determine whether information is “material” prior to seeing the documents. As an alternative, this commenter suggested explaining what we meant by “material.”

Response: Like the term “relevant,” the term “material” is commonly used in legal standards and well understood.

Comment: At least one commenter suggested deleting the phrase "reasonably practical" from the second prong of the test, because, the commenter believed, it was not clear who would decide what is "reasonably practical" if the law enforcement agency and covered entity disagreed.

Response: We allow covered entities to rely on a representation on the face of the subpoena that the three-part test, including the "reasonably practical" criteria, is met. If a covered entity believes that a subpoena is not valid, it may challenge that subpoena in court just as it may challenge any subpoena that today it believes is not lawfully issued. This is true regardless of the specific test that a subpoena must meet, and is not a function of the "reasonably practical" criteria.

Comment: Some commenters requested elimination of the third prong of the test. One of these commenters suggested that the regulation should specify when de-identified information could not be used. Another recommended deleting the phrase "could not reasonably be used" from the third prong of the test, because the commenter believed it was not clear who would determine whether de-identified information "could reasonably be used" if the law enforcement agency and covered entity disagreed.

Response: We cannot anticipate in regulation all the facts and circumstances surrounding every law enforcement activity today, or in the future as technologies change. Such a rigid approach could not account for the variety of situations faced by covered entities and law enforcement officials, and would become obsolete over time. Thus, we believe it would not be appropriate to specify when de-identified information can or cannot be used to meet legitimate law enforcement needs.

In the final rule, we allow the covered entity to rely on a representation on the face of the subpoena (or similar document) that the three-part test, including the "could not reasonably be used" criteria, is met. If a covered entity believes that a subpoena is not valid, it may challenge that subpoena in court just as it may challenge today any subpoena that it believes is not lawfully issued. This is true regardless of the specific test that a subpoena must meet, and it is not a function of the "could not reasonably be used" criteria.

Comments Regarding Proposed § 164.510(f)(2), Limited Information for Identifying Purposes

Comment: A number of commenters recommended deletion of this provision. These commenters argued that the legal process requirements in proposed § 164.510(f)(1) should apply when protected health information is disclosed for identification purposes. At least one privacy group recommended that if the provision were not eliminated in its entirety, "suspects" should be removed from the list of individuals whose protected health information may be disclosed for identifying purposes. Many commenters expressed concern that this provision would allow compilation of large data bases of health information that could be use for purposes beyond those specified in this provision.

Response: We retain this provision in the final rule. We continue to believe that identifying fugitives, material witnesses, missing persons, and suspects is an important national priority and that allowing disclosure of limited identifying information for this purpose is in the public interest. Eliminating this provision—or eliminating suspects from the list of types of individuals about whom disclosure of protected health information to law enforcement is allowed—would impede law enforcement agencies" ability to apprehend fugitives and suspects and to identify material witnesses and missing persons. As a result, criminals could remain at large for longer periods of time, thereby posing a threat to public safety, and missing persons could be more difficult to locate and thus endangered.

However, as described above and in the following paragraphs, we make significant changes to this provision, to narrow the information that may be disclosed and make clear the limited purpose of the provision. For example, the proposed rule did not state explicitly whether covered entities would have been allowed to initiate—in the absence of a request from law enforcement—disclosure of protected health information to law enforcement officials for the purpose of identifying a suspect, fugitive, material witness or missing person. In the final rule, we clarify that covered entities may disclose protected health information for identifying purposes only in response to a request by a law enforcement official or agency. A "request by a law enforcement official or agency" is not limited to direct requests, but also includes oral or written requests by individuals acting on behalf of a law enforcement agency, such as a media organization broadcasting a request for the public's assistance in identifying a

suspect on the evening news. It includes "Wanted" posters, public announcements, and similar requests to the general public for assistance in locating suspects or fugitives.

Comment: A few commenters recommended additional restrictions on disclosure of protected health information for identification purposes. For example, one commenter recommended that the provision should either (1) require that the information to be disclosed for identifying purposes be relevant and material to a legitimate law enforcement inquiry and that the request be as specific and narrowly drawn as possible; or (2) limit disclosures to circumstances in which (a) a crime of violence has occurred and the perpetrator is at large, (b) the perpetrator received an injury during the commission of the crime, (c) the inquiry states with specificity the type of injury received and the time period during which treatment would have been provided, and (d) "probable cause" exists to believe the perpetrator received treatment from the provider.

Response: We do not agree that these additional restrictions are appropriate for disclosures of limited identifying information for purposes of locating or identifying suspects, fugitives, material witnesses or missing persons. The purpose of this provision is to permit law enforcement to obtain limited time-sensitive information without the process requirements applicable to disclosures for other purposes. Only limited information may be disclosed under this provision, and disclosure is permitted only in limited circumstances. We believe that these ***82685** safeguards are sufficient, and that creating additional restrictions would undermine the purpose of the provision and that it would hinder law enforcement's ability to obtain essential, time-sensitive information.

Comment: A number of law enforcement agencies recommended that the provision in the proposed rule be broadened to permit disclosure to law enforcement officials for the purpose of "locating" as well as "identifying" a suspect, fugitive, material witness or missing person.

Response: We agree with the comment and have changed the provision in the final rule. We believe that locating suspects, fugitives, material witnesses and missing persons is an important public policy priority, and that it can be critical to identifying these individuals. Further, efforts to locate suspects, fugitives, material witnesses, and missing persons can be at least as time-sensitive as identifying such individuals.

Comment: Several law enforcement agencies requested that the provision be broadened to permit disclosure of additional pieces of identifying information, such as ABO blood type and Rh factor, DNA information, dental records, fingerprints, and/or body fluid and tissue typing, samples and analysis. These commenters stated that additional identifying information may be necessary to permit identification of suspects, fugitives, material witnesses or missing persons. On the other hand, privacy and consumer advocates, as well as many individuals, were concerned that this section would allow all computerized medical records to be stored in a large law enforcement data base that could be scanned for matches of blood, DNA, or other individually identifiable information.

Response: The final rule seeks to strike a balance in protecting privacy and facilitating legitimate law enforcement inquiries. Specifically, we have broadened the NPRM's list of data elements that may be disclosed pursuant to this section, to include disclosure of ABO blood type and rh factor for the purpose of identifying or locating suspects, fugitives, material witnesses or missing persons. We agree with the commenters that these pieces of information are important to law enforcement investigations and are no more invasive of privacy than the other pieces of protected health information that may be disclosed under this provision.

However, as explained below, protected health information associated with DNA and DNA analysis; dental records; or typing, samples or analyses of tissues and bodily fluids other than blood (e.g., saliva) cannot be disclosed for the location and identification purposes described in this section. Allowing disclosure of this information is not necessary to accomplish the purpose of this provision, and would be substantially more intrusive into individuals' privacy. In addition, we understand commenters' concern about the potential for such information to be compiled in law enforcement data bases. Allowing disclosure

of such information could make individuals reluctant to seek care out of fear that health information about them could be compiled in such a data base.

Comment: Many commenters argued that proposed § 164.510(f)(2) should be deleted because it would permit law enforcement to engage in "fishing expeditions" or to create large data bases that could be searched for suspects and others.

Response: Some of this fear may have stemmed from the inclusion of the phrase "other distinguishing characteristic"—which could be construed broadly—in the list of items that could have been disclosed pursuant to this section. In the final rule, we delete the phrase "other distinguishing characteristic" from the list of items that can be disclosed pursuant to § 164.512(f)(2). In its place, we allow disclosure of a description of distinguishing physical characteristics, such as scars, tattoos, height, weight, gender, race, hair and eye color, and the presence or absence of facial hair such as a beard or moustache. We believe that such a change, in addition to the changes described in the paragraph above, responds to commenters' concern that the NPRM would have allowed creation of a government data base of personal identifying information. Further, this modification provides additional guidance to covered entities regarding the type of information that may be disclosed under this provision.

Comment: At least one commenter recommended removing social security numbers (SSNs) from the list of items that may be disclosed pursuant to proposed § 164.510(f)(2). The commenter was concerned that including SSNs in the (f)(2) list would cause law enforcement agencies to demand that providers collect SSNs. In addition, the commenter was concerned that allowing disclosure of SSNs could lead to theft of identity by unscrupulous persons in policy departments and health care organizations.

Response: We disagree. We believe that on balance, the potential benefits from use of SSNs for this purpose outweigh the potential privacy intrusion from such use of SSNs. For example, SSNs can help law enforcement officials identify suspects are using aliases.

Comments Regarding Proposed § 164.510(f)(3), Information About a Victim of Crime or Abuse

Comment: Some law enforcement organizations expressed concern that proposed § 164.510(f)(3) could inhibit compliance with state mandatory reporting laws.

Response: We recognize that the NPRM could have preempted such state mandatory reporting laws, due to the combined impact of proposed §§ 164.510(m) and 164.510(f). As explained in detail in § 164.512(a) above, we did not intend that result, and we modify the final rule to make clear that this rule does not preempt state mandatory reporting laws.

Comment: Many commenters, including consumer and provider groups, expressed concern that allowing covered entities to disclose protected health information without authorization to law enforcement regarding victims of crime, abuse, and other harm could endanger victims, particularly victims of domestic violence, who could suffer further abuse if their abuser learned that the information had been reported. Provider groups also expressed concern about undermining provider-patient relationships. Some law enforcement representatives noted that in many cases, health care providers' voluntary reports of abuse or harm can be critical for the successful prosecution of violent crime. They argued, that by precluding providers from voluntarily reporting to law enforcement evidence of potential abuse, the proposed rule could make it more difficult to apprehend and prosecute criminals.

Response: We recognize the need for heightened sensitivity to the danger facing victims of crime in general, and victims of domestic abuse or neglect in particular. As discussed above, the final rule includes a new section (§ 164.512(c)) establishing strict conditions for disclosure of protected health information about victims of abuse, neglect, and domestic violence.

Victims of crime other than abuse, neglect, or domestic violence can also be placed in further danger by disclosure of protected health information relating to the crime. In § 164.512(f)(3) of the final rule, we establish conditions for disclosure of protected health information in these circumstances, and we make significant modifications to the proposed rule's provision for such disclosures. Under the final rule, unless a state or other ***82686** government authority has enacted a law requiring disclosure

of protected health information about a victim to law enforcement officials, in most instances, covered entities must obtain the victim's agreement before disclosing such information to law enforcement officials. This requirement gives victims control over decision making about their health information where their safety could be at issue, helps promote trust between patients and providers, and is consistent with health care providers' ethical obligation to seek patient authorization whenever possible before disclosing protected health information.

At the same time, the rule strikes a balance between protecting victims and providing law enforcement access to information about potential crimes that cause harm to individuals, by waiving the requirement for agreement in two situations. In allowing covered entities to disclose protected health information about a crime victim pursuant to a state or other mandatory reporting law, we defer to other governmental bodies' judgments on when certain public policy objectives are important enough to warrant mandatory disclosure of protected health information to law enforcement. While some mandatory reporting laws are written more broadly than others, we believe that it is neither appropriate nor practicable to distinguish in federal regulations between what we consider overly broad and sufficiently focused mandatory reporting laws.

The final rule waives the requirement for agreement if the covered entity is unable to obtain the individual's agreement due to incapacity or other emergency circumstance, and (1) the law enforcement official represents that the information is needed to determine whether a violation of law by a person other than the victim has occurred and the information is not intended to be used against the victim; (2) the law enforcement official represents that immediate law enforcement activity that depends on the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and (3) the covered entity determines, in the exercise of professional judgment, that the disclosure is in the individual's best interests. By allowing covered entities, in the exercise of professional judgment, to determine whether such disclosures are in the individual's best interests, the final rule recognizes the importance of the provider-patient relationship.

In addition, the final rule allows covered entities to initiate disclosures of protected health information about victims without the victim's permission to law enforcement officials only if such disclosure is required under a state mandatory reporting law. In other circumstances, plans and providers may disclose protected health information only in response to a request from a law enforcement official. We believe that such an approach recognizes the importance of promoting trust between victims and their health care providers. If providers could initiate reports of victim information to law enforcement officials absent a legal reporting mandate, victims may avoid give their providers health information that could facilitate their treatment, or they may avoid seeking treatment completely.

Comment: Many commenters believed that access to medical records pursuant to this provision should occur only after judicial review. Others believed that it should occur only with patient consent or after notifying the patient of the disclosure to law enforcement. Similarly, some commenters said that the minimum necessary standard should apply to this provision, and they recommended restrictions on law enforcement agencies' re-use of the information.

Response: As discussed above, the final rule generally requires individual agreement as a condition for disclosure of a victim's health information; this requirement provides greater privacy protection and individual control than would a requirement for judicial review. We also discuss above the situations in which this requirement for agreement may be waived, and why that is appropriate. The requirement that covered entities disclose the minimum necessary protected health information consistent with the purpose of the disclosure applies to disclosures of protected health information about victims to law enforcement, unless the disclosure is required by law. (See § 164.514 for more detail on the requirements for minimum necessary use and disclosure of protected health information.) As described above, HIPAA does not provide statutory authority for HHS to regulate law enforcement agencies' re-use of protected health information that they obtain pursuant to this rule.

Comment: A few commenters expressed concern that the NPRM would not have required law enforcement agencies' requests for protected health information about victims to be in writing. They believed that written requests could promote clarity in law enforcement requests, as well as greater accountability among law enforcement officials seeking information.

Response: We do not impose this requirement in the final rule. We believe that such a requirement would not provide significant new protection for victims and would unduly impede the completion of legitimate law enforcement investigations.

Comment: A provider group was concerned that it would be difficult for covered entities to evaluate law enforcement officials' claims that information is needed and that law enforcement activity may be necessary. Some comments from providers and individuals expressed concern that the proposed rule would have provided open-ended access by law enforcement to victims' medical records because of this difficulty in evaluating law enforcement claims of their need for the information.

Response: We modify the NPRM in several ways that reduce covered entities' decisionmaking burdens. The final rule clarifies that covered entities may disclose protected health information about a victim of crime where a report is required by state or other law, and it requires the victim's agreement for disclosure in most other instances. The covered entity must make the decision whether to disclose only in limited circumstances: when there is no mandatory reporting law; or when the victim is unable to provide agreement and the law enforcement official represents that: the protected health information is needed to determine whether a violation of law by a person other than the victim has occurred, that the information will not be used against the victim, and that immediate law enforcement activity that depends on such information would be materially and adversely affected by waiting until the individual is able to agree to the disclosure. In these circumstances, we believe it is appropriate to rely on the covered entity, in the exercise of professional judgment, to determine whether the disclosure is in the individual's best interests. Other sections of this rule allow covered entities to reasonably rely on certain representations by law enforcement officials (see § 164.514, regarding verification,) and require disclosure of the minimum necessary protected health information for this purpose. Together, these provisions do not allow open-ended access or place undue responsibility on providers.

Comments Regarding Proposed § 164.510(f)(4), Intelligence and National Security Activities

In the final rule, we recognize that disclosures for intelligence and national security activities do not always involve ***82687** law enforcement. Therefore, we delete the provisions of proposed § 164.510(f)(4), and we address disclosures for intelligence and national security activities in § 164.512(k), on uses and disclosures for specialized government functions. Comments and responses on these issues are included below, in the comments for that section.

Comments Regarding Proposed § 164.510(f)(5), Health Care Fraud, Crimes on the Premises, and Crimes Witnessed by the Covered Entity's Workforce

Comment: Many commenters noted that proposed § 164.510(f)(5)(i), which covered disclosures for investigations and prosecutions of health care fraud, overlapped with proposed § 164.510(c) which covered disclosures for health oversight activities.

Response: As discussed more fully in § 164.512(d) of this preamble, above, we agree that proposed § 164.510(f)(5)(i) created confusion because all disclosures covered by that provision were already permitted under proposed § 164.510(c) without prior process. In the final rule, therefore, we delete proposed § 164.510(f)(5)(i).

Comment: One commenter was concerned the proposed provision would not have allowed an emergency room physician to report evidence of abuse when the suspected abuse had not been committed on the covered entity's premises.

Response: Crimes on the premises are only one type of crime that providers may report to law enforcement officials. The rules for reporting evidence of abuse to law enforcement officials are described in § 164.512(c) of the rule, and described in detail in § 164.512(c) of the preamble. An emergency room physician may report evidence of abuse if the conditions in § 164.512(c) are met, regardless of where the abuse occurred.

Comment: One commenter argued that covered entities should be permitted to disclose information that "indicates the potential existence" of evidence, not just information that "constitutes evidence" of crimes on the premises or crimes witnessed by a member of the covered entity's workforce.

Response: We agree that covered entities should not be required to guess correctly whether information will be admitted to court as evidence. For this reason, we include a good-faith standard in this provision. Covered entities may disclose information that it believes in good faith constitutes evidence of a crime on the premises. If the covered entity discloses protected health information in good faith but is wrong in its belief that the information is evidence of a violation of law, the covered entity will not be subject to sanction under this regulation.

Section 164.512(g)—Uses and Disclosures About Decedents

Coroners and Medical Examiners

Comment: We received several comments, for example, from state and county health departments, a private foundation, and a provider organization, in support of the NPRM provision allowing disclosure without authorization to coroners and medical examiners.

Response: The final rule retains the NPRM's basic approach to disclosure of coroners and medical examiners. It allows covered entities to disclose protected health information without authorization to coroners and medical examiners, for identification of a deceased person, determining cause of death, or other duties authorized by law.

Comment: In the preamble to the NPRM, we said we had considered but rejected the option of requiring covered entities to redact from individuals' medical records any information identifying other persons before disclosing the record to a coroner or medical examiner. We solicited comment on whether health care providers routinely identify other persons specifically in an individual's medical record and if so, whether in the final rule we should require health care providers to redact information about the other person before providing it to a coroner or medical examiner.

A few commenters said that medical records typically do not include information about persons other than the patient. One commenter said that patient medical records occasionally reference others such as relatives or employers. These commenters recommended requiring redaction of such information in any report sent to a coroner or medical examiner. On the other hand, other commenters said that redaction should not be required. These commenters generally based their recommendation on the burden and delay associated with redaction. In addition to citing the complexity and time involved in redaction of medical records provided to coroners, one commenter said that health plans and covered health care providers were not trained to determine the identifiable information necessary for coroners and medical examiners to do thorough investigations. Another commenter said that redaction should not be required because coroners and medical examiners needed some additional family information to determine what would be done with the deceased after their post-mortem investigation is completed.

Response: We recognize the burden associated with redacting medical records to remove the names of persons other than the patient. In addition, as stated in the preamble to the NPRM, we recognize that there is a limited time period after death within which an autopsy must be conducted. We believe that the delay associated with this burden could make it impossible to conduct a post-mortem investigation within the required time frame. In addition, we agree that health plans and covered health care providers may lack the training necessary to determine the identifiable information necessary for coroners and medical examiners to do thorough investigations. Thus, in the final rule, we do not require health plans or covered providers to redact information about persons other than the patient who may be identified in a patient's medical record before disclosing the record to a coroner or medical examiner.

Comment: One commenter said that medical records sent to coroners and medical examiners were considered their work product and thus were not released from their offices to anyone else. The commenter recommended that HHS establish regulations on how to dispose of medical records and that we create a “no re-release” statement to ensure that individual privacy is maintained without compromising coroners' or medical examiners' access to protected health information. The organization said that such a policy should apply regardless of whether the investigation was civil or criminal.

Response: HIPAA does not provide HHS with statutory authority to regulate coroners' or medical examiners' re-use or re-disclosure of protected health information unless the coroner or medical examiner is also a covered entity. However, we consistently have supported comprehensive privacy legislation to regulate disclosure and use of individually identifiable health information by all entities that have access to it.

Funeral Directors

Comment: One commenter recommended modifying the proposed rule to allow disclosure without authorization to funeral directors. To accomplish this change, the commenter suggested either: (1) Adding another subsection to proposed § 164.510 of the NPRM, to allow disclosure without authorization to funeral directors as needed to make arrangements for ***82688** funeral services and for disposition of a deceased person's remains; or (2) revising proposed § 164.510(e) to allow disclosure of protected health information to both coroners and funeral directors. According to this commenter, funeral directors often need certain protected health information for the embalming process, because a person's medical condition may affect the way in which embalming is performed. For example, the commenter noted, funeral directors increasingly receive bodies after organ and tissue donation, which has implications for funeral home staff duties associated with embalming.

Response: We agree with the commenter. In the final rule, we permit covered entities to disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to a decedent. When necessary for funeral directors to carry out their duties, covered entities may disclose protected health information prior to and in reasonable anticipation of the individual's death.

Comment: One commenter recommended clarifying in the final rule that it does not restrict law enforcement agencies' release of medical information that many state records laws require to be reported, for example, as part of autopsy reports. The commenter recommended stating that law enforcement officials may independently gather medical information, that such information would not be covered by these rules, and that it would continue to be covered under applicable state and federal access laws.

Response: HIPAA does not give HHS statutory authority to regulate law enforcement officials' use or disclosure of protected health information. As stated elsewhere, we continue to support enactment of comprehensive privacy legislation to cover disclosure and use of all individually identifiable health information.

Comment: One commenter recommended prohibiting health plans and covered health care providers from disclosing psychotherapy notes to coroners or medical examiners.

Response: We disagree with the commenter who asserted that psychotherapy notes should only be used by or disclosed to coroners and medical examiners with authorization. Psychotherapy notes are sometimes needed by coroners and medical examiners to determine cause of death, such as in cases where suicide is suspected as the cause of death. We understand that several states require the disclosure of protected health information, including psychotherapy notes, to medical examiners and coroners. However, in the absence of a state law requiring such disclosure, we do not intend to prohibit coroners or medical examiners from obtaining the protected health information necessary to determine an individual's cause of death.

Section 164.512(h)—Uses and Disclosures for Organ Donation and Transplantation Purposes

Comment: Commenters noted that under the organ donation system, information about a patient is disclosed before seeking consent for donation from families. These commenters offered suggestions for ensuring that the system could continue to operate without consent for information sharing with organ procurement organizations and tissue banks. Commenters suggested that organ and tissue procurement organizations should be “covered entities” or that the procurement of organs and tissues be included in the definition of health care operations or treatment, or in the definition of emergency circumstances.

Response: We agree that organ and tissue donation is a special situation due to the need to protect potential donors' families from the stress of considering whether their loved one should be a donor before a determination has been made that donation

would be medically suitable. Rather than list the entities that are "covered entities" or modify the definitions of health care operations and treatment or emergency circumstances to explicitly include organ procurement organizations and tissue banks, we have modified § 164.512 to permit covered entities to use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissues.

Comment: Commenters asked that the rule clarify that organ procurement organizations are health care providers but not business partners of the hospitals.

Response: We agree that organ procurement organizations and tissue banks are generally not business associates of hospitals.

Disclosures and Uses for Government Health Data Systems

Comment: We received a number of comments supporting the exception for disclosure of protected health information to government health data systems. Some supporters stated a general belief that the uses of such information were important to improve and protect the health of the public. Commenters said that state agencies used the information from government health data systems to contribute to the improvement of the health care system by helping prevent fraud and abuse and helping improve health care quality, efficiency, and cost-effectiveness. Commenters asserted that state agencies take action to ensure that data they release based on these data systems do not identify individuals

We also received a large volume of comments opposed to the exception for use and disclosure of protected health information for government health data systems. Many commenters expressed general concern that the provision threatened their privacy, and many believed that their health information would be subject to abuse by government employees. Commenters expressed concern that the provision would facilitate collection of protected health information in one large, centralized government health database that could threaten privacy. Others argued that the proposed rule would facilitate law enforcement access to protected health information and could, in fact, become a database for law enforcement use.

Many commenters asserted that this provision would make individuals concerned about confiding in their health care providers. Some commenters argued that the government should not be allowed to collect individually identifiable health information without patient consent, and that the government could use de-identified data to perform the public policy analyses. Many individual commenters said that HHS lacked statutory and Constitutional authority to give the government access and control of their medical records without consent.

Many commenters believed that the NPRM language on government health data systems was too broad and would allow virtually any government collection of data to be covered. They argued that the government health data system exception was unnecessary because there were other provisions in the proposed rules providing sufficient authority for government agencies to obtain the information they need.

Some commenters were concerned that the NPRM's government health data system provisions would allow disclosure of protected health information for purposes unrelated to health care. These commenters recommended narrowing the provision to allow disclosure of protected health ***82689** information without consent to government health data systems in support of health care-related policy, planning, regulatory, or management functions. Others recommended narrowing the exception to allow use and disclosure of protected health information for government health databases only when a specific statute or regulation has authorized collection of protected health information for a specific purpose.

Response: We agree with the commenters who suggested that the proposed provision that would have permitted disclosures to government health data bases was overly broad, and we remove it from the final rule.

We reviewed the important purposes identified in the comments for government access to protected health information, and believe that the disclosures of protected health information that should appropriately be made without individuals' authorization can be achieved through the other disclosures provided for in the final rule, including provisions permitting covered entities

to disclose information (subject to certain limitations) to government agencies for public health, research, health oversight, law enforcement, and otherwise as required by law. For example, the final rule continues to allow a covered entity to disclose protected health information without authorization to a public health authority to monitor trends in the spread of infectious disease, morbidity, and mortality. Under the rule's health oversight provision, covered entities can continue to disclose protected health information to public agencies for purposes such as analyzing the cost and quality of services provided by covered entities; evaluating the effectiveness of federal, state, and local public programs; examining trends in health insurance coverage of the population; and analyzing variations in access to health coverage among various segments of the population. We believe that it is better to remove the proposed provision for government health data systems generally and to rely on other, more narrowly tailored provisions in the rule to authorize appropriate disclosures to government agencies.

Comment: Some provider groups, private companies, and industry organizations recommended expanding the exception for government health data systems to include data collected by private entities. These commenters said that such an expansion would be justified, because private entities often perform the same functions as public agencies collecting health data.

Response: We eliminate the exception for government health data systems because it was over broad and the uses and disclosures we were trying to permit are permitted by other provisions. We note that private organizations may use or disclose protected health information pursuant to multiple provisions of the rule.

Comment: One commenter recommended clarifying in the final rule that the government health data system provisions apply to: (1) Manufacturers providing data to HCFA and its contractors to help the agency make reimbursement and related decisions; and to (2) third-party payors that must provide data collected by device manufacturers to HCFA to help the agency make reimbursement and related decisions.

Response: The decision to eliminate the general provision permitting disclosures to government health data systems makes this issue moot with respect to such disclosures. We note that the information used by manufacturers to support coverage determinations often is gathered pursuant to patient authorization (as part of informed consent for research) or as an approved research project. There also are many cases in which information can be de-identified before it is disclosed. Where HCFA hires a contractor to collect such protected health information, the contractor may do so under HCFA's authority, subject to the business associate provisions of this rule.

Comment: One commenter recommended stating in the final rule that de-identified information from government health data systems can be disclosed to other entities.

Response: HHS does not have the authority to regulate re-use or re-disclosure of information by agencies or institutions that are not covered entities under the rule. However, we support the policies and procedures that public agencies already have implemented to de-identify any information that they redisclose, and we encourage the continuation of these activities.

Disclosures for Payment Processes

Proposed § 164.510(j) of the NPRM would have allowed disclosure of protected health information without authorization for banking and payment processes. In the final rule, we eliminate this provision. Disclosures that would have been allowed under it, as well as comments received on proposed § 164.510(j), are addressed under § 164.501 of the final rule, under the definition of "payment."

Section 164.512(i)—Uses and Disclosures for Research Purposes

Documentation Requirements of IRB or Privacy Board Approval of Waiver

Comment: A number of commenters argued that the proposed research requirements of § 164.510(j) exceeded the Secretary's authority under section 246(c) of HIPAA. In particular, several commenters argued that the Department was proposing to

extend the Common Rule and the use of the IRB or privacy boards beyond federally-funded research projects, without the necessary authority under HIPAA to do so. One commenter stated that, "Section 246(c) of HIPAA requires the Secretary to issue a regulation setting privacy standards for individually identifiable health information transmitted in connection with the transactions described in section 1173(a)," and thus concluded that the disclosure of health information to researchers is not covered. Some of these commenters also argued that the documentation requirements of proposed § 164.510(j), did not shield the NPRM from having the effect of regulating research by placing the onus on covered health care providers to seek documentation that certain standards had been satisfied before providing protected health information to researchers. These commenters argued that the proposed rule had the clear and intended effect of directly regulating researchers who wish to obtain protected health information from a covered entity.

Response: As discussed above, we do not agree with commenters that the Secretary's authority is limited to individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of HIPAA. We also disagree that the proposed research documentation requirements would have constituted the unauthorized regulation of researchers. The proposed requirements established conditions for the use of protected health information by covered entities for research and the disclosure of protected health information by covered entities to researchers. HIPAA authorizes the Secretary to regulate such uses and disclosures, and the final rule retains documentation requirements similar to those proposed.

Comment: Several commenters believed that the NPRM was proposing either directly or indirectly to modify the Common Rule and, therefore, stated that such modification was beyond the Secretary's authority under HIPAA. Many of these commenters arrived at this conclusion because the waiver of ***82690** authorization criteria proposed in § 164.510(j) differed from the Common Rule's criteria for the waiver of informed consent (Common Rule, §_. 116(d)).

Response: We do not agree that the proposed provision relating to research would have modified the Common Rule. The provisions that we proposed and provisions that we include in the final rule place conditions that must be met before a covered entity may use or disclose protected health information. Those conditions are in addition to any conditions required of research entities under the Common Rule. Covered entities will certainly be subject to laws and regulations in addition to the rule, but the rule does not require compliance with these other laws or regulations. For covered health care providers and health plans that are subject to both the final rule and the Common Rule, both sets of regulations will need to be followed.

Comment: A few commenters suggested that the Common Rule should be extended to all research, regardless of funding source.

Response: We generally agree with the commenters on the need to provide protections to all human subjects research, regardless of funding source. HIPAA, however, did not provide the Department with authority to extend the Common Rule beyond its current purview. For research that relies on the use or disclosure of protected health information by covered entities without authorization, the final rule applies the Common Rule's principles for protecting research subjects by, in most instances, requiring documentation of independent board review, and a finding that specified criteria designed to protect the privacy of prospective research subjects have been met.

Comment: A large number of commenters agreed that the research use and disclosure of protected health information should not require authorization. Of these commenters, many supported the proposed rule's approach to research uses and disclosures without authorization, including many from health care provider organizations, the mental health community, and members of Congress. Others, while they agreed that the research use and disclosure should not require authorization disagreed with the NPRM's approach and proposed alternative models.

The commenters who supported the NPRM's approach to permitting researchers access to protected health information without authorization argued that it was appropriate to apply "Common Rule-like" provisions to privately funded research. In addition, several commenters explicitly argued that the option to use a privacy board, in lieu of an IRB, must be maintained because requiring IRB review to include all aspects of patient privacy could diffuse focus and significantly compromise an IRB's ability

to execute its primary patient protection role. Furthermore, several commenters believed that privacy board review should be permitted, but wanted equal oversight and accountability for privacy boards and IRBs.

Many other commenters agreed that the research use and disclosure should not require authorization, but disagreed with the proposed rule's approach and proposed alternative models. Several of these commenters argued that the final rule should eliminate the option for privacy board review and that all research to be subject to IRB review. These commenters stated that having separate and unequal systems to approve research based on its funding source would complicate compliance and go against the spirit of the regulations. Several of these commenters, many from patient and provider organizations, opposed the permitted use of privacy boards to review research studies and instead argued that IRB review should be required for all studies involving the use or disclosure of protected health information. These commenters argued that although privacy board requirements would be similar, they are not equitable; for example, only three of the Common Rule's six requirements for the membership of IRBs were proposed to be required for the membership on privacy boards, and there was no proposed requirement for annual review of ongoing research studies that used protected health information. Several commenters were concerned that the proposed option to obtain documentation of privacy board review, in lieu of IRB review, would perpetuate the divide in the oversight of federally-funded versus publically-funded research, rather than eliminate the differential oversight of publically- and privately-funded research, with the former still being held to a stricter standard. Some of these commenters argued that these unequal protections would be especially apparent for the disclosure of research with authorization, since under the Common Rule, IRB review of human subjects studies is required, regardless of the subject's consent, before the study may be conducted.

Response: Although we share the concern raised by commenters that the option for the documentation of privacy board approval for an alteration or waiver of authorization may perpetuate the unequal mechanisms of protecting the privacy of human research subjects for federally-funded versus publically-funded research, the final rule is limited by HIPAA to addressing only the use and disclosure of protected health information by covered entities, not the protection of human research subjects more generally. Therefore, the rule cannot standardize human subjects protections throughout the country. Given the limited scope of the final rule with regard to research, the Department believes that the option to obtain documentation of privacy board approval for an alteration or waiver of authorization in lieu of IRB approval provides covered entities with needed flexibility. Therefore, in the final rule we have retained the option for covered entities to rely on documentation of privacy board approval that specified criteria have been met.

We disagree with the rationale suggested by commenters who argued that the option for privacy board review must be maintained because requiring IRB review to include all aspects of patient privacy could diffuse focus and significantly compromise an IRB's ability to execute its primary patient protection role. For research that involves the use of individually identifiable health information, assessing the risk to the privacy of research subjects is currently one of the key risks that must be assessed and addressed by IRBs. In fact, we expect that it will be appropriate for many research organizations that have existing IRBs to rely on these IRBs to meet the documentation requirements of § 164.512(i).

Comment: One health care provider organization recommended that the IRB or privacy board mechanism of review should be applied to non-research uses and disclosures.

Response: We disagree. Imposing documentation of privacy board approval for other public policy uses and disclosures permitted by § 164.512 would result in undue delays in the use or disclosure of protected health information that could harm individuals and the public. For example, requiring that covered health care providers obtain third-party review before permitting them to alert a public health authority that an individual was infected with a serious communicable disease could cause delay appropriate intervention by a public health authority and could present a serious threat to the health of many individuals.

Comment: A number of commenters, including several members of Congress, ***82691** argued that since the research provisions in proposed § 164.510(j) were modeled on the existing system of human subjects protections, they were inadequate and would shatter public trust if implemented. Similarly, some commenters, asserted that IRBs are not accustomed to reviewing and approving utilization reviews, outcomes research, or disease management programs and, therefore, IRB review may not be an

effective tool for protecting patient privacy in connection with these activities. Some of these commenters noted that proposed § 164.510(j) would exacerbate the problems inherent in the current federal human subjects protection system especially in light of the recent GAO reports that indicate the IRB system is already over-extended. Furthermore, a few commenters argued that the Common Rule's requirements may be suited for interventional research involving human subjects, but is ill suited to the archival and health services research typically performed using medical records without authorization. Therefore, these commenters concluded that extending "Common Rule-like" provisions to the private sector would be inadequate to protect human subjects and would result in significant and unnecessary cost increases.

Response: While the vast majority of government-supported and regulated research adheres to strict protocols and the highest ethical standards, we agree that the federal system of human subjects protections can and must be strengthened. To work toward this goal, on May 23, the Secretary announced several additional initiatives to enhance the safety of subjects in clinical trials, strengthen government oversight of medical research, and reinforce clinical researchers' responsibility to follow federal guidelines. As part of this initiative, the National Institutes of Health have undertaken an aggressive effort to ensure IRB members and IRB staff receive appropriate training in bioethics and other issues related to research involving human subjects, including research that involves the use of individually identifiable health information. With these added improvements, we believe that the federal system of human subjects protections continues to be a good model to protect the privacy of individually identifiable health information that is used for research purposes. This model of privacy protection is also consistent with the recent recommendations of both the Institute of Medicine in their report entitled, "Protecting Data Privacy in Health Services Research," and the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance in their report entitled, "Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment." Both of these reports similarly concluded that health services research that involves the use of individually identifiable health information should undergo IRB review or review by another board with sufficient expertise in privacy and confidentiality protection.

Furthermore, it is important to recognize that the Common Rule applies not only to interventional research, but also to research that uses individually identifiable health information, including archival research and health services research. The National Bioethics Advisory Commission (NBAC) is currently developing a report on the federal oversight of human subjects research, which is expected to address the unique issues raised by non-interventional human subjects research. The Department looks forward to receiving NBAC's report, and carefully considering the Commission's recommendations. This final rule is the first step in enhancing patients' privacy and we will propose modifications to the rule if changes are warranted by the Commission's findings and recommendations.

Comment: Many commenters argued that the proposed research provision would have a chilling affect on the willingness of health plans and covered providers to participate in research because of the criminal and civil penalties that could be imposed for failing to meet the requirements that would have been required by proposed § 164.510(j). Some of these commenters cautioned, that over time, research could be severely hindered if covered entities choose not to disclose protected health information to researchers. In addition, one commenter recommended that a more reasonable approach would be to require IRB or privacy board approval only if the results of the research were to be broadly published. Another commenter expressed concern that the privacy rule could influence IRBs or privacy boards to refuse to recognize the validity of decisions by other IRBs or privacy boards and specifically recommended that the privacy rule include a preamble statement that: (1) The "risk" balancing consider only the risk to the patient, not the risk to the institution, and (2) add a phrase that the decision by the initial IRB or privacy board to approve the research shall be given deference by other IRBs or privacy boards. This commenter also recommended that to determine whether IRBs or privacy boards were giving such deference to prior IRB or privacy board review, HHS should monitor the disapproval rate by IRB or privacy boards conducting secondary reviews.

Response: As the largest federal sponsor of medical research, we understand the important role of research in improving our Nation's health. However, the benefits of research must be balanced against the risks, including the privacy risks, for those who participate in research. An individual's rights and welfare must never be sacrificed for scientific or medical progress. We believe that the requirements for the use and disclosure of protected health information for research without authorization provides

an appropriate balance. We understand that some covered health care providers and health plans may conclude that the rule's documentation requirements for research uses and disclosures are too burdensome.

We rejected the recommendation that documentation of IRB or privacy board approval of the waiver of authorization should only be required if the research were to be "broadly published." Research findings that are published in de-identified form have little influence on the privacy interests of individuals. We believe that it is the use or disclosure of individually identifiable health information to a researcher that poses the greater risk to individuals' privacy, not publication of de-identified information.

We agree with the commenters that IRB or privacy board review should address the privacy interests of individuals and not institutions. This provision is intended to protect individuals from unnecessary uses and disclosures of their health information and does not address institutional privacy.

We disagree with the comment that documentation of IRB or privacy board approval of the waiver of authorization should be given deference by other IRBs or privacy boards conducting secondary reviews. We do not believe that it is appropriate to restrict the deliberations or judgments of privacy boards, nor do we have the authority under this rule to instruct IRBs on this issue. Instead, we reiterate that all disclosures for research purposes under § 164.512(i) are voluntary, and that institutions may choose to impose more stringent requirements for any use and disclosure permitted under § 164.512. ***82692**

Comment: Some commenters were concerned about the implications of proposed § 164.510(j) on multi-center research. These commenters argued that for multi-center research, researchers may require protected health information from multiple covered entities, each of whom may have different requirements for the documentation of IRB or privacy board review. Therefore, there was concern that documentation that may suffice for one covered entity, may not for another, thereby hindering multi-center research.

Response: Since § 164.512(i) establishes minimum documentation standards for covered health care providers and health plans using or disclosing protected health information for research purposes, we understand that some covered providers and health plans may choose to require additional documentation requirements for researchers. We note, however, that nothing in the final rule would preclude a covered health care provider or health plan from developing the consistent documentation requirements provided they meet the requirements of § 164.512(i).

Comment: One commenter who was also concerned that the minimum necessary requirements of proposed § 164.506(b) would negatively affect multi-center research because covered entities participating in multi-site research studies would no longer be permitted to rely upon the consent form approved by a central IRB, and nor would participating entities be permitted to report data to the researcher using the case report form approved by the central IRB to guide what data points to include. This commenter noted that the requirement that each site would need to undertake a separate minimum necessary review for each disclosure would erect significant barriers to the conduct of research and may compromise the integrity and validity of data combined from multiple sites. This commenter recommended that the Secretary absolve a covered entity of the responsibility to make its own individual minimum necessary determinations if the entity is disclosing information pursuant to an IRB or privacy board-approved protocol.

Response: The minimum necessary requirements in the final rule have been revised to permit covered entities to rely on the documentation of IRB or privacy board approval as meeting the minimum necessary requirements of § 164.514. However, we anticipate that much multi-site research, such as multi-site clinical trials, will be conducted with patients' informed consent as required by the Common Rule and FDA's protection of human subjects regulations, and that patients' authorization will also be sought for the use or disclosure of protected health information for such studies. Therefore, it should be noted that the minimum necessary requirements do not apply for uses or disclosures made with an authorization. In addition, the final rule allows a covered health care provider or health plan to use or disclose protected health information pursuant to an authorization that was approved by a single IRB or privacy board, provided the authorization met the requirements of § 164.508. The final rule

does not, however, require IRB or privacy board review for the use or disclosure of protected health information for research conducted with individuals' authorization.

Comment: Some commenters believed that proposed § 164.510(j) would have required documentation of both IRB and privacy board review before a covered entity would be permitted to disclose protected health information for research purposes without an individual's authorization.

Response: This is incorrect. Section 164.512(i)(1)(i) of the final rule requires documentation of alteration or waiver approval by either an IRB or a privacy board.

Comment: Some commenters believed that the proposed rule would have required that patients be notified whenever protected health information about themselves was disclosed for research purposes.

Response: This is incorrect. Covered entities are not required to inform individuals that protected health information about themselves has been disclosed for research purposes. However, as required in § 164.520 of the final rule, the covered entity must include research disclosures in their notice of information practices. In addition, as required by § 164.528 of the rule, covered health care providers and health plans must provide individuals, upon request, with an accounting of disclosures made of protected health information about the individual.

Comment: One commenter recommended that IRB and privacy boards also be required to be accredited.

Response: While we agree that the issue of accrediting IRBs and privacy boards deserves further consideration, we believe it is premature to require covered entities to ensure that the IRB or privacy board that approves an alteration or waiver of authorization is accredited. Currently, there are no accepted accreditation standards for IRBs or privacy boards, nor a designated accreditation body. Recognizing the need for and value of greater uniformity and public accountability in the review and approval process, HHS, with support from the Office of Human Research Protection, National Institutes of Health, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Health Care Research and Quality, has engaged the Institute of Medicine to recommend uniform performance resource-based standards for private, voluntary accreditation of IRBs. This effort will draw upon work already undertaken by major national organizations to develop and test these standards by the spring of 2001, followed by initiation of a formal accreditation process before the end of next year. Once the Department has received the Institute of Medicine's recommended accreditation standards and process for IRBs, we plan to consider whether this accreditation model would also be applicable to privacy boards.

Comment: A few commenters also noted that if both an IRB and a privacy board reviewed a research study and came to conflicting decisions, proposed § 164.510(j) was unclear about which board's decision would prevail.

Response: The final rule does not stipulate which board's decision would prevail if an IRB and a privacy board came to conflicting decisions. The final rule requires covered entities to obtain documentation that one IRB or privacy board has approved of the alteration or waiver of authorization. The covered entity, however, has discretion to request information about the findings of all IRBs and/or privacy boards that have reviewed a research proposal. We strongly encourage researchers to notify IRBs and privacy boards of any prior IRB or privacy board review of a research protocol.

Comment: Many commenters noted that the NPRM included no guidance on how the privacy board should approve or deny researchers' requests. Some of these commenters recommended that the regulation stipulate that privacy boards be required to follow the same voting rules as required under the Common Rule.

Response: We agree that the Common Rule (§__.108(b)) provides a good model of voting procedures for privacy boards and incorporate such procedures to the extent they are relevant. In the final rule, we require that the documentation of alteration or waiver of authorization state that the alteration or waiver has been reviewed and approved by either (1) an IRB that has followed

the voting requirements of the Common Rule (§__.108(b)), or the expedited review ***82693** procedures of the Common Rule (§__.110); or (2) unless an expedited review procedure is used, a privacy board that has reviewed the proposed research at a convened meeting at which a majority of the privacy board members are present, including at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any such entities, and the alteration or waiver of authorization is approved by the majority of privacy board members present at the meeting.

Comment: A few commenters were concerned that the research provisions would be especially onerous for small non-governmental entities, furthering the federal monopoly on research.

Response: We understand that the documentation requirements of § 164.512(i), as well as other provisions in the final rule, may be more onerous for small entities than for larger entities. We believe, however, that when protected health information is to be used or disclosed for research without an individual's authorization, the additional privacy protections in § 164.512(i) are essential to reduce the risk of harm to the individual.

Comment: One commenter believed that it was paradoxical that, under the proposed rule, the disclosure of protected health information for research conducted with an authorization would have been more heavily burdened than research that was conducted without authorization, which they reasoned was far less likely to bring personal benefit to the research subjects.

Response: It was not our intent to impose more requirements on covered entities using or disclosing protected health information for research conducted with authorization than for research conducted without authorization. In fact, the proposed rule would have required only authorization as stipulated in proposed § 164.508 for research disclosures made with authorization, and would have been exempt from the documentation requirements in proposed § 164.510(j). We retain this treatment in the final rule. We disagree with the commenter who asserted that the requirements for research conducted with authorization are more burdensome for covered health care providers and plans than the documentation provisions of this paragraph.

Comment: A number of comments, mostly from the pharmaceutical industry, recommended that the final rule state that privacy boards be permitted to waive authorization only with respect to research uses of medical information collected in the course of treatment or health care operations, and not with respect to clinical research. Similarly, one commenter recommended that IRBs and privacy boards be authorized to review privacy issues only, not the entire research project. These commenters were concerned that by granting waiver authority to privacy boards and IRBs, and by incorporating the Common Rule waiver criteria into the waiver criteria included in the proposed rule, the Secretary has set the stage for privacy boards to review and approve waivers in circumstances that involve interventional research that is not subject to the Common Rule.

Response: We agree with the commenters who recommended that the final rule clarify that the documentation of IRB or privacy board approval of the waiver of authorization would be based only on an assessment of the privacy risks associated with a research study, not an assessment of all relevant risks to participants. In the final rule, we have amended the language in the waiver criteria to make clear that these criteria relate only to the privacy interests of the individual. We anticipate, however, that the vast majority of uses and disclosures of protected health information for interventional research will be made with individuals' authorization. Therefore, we expect it will be rare that a researcher will seek IRB or privacy board approval for the alteration or waiver of authorization, but seek informed consent for participation for the interventional component of the research study. Furthermore, we believe that interventional research, such as most clinical trials, could not meet the waiver criteria in the final rule (§ 164.512(i)(2)(ii)(C)), which states “the research could not practicably be conducted without the alteration or waiver.” If a researcher is to have direct contact with research subjects, the researcher should in virtually all cases be able to seek and obtain patients' authorization for the use and disclosure of protected health information about themselves for the research study.

Comment: A few commenters recommended that the rule explicitly state that covered entities would be permitted to rely upon an IRB or privacy boards' representation that the research proposal meets the requirements of proposed § 164.510(j).

Response: We agree with this comment. The final rule clarifies that covered health care providers and health plans are allowed to rely on an IRB's or privacy board's representation that the research proposal meets the requirements of § 164.512(i).

Comment: One commenter recommended that IRBs be required to maintain web sites with information on proposed and approved projects.

Response: We agree that it could be useful for IRBs and privacy boards to maintain web sites with information on proposed and approved projects. However, requiring this of IRBs and privacy boards is beyond the scope of our authority under HIPAA. In addition, this recommendation raises concerns that would need to be addressed, including concerns about protecting the confidentiality of research participants and propriety information that may be contained in research proposals. For these reasons, we decided not to incorporate this requirement into the final rule.

Comment: One commenter recommended that HHS collect data on research-related breaches of confidentiality and investigate existing anecdotal reports of such breaches.

Response: This recommendation is beyond HHS' legal authority, since HIPAA did not give us the authority to regulate researchers. Therefore, this recommendation was not included in the final rule.

Comment: A number of commenters were concerned that HIPAA did not give the Secretary the authority to protect information once it was disclosed to researchers who were not covered entities.

Response: The Secretary shares these commenters' concerns about the Department's limited authority under HIPAA. We strongly support the enactment of additional federal legislation to fill these crucial gaps in the Secretary's authority.

Comment: One commenter recommended that covered entities should be required to retain the IRB's or privacy board's documentation of approval of the waiver of individuals' authorization for at least six years from when the waiver was obtained.

Response: We agree with this comment and have included such a requirement in the final rule. See § 164.530(j).

Comment: One commenter recommended that whenever health information is used for research or administrative purposes, a plan is in place to evaluate whether to and how to feed patient-specific information back into the health system to benefit an individual or group of patients from whom the health information was derived.

Response: While we agree that this recommendation is consistent with the ***82694** responsible conduct of research, HIPAA did not give us the authority to regulate research. Therefore, this recommendation was not included in the final rule.

Comment: A few commenters recommended that contracts between covered entities and researcher be pursued. Comments received in favor of requiring contractual agreements argued that such a contract would be enforceable under law, and should prohibit secondary disclosures by researchers. Some of these commenters recommended that contracts between covered entities and researchers should be the same as, or modeled on, the proposed requirements for business partners. In addition, some commenters argued that contracts between covered entities and researchers should be required as a means of placing equal responsibility on the researcher for protecting protected health information and for not improperly re-identifying information.

Response: In the final rule, we have added an additional waiver criteria to require that there are adequate written assurances from the researcher that protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart. We believe that this additional waiver criteria provides additional assurance that protected health information will not be misused by researchers, while not imposing the additional burdens of a contractual

requirement on covered health care providers and health plans. We were not persuaded by the comments received that contractual requirements would provide necessary additional protections, that would not also be provided by the less burdensome waiver criteria for adequate written assurance that the researcher will not re-use or disclose protected health information, with few exceptions. Our intent was to strengthen and extend existing privacy safeguards for protected health information that is used or disclosed for research, while not creating unnecessary disincentives to covered health care providers and health plans who choose to use or disclose protected health information for research purposes.

Comment: Some commenters explicitly opposed requiring contracts between covered entities and researchers as a condition of permitting the use or disclosure of protected health information for research purposes. These commenters argued that such a contractual requirement would be too onerous for covered entities and researchers and would hinder or halt important research.

Response: We agree with the arguments raised by these commenters, and thus, the final rule does not require contracts between covered entities and researchers as a condition of using or disclosing protected health information for research purposes without authorization.

Comment: A large number of commenters strongly supported requiring patient consent before protected health information could be used or disclosed, including but not limited to use and disclosure for research purposes. These commenters argued that the unconsented-to use of their medical records abridged their autonomy right to decide whether or not to participate in research. A few referenced the Nuremberg Code in support of their view, noting that the Nuremberg Code required individual consent for participation in research.

Response: We agree that it is of foremost importance that individuals' privacy rights and welfare be safeguarded when protected health information about themselves is used or disclosed for research studies. We also strongly believe that continued improvements in the nation's health requires that researchers be permitted access to protected health information without authorization in certain circumstances. Additional privacy protections are needed, however, and we have included several in the final rule. If covered entities plan to disclose protected health without individuals' authorization for research purposes, individuals must be informed of this through the covered entity's notice to patients of their information practices. In addition, before covered health care providers or health plans may use or disclose protected health information for research without authorization, they must obtain documentation that an IRB or privacy board has found that specified waiver criteria have been met, unless the research will include protected health information about deceased individuals only, or is solely for reviews that are preparatory to research.

While it is true that the first provision of the Nuremberg Code states that “the voluntary consent of the human subject is absolutely essential,” it is important to understand the context of this important document in the history of protecting human subjects research from harm. The Nuremberg Code was developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis, and was one of the first documents setting forth principles for the ethical conduct of human subjects research. The acts of atrocious cruelty that the Nuremberg Code was developed to address, focused on preventing the violations to human rights and dignity that occurred in the name of “medical advancement.” The Code, however, did not directly address the ethical conduct of non-interventional research, such as medical records research, where the risk of harm to participants can be unlike those associated with clinical research.

We believe that the our proposed requirements for the use or disclosure of protected health information for research are consistent with the ethical principles of “respect for persons,” “beneficence,” and “justice,” which were established by the Belmont Report in 1978, and are now accepted as the quintessential requirements for the ethical conduct of research involving human subjects, including research using individually identifiable health information. These ethical principles formed the foundation for the requirements in the Common Rule, on which our proposed requirements for research uses and disclosures were modeled.

Comment: Many commenters recommended that the privacy rule permit individuals to opt out of having their records used for the identified “important” public policy purposes in § 164.510, including for research purposes. These commenters asserted

that permitting the use and disclosure of their protected health information without their consent, or without an opportunity to "opt out" of having their information used or disclosed, abridged individuals' right to decide who should be permitted access to their medical records. In addition, one commenter argued that although the research community has been sharply critical of a Minnesota law that limits access to health records (Minnesota Statute Section 144.335 (1998)), researchers have cited a lack of response to mailed consent forms as the primary factor behind a decrease in the percentage of medical records available for research. This commenter argued that an opt-out provision would not be subject to this "nonresponder" problem.

Response: We believe that a meaningful right to "opt out" of a research study requires that individuals be contacted and informed about the study for which protected health information about themselves is being requested by a researcher. We concluded, therefore, that an "opt out" provision of this nature may suffer from ***82695** the same decliner bias that has been experienced by researchers who are subject to laws that require patient consent for medical records research. Furthermore, evidence on the effect of a mandatory "opt out" provision for medical records research is only fragmentary at this time, but at least one study has preliminarily suggested that those who refuse to consent for research access to their medical records may differ in statistically significant ways from those who consent with respect to variables such as age and disease category (SJ Jacobsen et al. "Potential Effect of Authorization Bias on Medical Records Research." Mayo Clin Proc 74: (1999) 330-338). For these reasons, we disagree with the commenters who recommended that an "opt out" provision be included in the final rule. In the final rule, we do require covered entities to include research disclosures in their notice of information practices. Therefore, individuals who do not wish for protected health information about themselves to be disclosed for research purposes without their authorization could select a health care provider or health plan on this basis. In addition, the final rule also permits covered health care providers or health plans to agree not to disclose protected health information for research purposes, even if research disclosures would otherwise be permitted under their notice of information practices. Such an agreement between a covered health care provider or health plan and an individual would not be enforceable under the final rule, but might be enforceable under applicable state law.

Comment: Some commenters explicitly recommended that there should be no provision permitting individuals to opt out of having their information used for research purposes.

Response: We agree with these commenters for the reasons discussed above.

IRB and Privacy Board Review

Comments: The NPRM imposed no requirements for the location or sponsorship of the IRB or privacy board. One commenter supported the proposed approach to permit covered entities to rely on documentation of a waiver by a IRB or privacy board that was convened by the covered entity, the researcher, or another entity.

In contrast, a few commenters recommended that the NPRM require that the IRB or privacy board be outside of the entity conducting the research, although the rationale for these recommendations was not provided. Several industry and consumer groups alternatively recommended that the regulation require that privacy boards be based at the covered entity. These comments argued that "if the privacy board is to be based at the entity receiving data, and that entity is not a covered entity, there will be little ability to enforce the regulation or study the effectiveness of the standards."

Response: We agree with the comment supporting the proposed rule's provision to impose no requirements for the location or sponsorship of the IRB or privacy board that was convened to review a research proposal for the alteration or waiver of authorization criteria. In the absence of a rationale, we were not persuaded by the comments asserting that the IRB or privacy board should be convened outside of the covered entity. In addition, while we agree with the comments that asserted HHS would have a greater ability to enforce the rule if a privacy board was established at the covered entity rather than an uncovered entity, we concluded that the additional burden that such a requirement would place on covered entities was unwarranted. Furthermore, under the Common Rule and FDA's protection of human subjects regulations, IRB review often occurs at the site of the recipient researchers' institution, and it was not our intent to change this practice. Therefore, in the final rule, we continue to impose no requirements for the location or sponsorship of the IRB or privacy board.

Privacy Board Membership

Comment: Some commenters were concerned that the proposed composition of the privacy board did not adequately address potential conflicts of interest of the board members, particularly since the proposed rule would have permitted the board's "unaffiliated" member to be affiliated with the entity disclosing the protected health information for research purposes. To address this concern, some commenters recommended that the required composition of privacy boards be modified to require "* * * at least one member who is not affiliated with the entity receiving or disclosing protected health information." These commenters believed that this addition would be more sound and more consistent with the Common Rule's requirements for the composition of IRBs. Furthermore, it was argued that this requirement would prohibit covered entities from creating a privacy board comprised entirely of its own employees.

Response: We agree with these comments. In the final rule we have revised the proposed membership for privacy board to reduce potential conflict of interest among board members. The final rule requires that documentation of alteration or waiver from a privacy board, is only valid under § 164.512(i) if the privacy board includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to a person who is affiliated with such entities.

Comment: One commenter recommended that privacy boards be required to include more than one unaffiliated member to address concerns about conflict of interest among members.

Response: We disagree that privacy boards should be required to include more than one unaffiliated member. We believe that the revised membership criterion for the unaffiliated member of the privacy board, and the criterion that requires that the board have no member participating in a review of any project in which the member has a conflict of interest, are sufficient to ensure that no member of the board has a conflict of interest in a research proposal under their review.

Comment: Many commenters also recommended that the membership of privacy boards be required to be more similar to that of IRBs. These commenters were concerned that privacy boards, as described in the proposed rule, would not have the needed expertise to adequately review and oversee research involving the use of protected health information. A few of these commenters also recommended that IRBs be required to have at least one member trained in privacy or security matters.

Response: We disagree with the comments asserting that the membership of privacy boards should be required be more similar to IRBs. Unlike IRBs, privacy boards only have responsibility for reviewing research proposals that involve the use or disclosure of protected health information without authorization. We agree, however, that the proposed rule may not have ensured that the privacy board had the necessary expertise to protect adequately individuals' privacy rights and interests. Therefore, in the final rule, we have modified one of the membership criteria for privacy board to require that the board has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests.

Comment: Two commenters recommended that IRBs and privacy ***82696** boards be required to include patient advocates.

Response: The Secretary's legal authority under HIPAA does not permit HHS to modify the membership of IRBs. Moreover, we disagree with the comments recommending that IRBs and privacy board should be required to include patient advocates. We were not persuaded that patient advocates are the only persons with the needed expertise to protect patients' privacy rights and interests. Therefore, in the final rule, we do not require that patient advocates be included as members of a privacy board. However, under the final rule, IRBs and privacy board members could include patient advocates provided they met the required membership criteria in § 164.512(i).

Comment: A few commenters requested clarification of the term "conflict of interest" as it pertained to the proposed rule's criteria for IRB and privacy board membership. In particular, some commenters recommended that the final rule clarify what

degree of involvement in a research project by a privacy board member would constitute a conflict, thereby precluding that individual's participation in a review. One commenter specifically requested clarification about whether employment by the covered entity constituted a conflict of interest, particularly if the covered entity is receiving a financial gain from the conduct of the research.

Response: We understand that determining what constitutes conflict of interest can be complex. We do not believe that employees of covered entities or employees of the research institution requesting protected health information for research purposes are necessarily conflicted, even if those employees may benefit financially from the research. However, there are many factors that should be considered in assessing whether a member of an IRB has a conflict of interest, including financial and intellectual conflicts.

As part of a separate, but related effort to the final rule, during the summer of 2000, HHS held a conference on human subject protection and financial conflicts of interest. In addition, HHS solicited comments from the public about financial conflicts of interest associated with human subjects research for researchers, IRB members and staff, and research sponsors. The findings from the conference and the public comments received are forming the basis for guidance that HHS is now developing on financial conflicts of interest.

Privacy Training for IRB and Privacy Boards

Comment: A few commenters expressed support for training IRB members and chairs about privacy issues, recommending that such training either be required or that it be encouraged in the final rule.

Response: We agree with these comments and thus encourage institutions that administer IRBs and privacy boards to ensure that the members of these boards are adequately trained to protect the privacy rights and welfare of individuals about whom protected health information is used for research purposes. In the final rule, we require that privacy board members have varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests. We believe that this criterion for privacy board membership requires that members already have the necessary knowledge or that they be trained to address privacy issues that arise in the conduct of research that involves the use of protected health information. In addition, we note that the Common Rule (§__.107(a)) already imposes a general requirement that IRB members posses adequate training and experience to adequately evaluate the research which it reviews. IRBs are also authorized to obtain the services of consultants (§__.107(f)) to provide expertise not available on the IRB. We believe that these existing requirements in the Common Rule already require that an IRB have the necessary privacy expertise.

Waiver Criteria

Comment: A large number of comments supported the proposed rule's criteria for the waiver of authorization by an IRB or privacy board.

Response: While we agree that several of the waiver criteria should be retained in the final rule, we have made changes to the waiver criteria to address some of the comments we received on specific criteria. These reason for these changes are discussed in the response to comments below.

Comment: In addition to the proposed waiver criteria, several commenters recommended that the final rule also instruct IRBs and privacy boards to consider the type of protected health information and the sensitivity of the information to be disclosed in determining whether to grant a waiver, in whole or in part, of the authorization requirements.

Response: We agree with these comments, but believe that the requirement to consider the type and sensitivity of protected health information was already encompassed by the proposed waiver criteria. We encourage and expect that IRBs and privacy

boards will take into consideration the type and sensitivity of protected health information, as appropriate, in considering the waiver criteria included in the final rule.

Comment: Many commenters were concerned that the criteria were not appropriate in the context of privacy risks and recommended that the waiver criteria be rewritten to more precisely focus on the protection of patient privacy. In addition, some commenters argued that the proposed waiver criteria were redundant with the Common Rule and were confusing because they mix elements of the Common Rule's waiver criteria—some of which they argued were relevant only to interventional research. In particular, a number of commenters raised these concerns about proposed criterion (ii). Some of these commenters suggested that the word “privacy” be inserted before “rights.”

Response: We agree with these comments. To focus all of the criterion on individuals' privacy interests, in the final rule, we have modified one of the proposed waiver criteria, eliminated one proposed criterion, and added an additional criterion : (1) the proposed criterion which stated, “the waiver will not adversely affect the rights and welfare of the subjects,” has been revised in the final rule as follows: “the alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;” (2) the proposed criterion which stated, “whenever appropriate, the subjects will be provided with additional pertinent information after participation,” has been eliminated; and (3) a criterion has been added in the final rule which states, “there are adequate written assurances that the protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.” In addressing these criteria, we expect that IRBs and privacy boards will not only consider the immediate privacy interests of the individual that would arise from the proposed research study, but also the possible implications from a loss of privacy, such as the loss of employment, loss or change in cost of health insurance, and social stigma. ***82697**

Comment: A number of commenters were concerned about the interaction between the proposed rule and the Common Rule. One commenter opposed the four proposed waiver criteria which differed from the Common Rule's criteria for the waiver of informed consent (§__.116(d)) on the grounds that the four criteria proposed in addition to the Common Rule's waiver criteria would apply only to the research use and disclosure of protected health information by covered entities. This commenter argued that this would lead to different standards for the protection of other kinds of individually identifiable health information used in research that will fall outside of the scope of the final rule. This commenter concluded that this inconsistency would be difficult for IRBs to administer, difficult for IRB members to distinguish, and would be ethically questionable. For these reasons, many commenters recommended that the final rule should permit the waiver criteria of the Common Rule, to be used in lieu of the waiver criteria identified in the proposed rule.

Response: We disagree with the comments recommending that the waiver criteria of the Common Rule should be permitted to be used in lieu of the waiver criteria identified in the proposed rule. The Common Rule's waiver criteria were designed to protect research subjects from all harms associated with research, not specifically to protect individuals' privacy interests. We understand that the waiver criteria in the final rule may initially cause confusion for IRBs and researchers that must attend to both the final rule and the Common Rule, but we believe that the additional waiver criteria adopted in the final rule are essential to ensure that individuals' privacy rights and welfare are adequately safeguarded when protected health information about themselves is used for research without their authorization. We agree that ensuring that the privacy rights and welfare of all human subjects—involved in all forms of research—is ethically required, and the new Office of Human Research Protection will immediately initiate plans to review the confidentiality provisions of the Common Rule.

In addition, at the request of the President, the National Bioethics Advisory Commission has begun an examination of the current federal human system for the protection of human subjects in research. The current scope of the federal regulatory protections for protecting human subjects in research is just one of the issues that will be addressed in the by the Commission's report, and the Department looks forward to receiving the Commission's recommendations.

Concerns About Specific Waiver Criteria

Comment: One commenter argued that the term "welfare" was vague and recommended that it be deleted from the proposed waiver of authorization criterion which stated, "the waiver will not adversely affect the rights and welfare of the subjects."

Response: We disagree with the comment recommending that the final rule eliminate the term "welfare" from this waiver criterion. As discussed in the National Bioethics Advisory Commission's 1999 report entitled, "Research Involving Human Biological Materials: Ethical Issues and Policy Guidance," "Failure to obtain consent may adversely affect the rights and welfare of subjects in two basic ways. First, the subject may be improperly denied the opportunity to choose whether to assume the risks that the research presents, and second, the subject may be harmed or wronged as a result of his or her involvement in research to which he or she has not consented * * *. Subjects' interest in controlling information about themselves is tied to their interest in, for example, not being stigmatized and not being discriminated against in employment and insurance." Although this statement by the Commission was made in the context of research involving human biological materials, we believe research that involves the use of protected health information similarly requires that social and psychological harms be considered when assessing whether an alteration or waiver will adversely affect the privacy rights and welfare of individuals. We believe it would be insufficient to attend only to individuals' privacy "rights" since some of the harms that could result from a breach of privacy, such as stigmatization, and discrimination in employment or insurance, may not be tied directly to an individuals' "rights," but would have a significant impact on their welfare. Therefore, in the final rule, we have retained the term "welfare" in this criterion for the alteration or waiver of authorization but modified the criterion as follows to focus more specifically on privacy concerns and to clarify that it pertains to alterations of authorization: "the alteration or waiver will not adversely affect the privacy rights and the welfare of the individual."

Comment: A few commenters recommended that the proposed waiver criteria that stated, "the research could not practicably be conducted without the waiver," be modified to eliminate the term "practicably." These commenters believed that determining "practicably" was subjective and that its elimination would facilitate IRBs' and privacy boards' implementation of this criterion. In addition, one commenter was concerned that this term could be construed to require authorization if enough weight is given to a privacy interest, and little weight is given to cost or administrative burden. This commenter recommended that the criterion be changed to allow a waiver if the "disclosure is necessary to accomplish the research or statistical purpose for which the disclosure is to be made."

Response: We disagree with the comments recommending that the term "practicability" be deleted from this waiver criterion. We believe that an assessment of practicability is necessary to account for research that may be possible to conduct with authorization but that would be impracticable if authorization were required. For example, in research study that involves thousands of records, it may be possible to track down all potential subjects, but doing so may entail costs that would make the research impracticable. In addition, IRBs have experience implementing this criterion since it is nearly identical to a waiver criterion in the Common Rule (§__.116(d)(3)).

We also disagree with the recommendation to change the criterion to state, "disclosure is necessary to accomplish the research or statistical purpose for which the disclosure is to be made." We believe it is essential that consideration be given as to whether it would be practicable for research to be conducted with authorization in determining whether a waiver of authorization is justified. If the research could practicably be conducted with authorization, then authorization must be sought. Authorization must not be waived simply for convenience.

Therefore, in the final rule, we have retained this criterion and clarified that it also applies to alterations of authorization. This waiver criterion in the final rule states, "the research could not practicably be conducted without the alteration or waiver."

Comment: Some commenters argued that the criterion which stated, "whenever appropriate, the subjects will be provided with additional pertinent information after participation," should be deleted. Some comments recommended that the criterion should be deleted for privacy reasons, arguing that it would be inappropriate to create a reason for the researcher to contact the individual ***82698** whose data were analyzed, without IRB review of the proposed contact as a patient intervention. Other commenters argued for the deletion of the criterion on grounds that requiring researchers to contact patients whose records were used for

archival research would be unduly burdensome, while adding little to the patient's base of information. Several commenters also argued that the criterion was not pertinent to non-interventional retrospective research requiring access to archived protected health information.

In addition, one commenter asserted that this criterion was inconsistent with the Secretary's rationale for prohibiting disclosures of "research information unrelated to treatment" for purposes other than research. This commenter argued that the privacy regulations should not mandate that a covered entity provide information with unknown validity or utility directly to patients. This commenter recommended that a patient's physician, not the researcher, should be the one to contact a patient to discuss the significance of new research findings for that individual patient's care.

Response: Although we disagree with the arguments made by commenters recommending that this criterion be eliminated in the final rule, we concluded that the criterion was not directly related to ensuring the privacy rights and welfare of individuals. Therefore, we eliminated this criterion in the final rule.

Comment: A few commenters recommended that the criterion, which required that "the research would be impracticable to conduct without access to and use of the protected health information," be deleted because it would be too subjective to be meaningful.

Response: We disagree with comments asserting that this proposed criterion would be too subjective. We believe that researchers should be required to demonstrate to an IRB or privacy board why protected health information is necessary for their research proposal. If a researcher could practicably use de-identified health information for a research study, protected health information should not be used or disclosed for the study without individuals' authorization. Therefore, we retain this criterion in the final rule. In considering this criterion, we expect IRBs and privacy boards to consider the amount of information that is needed for the study. To ensure the covered health care provider or health plan is informed of what information the IRB or privacy board has determined may be used or disclosed without authorization, the final rule also requires that the documentation of IRB or privacy board approval of the alteration or waiver describe the protected health information for which use or access has been determined to be necessary.

Comment: A large number of comments objected to the proposed waiver criterion, which stated that, "the research is of sufficient importance so as to outweigh the intrusion of the privacy of the individual whose information is subject to the disclosure." The majority of these commenters argued that the criterion was overly subjective, and that due to its subjectivity, IRBs and privacy boards would inevitably apply it inconsistently. Several commenters asserted that this criterion was unsound in that it would impose on reviewing bodies the explicit requirement to form and debate conflicting value judgments about the relative weights of the research proposal versus an individual's right to privacy. Furthermore these commenters argued that this criterion was also unnecessary because the Common Rule already has a requirement that deals with this issue more appropriately. In addition, one commenter argued that the rule eliminate this criterion because common purposes should not override individual rights in a democratic society. Based on these arguments, these commenters recommended that this criterion be deleted.

Response: We disagree that it is inappropriate to ask IRBs and privacy boards to ensure that there is a just balance between the expected benefits and risks to individual participants from the research. As noted by several commenters, IRBs currently conduct such a balancing of risks and benefits because the Common Rule contains a similar criterion for the approval of human subjects research (§__.111(a)(2)). However, we disagree with the comments asserting that the proposed criterion was unnecessary because the Common Rule already contains a similar criterion. The Common Rule does not explicitly address the privacy interests of research participants and does not apply to all research that involves the use or disclosure of protected health information. However, we agree that the relevant Common Rule criterion for the approval of human subjects research provides better guidance to IRBs and privacy boards for assessing the privacy risks and benefits of a research proposal. Therefore, in the final rule, we modeled the criterion on the relevant Common Rule requirement for the approval of human subjects research, and revised the proposed criterion to state: "the privacy risks to individuals whose protected health information is to be used or

disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research."

Comment: One commenter asserted that as long as the research organization has adequate privacy protections in place to keep the information from being further disclosed, it is unnecessary for the IRB or privacy board to make a judgment on whether the value of the research outweighs the privacy intrusion.

Response: The Department disagrees with the assertion that adequate safeguards of protected health information are sufficient to ensure that the privacy rights and welfare of individuals are adequately protected. We believe it is imperative that there be an assessment of the privacy risks and anticipated benefits of a research study that proposes to use protected health information without authorization. For example, if a research study was so scientifically flawed that it would provide no useful knowledge, any risk to patient privacy that might result from the use or disclosure of protected health information without individuals' authorization would be too great.

Comment: A few commenters asserted that the proposed criterion requiring "an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining identifiers," conflicted with the regulations of the FDA on clinical record keeping (21 CFR 812.140(d)) and the International Standard Organization on control of quality records (ISO 13483, 4.16), which require that relevant data be kept for the life of a device.

In addition, one commenter asserted that this criterion could prevent follow up care. Similarly, other commenters argued that the new waiver criteria would be likely to confuse IRBs and may impair researchers' ability to go back to IRBs to request extensions of time for which samples or data can be stored if researchers are unable to anticipate future uses of the data.

Response: We do not agree with the comment that there is a conflict between either the FDA or the ISO regulations and the proposed waiver criteria in the rule. We believe that compliance with such recordkeeping requirements would be "consistent with the conduct of research" which is subject to such requirements. Nonetheless, to avoid any confusion, in the final rule we have added the phrase "or such retention is ***82699** otherwise required by law" to this waiver criterion.

We also disagree with the comments that this criterion would prevent follow up care to individuals or unduly impair researchers from retaining identifiers on data for future research. We believe that patient care would qualify as a "health * * * justification for retaining identifiers." In addition, we understand that researchers may not always be able to anticipate that the protected health information they receive from a covered health care provider or health plan for one research project may be useful for the conduct of future research studies. However, we believe that the concomitant risk to patient privacy of permitting researchers to retain identifiers they obtained without authorization would undermine patient trust, unless researchers could identify a health or research justification for retaining the identifiers. In the final rule, an IRB or privacy board is not required to establish a time limit on a researcher's retention of identifiers.

Additional Waiver Criteria

Comment: A few comments recommended that there be a additional waiver criterion to safeguard or limit subsequent use or disclosure of protected health information by the researcher.

Response: We agree with these comments. In the final rule, we include a waiver criterion requiring "there are adequate written assurances that the protected health information will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart."

Waiving Authorization, in Whole or in Part

Comment: A few commenters requested that the final rule clarify what "in whole or in part" means if authorization is waived or altered.

Response: In the proposed rule, it was HHS' intent to permit IRBs and privacy boards to either waive all of the elements for authorization, or alternatively, waive only some of the elements of authorization. Furthermore, we also intended to permit IRBs and privacy boards to alter the authorization requirements. Therefore, in the final rule, we clarify that the alteration to and waiver of authorization, in whole or in part, are permitted as stipulated in § 164.512(i).

Expedited Review

Comment: One commenter asserted that the proposed rule would prohibit expedited review as permitted under the Common Rule. Many commenters supported the proposal in the rule to incorporate the Common Rule's provision for expedited review, and strongly recommended that this provision be retained in the final rule. Several of these commenters argued that the expedited review mechanism provides IRBs with the much-needed flexibility to focus volunteer-IRB members' limited resources.

Response: We agree that expedited review should be available, and included a provision permitting expedited review under specified conditions. We understand that the National Bioethics Advisory Commission is currently developing a report on the federal oversight of human subjects research, which is expected to address the Common Rule's requirements for expedited review. HHS looks forward to receiving the National Bioethics Advisory Commission's report, and will modify the provisions for expedited review in the privacy rule if changes are warranted by the Commission's findings and recommendations.

Required Signature

Comment: A few commenters asserted that the proposed requirement that the written documentation of IRB or privacy board approval be signed by the chair of the IRB or the privacy board was too restrictive. Some commenters recommended that the final rule permit the documentation of IRB or privacy board approval to be signed by persons other than the IRB or privacy board chair, including: (1) Any person authorized to exercise executive authority under IRB's or privacy board's written procedures; (2) the IRB's or privacy board's acting chair or vice chair in the absence of the chair, if permitted by IRB procedures; and (3) the covered entity's privacy official.

Response: We agree with the commenters who argued that the final rule should permit the documentation of IRB or privacy board approval to be signed by someone other than the chair of the board. In the final rule, we permit the documentation of alteration or waiver of authorization to be signed by the chair or other member, as designated by the chair of the IRB or privacy board, as applicable.

Research Use and Disclosure With Authorization

Comment: Some commenters, including several industry and consumer groups, argued that the proposed rule would establish a two-tiered system for public and private research. Privately funded research conducted with an authorization for the use or disclosure of protected health information would not require IRB or privacy board review, while publically funded research conducted with authorization would require IRB review as required by the Common Rule. Many of these commenters argued that authorization is insufficient to protect patients involved in research studies and recommended that IRB or privacy board review should be required for all research regardless of sponsor. These commenters asserted that it is not sufficient to obtain authorization, and that IRBs and privacy boards should review the authorization document, and assess the risks and benefits to individuals posed by the research.

Response: For the reasons we rejected the recommendation that we eliminate the option for privacy board review and require IRB review for the waiver of authorization, we also decided against requiring documentation of IRB or privacy board approval for research conducted with authorization. HHS strongly agrees that IRB review is essential for the adequate protection of human subjects involved in research, regardless of whether informed consent and/or individuals' authorization is obtained.

In fact, IRB review may be even more important for research conducted with subjects' informed consent and authorization since such research may present greater than minimal risk to participants. However, HHS' authority under HIPAA is limited to safeguarding the privacy of protected health information, and does not extend to protecting human subjects more broadly. Therefore, in the final rule we have not required documentation of IRB or privacy board review for the research use or disclosure of protected health information conducted with individuals' authorization. As mentioned above, HHS looks forward to receiving the recommendations of the National Bioethics Advisory Commission, which is currently examining the current scope of federal regulatory protections for protecting human subjects in research as part of its overarching report on the federal oversight of human subjects protections.

Comment: Due to concern about several of the elements of authorization, many commenters recommended that the final rule stipulate that "informed consent" obtained pursuant to the Common Rule be deemed to meet the requirements for "authorization." These commenters argued that the NPRM's ***82700** additional authorization requirements offered no additional protection to research participants but would be a substantive impediment to research.

Response: We disagree with the comments asserting that the proposed requirements for authorization for the use or disclosure of protected health information would have offered research subjects no additional privacy protection. Because the purposes of authorization and informed consent differ, the proposed rule's requirements for authorization pursuant to a request from a researcher (§ 164.508) and the Common Rule's requirements for informed consent (Common Rule, §__.116) contain important differences. For example, unlike the Common Rule, the proposed rule would have required that the authorization include a description of the information to be used or disclosed that identifies the information in a specific and meaningful way, an expiration date, and where, use of disclosure of the requested information will result in financial gain to the entity, a statement that such gain will result. We believe that the authorization requirements provide individuals with information necessary to determine whether to authorize a specific use or disclosure of protected health information about themselves, that are not required by the Common Rule.

Therefore, in the final rule, we retain the requirement for authorization for all uses and disclosures of protected health information not otherwise permitted without authorization by the rule. Some of the proposed requirements for authorization were modified in the final rule as discussed in the preamble on § 164.508. The comments received on specific proposed elements of authorization as they would have pertained to research are addressed below.

Comment: A number of commenters, including several from industry and consumer groups, recommended that the final rule require patients' informed consent as stipulated in the Common Rule. These commenters asserted that the proposed authorization document was inadequate for research uses and disclosures of protected health information since it included fewer elements than required for informed consent under the Common Rule, including for example, the Common Rule's requirement that the informed consent document include: (1) A description of any reasonably foreseeable risks or discomforts to the subject; (2) a description of any benefits to the subject or to others which may reasonably be expected from the research (Common Rule, §__.116(a)).

Response: While we agree that the ethical conduct of research requires the voluntary informed consent of research subjects, as stipulated in the Common Rule, as we have stated elsewhere, the privacy rule is limited to protecting the confidentiality of individually identifiable health information, and not protecting human subjects more broadly. Therefore, we believe it would not be within the scope of the final rule to require informed consent as stipulated by the Common Rule for research uses and disclosures of protected health information.

Comment: Several commenters specifically objected to the authorization requirement for a "expiration date." To remedy this concern, many of these commenters proposed that the rule exempt research from the requirement for an expiration date if an IRB has reviewed and approved the research study. In particular, some commenters asserted that the requirement for an expiration date would be impracticable in the context of clinical trials, where the duration of the study depends on several different factors that cannot be predicted in advance. These commenters argued that determining an exact date would be impossible

due to the legal requirements that manufactures and the Food and Drug Administration be able to retrospectively audit the source documents when patient data are used in clinical trials. In addition, some commenters asserted that a requirement for an expiration date would force researchers to designate specific expiration dates so far into the future as to render them meaningless.

Response: We agree with commenters that an expiration date is not always possible or meaningful. In the final rule, we continue to require an identifiable expiration, but permit it to be a specific date or an event directly relevant to the individual or the purpose of the authorization (e.g., for the duration of a specific research study) in which the individual is a participant.

Comment: A number of commenters, including those from the pharmaceutical industry, were concerned about the authorization requirement that gave patients the right to revoke consent for participation in clinical research. These commenters argued that such a right to revoke authorization for the use of their protected health information would require complete elimination of the information from the record. Some stated that in the conduct of clinical trials, the retrieval of individually identifiable health information that has already been blinded and anonymized, is not only burdensome, but should this become a widespread practice, would render the trial invalid. One commenter suggested that the Secretary modify the proposed regulation to allow IRBs or privacy boards to determine the duration of authorizations and the circumstances under which a research participant should be permitted to retroactively revoke his or her authorization to use data already collected by the researcher.

Response: We agree with these concerns. In the final rule we have clarified that an individual cannot revoke an authorization to the extent that action has been taken in reliance on the authorization. Therefore, if a covered entity has already used or disclosed protected health information for a research study pursuant to an authorization obtained as required by § 164.508, the covered entity is not required under the rule, unless it agreed otherwise, to destroy protected health information that was collected, nor retrieve protected health information that was disclosed under such an authorization. However, once an individual has revoked an authorization, no additional protected health information may be used or disclosed unless otherwise permitted by this rule.

Comment: Some commenters were concerned that the authorization requirement to disclose "financial gain" would be problematic as it would pertain to research. These commenters asserted that this requirement could mislead patients and would make it more difficult to attract volunteers to participate in research. One commenter recommended that the statement be revised to state "that the clinical investigator will be compensated for the value of his/her services in administrating this clinical trial." Another commenter recommended that the authorization requirement for disclosure of financial gain be defined in accordance with FDA's financial disclosure rules.

Response: We strongly believe that a requirement for the disclosure of financial gain is imperative to ensure that individuals are informed about how and why protected health information about themselves will be used or disclosed. We agree, however, that the language of the proposed requirement could cause confusion, because most activities involve some type of financial gain. Therefore, in the final rule, we have modified the language to provide that when the covered entity initiates ***82701** the authorization and the covered entity will receive direct or indirect remuneration (rather than financial gain) from a third party in exchange for using or disclosing the health information, the authorization must include a statement that such remuneration will result.

Comment: A few commenters asserted that the requirement to include a statement in which the patient acknowledged that information used or disclosed to any entity other than a health plan or health care provider may no longer be protected by federal privacy law would be inconsistent with existing protections implemented by IRBs under the Common Rule. In particular they stated that this inconsistency exists because IRBs are required to consider the protections in place to protect patients' confidential information and that IRBs are charged with ensuring that researchers comply with the confidentiality provisions of the informed consent document.

Response: We disagree that this proposed requirement would pose a conflict with the Common Rule since the requirement was for a statement that the "information may no longer be protected by the federal privacy law." This statement does not pertain to the protections provided under the Common Rule. In addition, while we anticipate that IRBs and privacy boards will most often

waive all or none of the authorization requirements, we clarify an IRB or privacy board could alter this requirement, among others, if the documentation requirements of § 164.512(i) have been met.

Reviews Preparatory to Research

Comment: Some industry groups expressed concern that the research provision would prohibit physicians from using patient information to recruit subjects into clinical trials. These commenters recommended that researchers continue to have access to hospitals' and clinics' patient information in order to recruit patients for studies.

Response: Under the proposed rule, even if the researcher only viewed the medical record at the site of the covered entity and did not record the protected health information in a manner that patients could be identified, such an activity would have constituted a use or disclosure that would have been subject to proposed § 164.508 or proposed § 164.510. Based on the comments received and the fact finding we conducted with the research community, we concluded that documentation of IRB or privacy board approval could halt the development of research hypotheses that require access to protected health information before a formal protocol can be developed and brought to an IRB or privacy board for approval. To avoid this unintended result, the final rule permits covered health care providers and health plans to use or disclose protected health information for research if the covered entity obtains from the researcher representations that: (1) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research; (2) no protected health information is to be removed from the covered entity by the researcher in the course of the review; and (3) the protected health information for which use or access is sought is necessary for the research purposes.

Comment: A few commenters asserted that the final rule should eliminate the possibility that research requiring access to protected health information could be determined to be "exempt" from IRB review, as provided by the Common Rule (§__.101(b)(4)).

Response: The rule did not propose nor intend to modify any aspect of the Common Rule, including the provision that exempts from coverage, "research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publically available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to the subjects' (§__.101(b)(4)). For the reasons discussed above, we have included a provision in the final rule for reviews preparatory to research that was modeled on this exemption to the Common Rule.

Deceased Persons Exception for Research

Comment: A few commenters expressed support for the proposal to allow use and disclosure of protected health information about decedents for research purposes without the protections afforded to the protected health information of living individuals. One commenter, for example, explained that it extensively uses such information in its research, and any restrictions were likely to impede its efforts. Alternately, a number of commenters provided arguments for eliminating the research exception for deceased persons. They commented that the same concerns regarding use and disclosure of genetic and hereditary information for other purposes apply in the research context. They believed that in many cases the risk of identification was greater in the research context because researchers may attempt to identify genetic and hereditary conditions of the deceased. Finally, they argued that while information of the deceased does not necessarily identify living relatives by name, living relatives could be identified and suffer the same harm as if their own medical records were used or disclosed for research purposes. Another commenter stated that the exception was unnecessary, and that existing research could and should proceed under the requirements in proposed § 164.510 that dictated the IRB/privacy board approval process or be conducted using de-identified information. This commenter further stated that in this way, at least there would be some degree of assurance that all reasonable steps are taken to protect deceased persons' and their families' confidentiality.

Response: Although we understand the concerns raised by commenters, we believe those concerns are outweighed by the need to keep the research-related policies in this rule as consistent as possible with standard research practice under the Common Rule,

which does not consider deceased persons to be "human subjects." Thus, we retain the exception in the final rule. With regard to the protected health information about a deceased individual, therefore, a covered entity is permitted to use or disclose such information for research purposes without obtaining authorization from a personal representative and absent approval by an IRB or privacy board as governed by § 164.512(i). We note that the National Bioethics Advisory Committee (NBAC) is currently considering revising the Common Rule's definition of "human subject" with regard to coverage of the deceased. However, at this time, NBAC's deliberations on this issue are not yet completed and any reliance on such discussions would be premature.

The final rule requires at § 164.512(i)(1)(iii) that covered entities obtain from the researcher (1) representation that the use or disclosure is sought solely for research on the protected health information of decedents; (2) documentation, at the request of the covered entity, of the death of such individuals; and (3) representation that the protected health information for which use or disclosure is sought is necessary for the research purposes. It is our intention with this change to reduce the burden and ambiguity on the part of the covered entity to determine whether or not the ***82702** request is for protected health information of a deceased individual.

Comment: Some commenters, in their support of the research exception, requested that HHS clarify in the final rule that protected health information obtained during the donation process of eyes and eye tissue could continue to be used or disclosed to or by eye banks for research purposes without an authorization and without IRB approval. They expressed concern over the impediments to this type of research these approvals would impose, such as added administrative burden and vulnerabilities to the time sensitive nature of the process.

Another commenter similarly expressed the position that, with regard to uses and disclosures of protected health information for tissue, fluid, or organ donation, the regulation should not present an obstacle to the transfer of donations unsuitable for transplant to the research community. However, they believed that consent can be obtained for such purposes since the donor or donor's family must generally consent to any transplant purposes, it would seem to be a minimal additional obligation to seek consent for research purposes at the same time, should the material be unsuitable for transplant.

Response: Protected health information about a deceased individual, including information related to eyes and eye tissue, can be used or disclosed further for research purposes by a covered entity in accordance with § 164.512(i)(1)(iii) without authorization or IRB or privacy board approval. This rule does not address whether organs unsuitable for transplant may be transferred to researchers with or without consent.

Modification of the Common Rule

Comment: We received a number of comments that interpreted the proposed rule as having unnecessarily and inappropriately amended the Common Rule. Assuming that the Common Rule was being modified, these comments argued that the rule was legally deficient under the Administrative Procedures Act, the Regulatory Flexibility Act, and other controlling Executive orders or laws.

In addition, one research organization expressed concern that, by involving IRBs in the process of approving a waiver of authorization for disclosure purposes and establishing new criteria for such waiver approvals, the proposed rule would have subjected covered entities whose IRBs failed to comply with the requirements for reviewing and approving research to potential sanctions under HIPAA. The comment recommended that the rule be changed to eliminate such a punitive result. Specifically, the comment recommended that the existing Common Rule structure be preserved for IRB-approved research, and that the waiver of authorization criteria for privacy purposes be kept separate from the other functions of the IRB.

Response: We disagree with the comments asserting the proposed rule attempted to change the Common Rule. It was not our intent to modify or amend the Common Rule or to regulate the activities of the IRBs with respect to the underlying research. We therefore reject the comments about legal deficiencies in the rule which are based on the mistaken perception that the Common Rule was being amended. The proposed rule established new requirements for covered entities before they could use or disclose protected health information for research without authorization. The proposed rule provided that one method by which a covered

entity could obtain the necessary documentation was to receive it from an IRB. We did not mandate IRBs to perform such reviews, and we expressly provided for means other than through IRBs for covered entities to obtain the required documentation.

In the final rule, we also have clarified our intent not to interfere with existing requirements for IRBs by amending the language in the waiver criteria to make clear that these criteria relate to the privacy interests of the individual and are separate from the criteria that would be applied by an IRB to any evaluation of the underlying research. Moreover, we have restructured the final rule to also make clear that we are regulating only the content and conditions of the documentation upon which a covered entity may rely in making a disclosure of protected health information for research purposes.

We cannot and do not purport to regulate IRBs or modify the Common Rule through this regulation. We cannot under this rule penalize an IRB for failure to comply with the Common Rule, nor can we sanction an IRB based on the documentation requirements in the rule. Health plans and covered health care providers may rely on documentation from an IRB or privacy board concerning the alteration or waiver of authorization for the disclosure of protected health information for research purposes, provided the documentation, on its face, meets the requirements in the rule. Health plans and covered health care providers will not be penalized for relying on facially adequate documentation from an IRB. Health plans and covered health providers will only be penalized for their own errors or omissions in following the requirements of the rule, and not those of the IRB.

Use Versus Disclosure

Comment: Many of the comments supported the proposed rule's provision that would have imposed the same requirements for both research uses and research disclosures of protected health information.

Response: We agree with these comments. In the final rule we retain identical use and disclosure requirements for research uses and disclosures of protected health information by covered entities.

Comment: In contrast, a few commenters recommended that there be fewer requirements on covered entities for internal research uses of protected health information.

Response: For the reasons discussed above in § 164.501 on the definition of “research,” we disagree that an individual's privacy interest is of less concern when covered entities use protected health information for research purposes than when covered entities disclose protected health information for research purposes. Therefore, in the final rule, the research-related requirements of § 164.512(i) apply to both uses and disclosures of protected health information for research purposes without authorization.

Additional Resources for IRBs

Comment: A few commenters recommended that HHS work to provide additional resources to IRBs to assist them in meeting their new responsibilities.

Response: This recommendation is beyond our statutory authority under HIPAA, and therefore, cannot be addressed by the final rule. However, we fully agree that steps should be taken to moderate the workload of IRBs and to ensure adequate resources for their activities. Through the Office for Human Research Protections, the Department is committed to working with institutions and IRBs to identify efficient ways to optimize utilization of resources, and is committed to developing guidelines for appropriate staffing and workload levels for IRBs.

Additional Suggested Requirements

Comment: One commenter recommended that the documentation of IRB or privacy board approval also be required to state that, “the health researcher has fully disclosed which of ***82703** the protected health information to be collected or created would

be linked to other protected health information, and that appropriate safeguards be employed to protect information against re-identification or subsequent unauthorized linkages."

Response: The proposed provision for the use or disclosure of protected health information for research purposes without authorization only pertained to individually identifiable health information. Therefore, since the information to be obtained would be individually identifiable, we concluded that it was illogical to require IRBs and privacy boards document that the researcher had "fully disclosed that * * * appropriate safeguards be employed to protect information against re-identification or subsequent unauthorized linkages." Therefore, we did not incorporate this recommendation into the final rule.

Section 164.512(j)—Uses and Disclosures To Avert a Serious Threat to Health or Safety

Comment: Several commenters generally stated support for proposed § 164.510(k), which was titled "Uses and Disclosures in Emergency Circumstances." One commenter said that "narrow exceptions to confidentiality should be permitted for emergency situations such as duty to warn, duty to protect, and urgent law enforcement needs." Another commented that the standard " * * * based on a reasonable belief that the disclosures are necessary to prevent or lessen a serious and imminent threat to the health or safety of an individual" would apply in only narrow treatment circumstances. Some commenters suggested that the provision be further narrowed, for example, with language specifically identifying "imminent threats" and a "chain-of-command clearance process," or by limiting permissible disclosures under this provision to "public health emergencies," or "national emergencies." Others proposed procedural requirements, such as specifying that such determinations may only be made by the patient's treating physician, a licensed mental health care professional, or as validated by three physicians. One commenter recommended stating that the rule is not intended to create a duty to warn or to disclose protected health information but rather permits such disclosure in emergency circumstances, consistent with other applicable legal or ethical standards.

Response: We agree with the commenters who noted that the proposed provision would apply in rare circumstances. We clarify, however, that we did not intend for the proposed provision to apply to emergency treatment scenarios as discussed below. In the final rule, to avoid confusion over the circumstances in which we intend this section to apply, we retitle it "Uses and Disclosures to Avert a Serious Threat to Health or Safety."

We do not believe it would be appropriate to narrow further the scope of permissible disclosures under this section to respond to specifically identified "imminent threats," a "public health emergency," or a "national emergency." We believe it would be impossible to enumerate all of the scenarios that may warrant disclosure of protected health information pursuant to this section. Such cases may involve a small number of people and may not necessarily involve a public health emergency or a national emergency.

Furthermore, in response to comments arguing that the proposed provision was too broad, we note that under both the NPRM and the final rule, we allow but do not require disclosures in situations involving serious and imminent threats to health or safety. Health plans and covered health care providers may make the disclosures allowed under § 164.512(j) consistent with applicable law and standards of ethical conduct.

As indicated in the preamble to the NPRM, the proposed approach is consistent with statutory and case law addressing this issue. The most well-known case on the topic is Tarasoff v. Regents of the University of California, 17 Cal. 3d 425 (1976), which established a duty to warn those at risk of harm when a therapist's patient made credible threats against the physical safety of a specific person. The Supreme Court of California found that the therapist involved in the case had an obligation to use reasonable care to protect the intended victim of his patient against danger, including warning the victim of the peril. Many states have adopted, in statute or through case law, versions of the Tarasoff duty to warn or protect. Although Tarasoff involved a psychiatrist, this provision is not limited to disclosures by psychiatrists or other mental health professionals. As stated in the preamble of the NPRM, we clarify that § 164.512(j) is not intended to create a duty to warn or disclose protected health information.

Comment: Several comments addressed the portion of proposed § 164.510(k) that would have provided a presumption of reasonable belief to covered entities that disclosed protected health information pursuant to this provision, when such disclosures were made in good faith, based on credible representation by a person with apparent knowledge or authority. Some commenters recommended that this standard be applied to all permissible disclosures without consent or to such disclosures to law enforcement officials.

Alternatively, a group representing health care provider management firms believed that the proposed presumption of reasonable belief would not have provided covered entities with sufficient protection from liability exposure associated with improper uses or disclosures. This commenter recommended that a general good-faith standard apply to covered entities' decisions to disclose protected health information to law enforcement officials. A health plan said that HHS should consider applying the standard of reasonable belief to all uses and disclosures that would have been allowed under proposed § 164.510. Another commenter questioned how the good-faith presumption would apply if the information came from a confidential informant or from a person rather than a doctor, law enforcement official, or government official. (The NPRM listed doctors, law enforcement officials, and other government officials as examples of persons who may make credible representations pursuant to this section.)

Response: As discussed above, this provision is intended to apply in rare circumstances—circumstances that occur much less frequently than those described in other parts of the rule. Due to the importance of averting serious and imminent threats to health and safety, we believe it is appropriate to apply a presumption of good faith to covered entities disclosing protected health information under this section. We believe that the extremely time-sensitive and urgent conditions surrounding the need to avert a serious and imminent threat to the health or safety are fundamentally different from those involved in disclosures that may be made pursuant to other sections of the rule. Therefore, we do not believe it would be appropriate to apply to other sections of the rule the presumption of good faith that applies in § 164.512(j). We clarify that we intend for the presumption of good faith to apply if the disclosure is made in good faith based upon a credible representation by any person with apparent knowledge or authority—not just by doctors, law enforcement or other government officials. Our listing of these persons in the NPRM was illustrative only, and it was not intended to limit the types of ***82704** persons who could make such a credible representation to a covered entity.

Comment: One commenter questioned under what circumstances proposed § 164.510(k) would apply instead of proposed § 164.510(f)(5), "Urgent Circumstances," which permitted covered entities to disclose protected health information to law enforcement officials about individuals who are or are suspected to be victims of a crime, abuse, or other harm, if the law enforcement official represents that the information is needed to determine whether a violation of law by a person other than the victim has occurred and immediate law enforcement activity that depends upon obtaining such information may be necessary.

Response: First, we note that inclusion of this provision as § 164.510(f)(5) was a drafting error which subsequently was clarified in technical corrections to the NPRM. In fact, proposed § 164.510(f)(3) addressed the identical circumstances, which in this subsection were titled "Information about a Victim of Crime or Abuse." The scenarios described under § 164.510(f)(3) may or may not involve serious and imminent threats to health or safety.

Second, as discussed in the main section of the preamble to § 164.512(j), we recognize that in some situations, more than one section of this rule potentially could apply with respect to a covered entity's potential disclosure of protected health information. We clarify that if a situation fits one section of the rule (e.g., § 164.512(j) on serious and imminent threats to health or safety), health plans and covered health care providers may disclose protected health information pursuant to that section, regardless of whether the disclosure also could be made pursuant to another section (e.g., §§ 164.512(f)(2) or 164.512(f)(3), regarding disclosure of protected health information about suspects or victims to law enforcement officials), except as otherwise stated in the rule.

Comment: A state health department indicated that the disclosures permitted under this section may be seen as conflicting with existing law in many states.

Response: As indicated in the regulation text for § 164.512(j), this section allows disclosure consistent with applicable law and standards of ethical conduct. We do not preempt any state law that would prohibit disclosure of protected health information in the circumstances to which this section applies. (See Part 160, Subpart B.)

Comment: Many commenters stated that the rule should require that any disclosures should not modify "duty to warn" case law or statutes.

Response: The rule does not affect case law or statutes regarding "duty to warn." In § 164.512(j), we specifically permit covered entities to disclose protected health information without authorization for the purpose of protecting individuals from imminent threats to health and safety, consistent with state laws and ethical obligations.

Section 164.512(k)—Uses and Disclosures for Specialized Government Functions

Military Purposes

Armed Forces Personnel and Veterans

Comment: A few comments opposed the proposed rule's provisions on the military, believing that they were too broad. Although acknowledging that the Armed Forces may have legitimate needs for access to protected health data, the commenters believed that the rule failed to provide adequate procedural protections to individuals. A few comments said that, except in limited circumstances or emergencies, covered entities should be required to obtain authorization before using or disclosing protected health information. A few comments also expressed concern over the proposed rule's lack of specific safeguards to protect the health information of victims of domestic violence and abuse. While the commenters said they understood why the military needed access to health information, they did not believe the rule would impede such access by providing safeguards for victims of domestic violence or abuse.

Response: We note that the military comprises a unique society and that members of the Armed Forces do not have the same freedoms as do civilians. The Supreme Court held in Goldman v. Weinberger, 475 US 503 (1986), that the military must be able to command its members to sacrifice a great many freedoms enjoyed by civilians and to endure certain limits on the freedoms they do enjoy. The Supreme Court also held in Parker v. Levy, 417 US 733 (1974), that the different character of the military community and its mission required a different application of Constitutional protections. What is permissible in the civilian world may be impermissible in the military. We also note that individuals entering military service are aware that they will not have, and enjoy, the same rights as others.

The proposed rule would have authorized covered entities to use and disclose protected health information about armed forces personnel only for activities considered necessary by appropriate military command authorities to assure the proper execution of the military mission. In order for the military mission to be achieved and maintained, military command authorities need protected health information to make determinations regarding individuals' medical fitness to perform assigned military duties.

The proposed rule required the Department of Defense (DoD) to publish a notice in the Federal Register identifying its intended uses and disclosures of protected health information, and we have retained this approach in the final rule. This notice will serve to limit command authorities' access to protected health information to circumstances in which disclosure of protected health information is necessary to assure proper execution of the military mission.

With respect to comments regarding the lack of procedural safeguards for individuals, including those who are victims of domestic violence and abuse, we note that the rule does not provide new authority for covered entities providing health care to individuals who are Armed Forces personnel to use and disclose protected health information. Rather, the rule allows the Armed Forces to use and disclose such information only for those military mission purposes which will be published separately in the Federal Register. In addition, we note that the Privacy Act of 1974, as implemented by the DoD, provides numerous protections to individuals.

We modify the proposal to publish privacy rules for the military in the Federal Register. The NPRM would have required this notice to include information on the activities for which use or disclosure of protected health information would occur in order to assure proper execution of the military mission. We believe that this proposed portion of the notice is redundant and thus unnecessary in light the rule's application to military services. In the final rule, we eliminate this proposed section of the notice, and we state that health plans and covered health care providers may use and disclose protected health information of Armed Forces personnel for activities considered necessary by appropriate military command authorities to assure the proper execution of a military mission, where the appropriate military authority has published a Federal Register notice identifying: (1) The appropriate military command authorities; and (2) the purposes for ***82705** which protected health information may be used or disclosed.

Comment: A few commenters, members of the affected beneficiary class, which numbers approximately 2.6 million (active duty and reserve military personnel), opposed proposed § 164.510(m) because it would have allowed a non-governmental covered entity to provide protected health information without authorization to the military. These commenters were concerned that military officials could use the information as the basis for taking action against individuals.

Response: The Secretary does not have the authority under HIPAA to regulate the military's re-use or re-disclosure of protected health information obtained from health plans and covered health care providers. This provision's primary intent is to ensure that proper military command authorities can obtain needed medical information held by covered entities so that they can make appropriate determinations regarding the individual's medical fitness or suitability for military service. Determination that an individual is not medically qualified for military service would lead to his or her discharge from or rejection for service in the military. Such actions are necessary in order for the Armed Forces to have medically qualified personnel, ready to perform assigned duties. Medically unqualified personnel not only jeopardize the possible success of a mission, but also pose an unacceptable risk or danger to others. We have allowed such uses and disclosures for military activities because it is in the Nation's interest.

Separation or Discharge from Military Service

Comment: The preamble to the NPRM solicited comments on the proposal to permit the DoD to transfer, without authorization, a service member's military medical record to the Department of Veterans Affairs (DVA) when the individual completed his or her term of military service. A few commenters opposed the proposal, believing that authorization should be obtained. Both the DoD and the DVA supported the proposal, noting that transfer allows the DVA to make timely determinations as to whether a veteran is eligible for benefits under programs administered by the DVA.

Response: We note that the transfer program was established based on recommendations by Congress, veterans groups, and veterans; that it has existed for many years; and that there has been no objection to, or problems associated with, the program. We also note that the Department of Transportation (DoT) and the Department of Veterans Affairs operate an analogous transfer program with respect to United States Coast Guard personnel, who comprise part of the U.S. Armed Forces. The protected health information involved the DoD/DVA transfer program is being disclosed and used for a limited purpose that directly benefits the individual. This information is covered by, and thus subject to the protections of, the Privacy Act. For these reasons, the final rule retains the DoD/DVA transfer program proposed in the NPRM. In addition, we expand the NPRM's proposed provisions regarding the Department of Veterans Affairs to include the DoT/DVA program, to authorize the continued transfer of these records.

Comment: The Department of Veterans Affairs supported the NPRM's proposal to allow it to use and disclose protected health information among components of the Department so that it could make determinations on whether an individual was entitled to benefits under laws administered by the Department. Some commenters said that the permissible disclosure pursuant to this section appeared to be sufficiently narrow in scope, to respond to an apparent need. Some commenters also said that the DVA's ability to make benefit determinations would be hampered if an individual declined to authorize release of his or her protected health information. A few commenters, however, questioned whether such an exchange of information currently occurs between

the components. A few commenters also believed the proposed rule should be expanded to permit sharing of information with other agencies that administer benefit programs.

Response: The final rule retains the NPRM's approach regarding use and disclosure of protected health information without authorization among components of the DVA for the purpose of making eligibility determinations based on commenters' assessment that the provision was narrow in scope and that an alternative approach could negatively affect benefit determinations for veterans. We modify the NPRM language slightly, to clarify that it refers to a health plan or covered health care provider that is a component of the DVA. These component entities may use or disclose protected health information without authorization among various components of the Department to determine eligibility for or entitlement to veterans' benefits. The final rule does not expand the scope of permissible disclosures under this provision to allow the DVA to share such information with other agencies. Other agencies may obtain this information only with authorization, subject to the requirements of § 164.508.

Foreign Military Personnel

Comments: A few comments opposed the exclusion of foreign diplomatic and military personnel from coverage under the rule. These commenters said that the mechanisms that would be necessary to identify these personnel for the purpose of exempting them from the rule's standards would create significant administrative difficulties. In addition, they believed that this provision would have prohibited covered entities from making disclosures allowed under the rule. Some commenters were concerned that implementation of the proposed provision would result in disparate treatment of foreign military and diplomatic personnel with regard to other laws, and that it would allow exploitation of these individuals' health information. These commenters believed that the proposed rule's exclusion of foreign military and diplomatic personnel was unnecessarily broad and that it should be narrowed to meet a perceived need. Finally, they noted that the proposed exclusion could be affected by the European Union's Data Protection Directive.

Response: We agree with the commenters' statement that the NPRM's exclusion of foreign military and diplomatic personnel from the rule's provisions was overly broad. Thus, the final rule's protections apply to these personnel. The rule covers foreign military personnel under the same provisions that apply to all other members of the U.S. Armed Forces, as described above. Foreign military authorities need access to protected health information for the same reason as must United States military authorities: to ensure that members of the armed services are medically qualified to perform their assigned duties. Under the final rule, foreign diplomatic personnel have the same protections as other individuals.

Intelligence Community

Comments: A few commenters opposed the NPRM's provisions regarding protected health information of intelligence community employees and their dependents being considered for postings overseas, on the grounds that the scope of permissible disclosure without authorization was too broad. While acknowledging that the intelligence community may have legitimate needs for its employees' protected health information, the commenters believed that the NPRM ***82706** failed to provide adequate procedural protections for the employees' information. A few comments also said that the intelligence community should be able to obtain their employees' health information only with authorization. In addition, commenters said that the intelligence community should make disclosure of protected health information a condition of employment.

Response: Again, we agree that the NPRM's provision allowing disclosure of the protected health information of intelligence community employees without authorization was overly broad. Thus we eliminate it in the final rule. The intelligence community can obtain this information with authorization (pursuant to § 164.508), for example, when employees or their family members are being considered for an oversees assignment and when individuals are applying for employment with or seeking a contract from an intelligence community agency.

National Security and Intelligence Activities and Protective Services for the President and Others

Comment: A number of comments opposed the proposed "intelligence and national security activities" provision of the law enforcement section (§ 164.510(f)(4)), suggesting that it was overly broad. These commenters were concerned that the provision lacked sufficient procedural safeguards to prevent abuse of protected health information. The Central Intelligence Agency (CIA) and the Department of Defense (DoD) also expressed concern over the provision's scope. The agencies said that if implemented as written, the provision would have failed to accomplish fully its intended purpose of allowing the disclosure of protected health information to officials carrying out intelligence and national security activities other than law enforcement activities. The CIA and DoD believed that the provision should be moved to another section of the rule, possibly to proposed § 164.510(m) on specialized classes, so that authorized intelligence and national security officials could obtain individuals' protected health information without authorization when lawfully engaged in intelligence and national security activities.

Response: In the final rule, we clarify that this provision does not provide new authority for intelligence and national security officials to acquire health information that they otherwise would not be able to obtain. Furthermore, the rule does not confer new authority for intelligence, national security, or Presidential protective service activities. Rather, the activities permissible under this section are limited to those authorized under current law and regulation (e.g., for intelligence activities, 50 U.S.C. 401, et seq., Executive Order 12333, and agency implementing regulatory authorities). For example, the provision regarding national security activities pertains only to foreign persons that are the subjects of legitimate and lawful intelligence, counterintelligence, or other national security activities. In addition, the provision regarding protective services pertains only to those persons who are the subjects of legitimate investigations for threatening or otherwise exhibiting an inappropriate direction of interest toward U.S. Secret Service protectees pursuant to 18 U.S.C. 871, 879, and 3056. Finally, the rule leaves intact the existing State Department regulations that strictly limit the disclosure of health information pertaining to employees (e.g., Privacy Issuances at State-24 Medical Records).

We believe that because intelligence/national security activities and Presidential/other protective service activities are discrete functions serving different purposes, they should be treated consistently but separately under the rule. For example, medical information is used as a complement to other investigative data that are pertinent to conducting comprehensive threat assessment and risk prevention activities pursuant to 18 U.S.C. 3056. In addition, information on the health of world leaders is important for the provision of protective services and other functions. Thus, § 164.512(k) of the final rule includes separate subsections for national security/intelligence activities and for disclosures related to protective services to the President and others.

We note that the rule does not require or compel a health plan or covered health care provider to disclose protected health information. Rather, two subsections of § 164.512(k) allow covered entities to disclose information for intelligence and national security activities and for protective services to the President and others only to authorized federal officials conducting these activities, when such officials are performing functions authorized by law.

We agree with DoD and CIA that the NPRM, by including these provisions in the law enforcement section (proposed § 164.510(f)), would have allowed covered entities to disclose protected health information for national security, intelligence, and Presidential protective activities only to law enforcement officials. We recognize that many officials authorized by law to carry out intelligence, national security, and Presidential protective functions are not law enforcement officials. Therefore, the final rule allows covered entities to disclose protected health information pursuant to this provision not only to law enforcement officials, but to all federal officials authorized by law to carry out the relevant activities. In addition, we remove this provision from the law enforcement section and include it in § 164.512(k) on uses and disclosures for specialized government functions

Medical Suitability Determinations

Comment: A few comments opposed the NPRM's provision allowing the Department of State to use protected health information for medical clearance determinations. These commenters believed that the scope of permissible disclosures under the proposed provision was too broad. While acknowledging that the Department may have legitimate needs for access to protected health data, the commenters believed that implementation of the proposed provision would not have provided adequate procedural safeguards for the affected State Department employees. A few comments said that the State Department should be able to obtain protected health information for medical clearance determinations only with authorization. A few comments also said that the

Department should be able to disclose such information only when required for national security purposes. Some commenters believed that the State Department should be subject to the Federal Register notice requirement that the NPRM would have applied to the Department of Defense. A few comments also opposed the proposed provision on the basis that it would conflict with the Rehabilitation Act of 1973 or that it appeared to represent an invitation to discriminate against individuals with mental disorders.

Response: We agree with commenters who believed that the NPRM's provision regarding the State Department's use of protected health information without authorization was unnecessarily broad. Therefore, in the final rule, we restrict significantly the scope of protected health information that the State Department may use and disclose without authorization. First, we allow health plans and covered health care providers that are a component of the State Department to use and disclose protected health information without authorization when making medical suitability determinations for security clearance purposes. For the purposes of a security investigation, these ***82707** components may disclose to authorized State Department officials whether or not the individual was determined to be medically suitable. Furthermore, we note that the rule does not confer authority on the Department to disclose such information that it did not previously possess. The Department remains subject to applicable law regarding such disclosures, including the Rehabilitation Act of 1973.

The preamble to the NPRM solicited comment on whether there was a need to add national security determinations under Executive Order 10450 to the rule's provision on State Department uses and disclosures of protected health information for security determinations. While we did not receive comment on this issue, we believe that a limited addition is warranted and appropriate. Executive Orders 10450 and 12968 direct Executive branch agencies to make certain determinations regarding whether their employees' access to classified information is consistent with the national security interests of the United States. Specifically, the Executive Orders state that access to classified information shall be granted only to those individuals whose personal and professional history affirmatively indicates, inter alia, strength of character, trustworthiness, reliability, and sound judgment. In reviewing the personal history of an individual, Executive branch agencies may investigate and consider any matter, including a mental health issue or other medical condition, that relates directly to any of the enumerated factors.

In the vast majority of cases, Executive agencies require their security clearance investigators to obtain the individual's express consent in the form of a medical release, pursuant to which the agency can conduct its background investigation and obtain any necessary health information. This rule does not interfere with agencies' ability to require medical releases for purposes of security clearances under these Executive Orders.

In the case of the Department of State, however, it may be impracticable or infeasible to obtain an employee's authorization when exigent circumstances arise overseas. For example, when a Foreign Service Officer is serving at an overseas post and he or she develops a critical medical problem which may or may not require a medical evacuation or other equally severe response, the Department's medical staff have access to the employee's medical records for the purpose of making a medical suitability determination under Executive Orders 10450 and 12968. To restrict the Department's access to information at such a crucial time due to a lack of employee authorization leaves the Department no option but to suspend the employee's security clearance. This action automatically would result in an immediate forced departure from post, which negatively would affect both the Department, due to the unexpected loss of personnel, and the individual, due to the fact that a forced departure can have a long-term impact on his or her career in the Foreign Service.

For this reason, the rule contains a limited security clearance exemption for the Department of State. The exemption allows the Department's own medical staff to continue to have access to an employee's medical file for the purpose of making a medical suitability determination for security purposes. The medical staff can convey a simple “yes” or “no” response to those individuals conducting the security investigation within the Department. In this way, the Department is able to make security determinations in exigent circumstances without disclosing any specific medical information to any employees other than the medical personnel who otherwise have routine access to these same medical records in an everyday non-security context.

Second, and similarly, the final rule establishes a similar system for disclosures of protected health information necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act. The Act requires that Foreign Service members be suitable for posting throughout the world and for certain specific assignments. For this reason, we permit a limited exemption to serve the purposes of the statute. Again, the medical staff can convey availability determinations to State Department officials who need to know if certain Foreign Service members are available to serve at post.

Third, and finally, the final rule recognizes the special statutory obligations that the State Department has regarding family members of Foreign Service members under sections 101(b)(5) and 904 of the Foreign Service Act. Section 101(b)(5) of the Foreign Service Act requires the Department of State to mitigate the impact of hardships, disruptions, and other unusual conditions on families of Foreign Service Officers. Section 904 requires the Department to establish a health care program to promote and maintain the physical and mental health of Foreign Service member family members. The final rule permits disclosure of protected health information to officials who need protected health information to determine whether a family member can accompany a Foreign Service member abroad.

Given the limited applicability of the rule, we believe it is not necessary for the State Department to publish a notice in the Federal Register to identify the purposes for which the information may be used or disclosed. The final rule identifies these purposes, as described above.

Correctional Institutions

Comments about the rule's application to correctional institutions are addressed in § 164.501, under the definition of "individual."

Section 164.512(l)—Disclosures for Workers' Compensation

Comment: Several commenters stated that workers' compensation carriers are excepted under the HIPAA definition of group health plan and therefore we have no authority to regulate them in this rule. These commenters suggested clarifying that the provisions of the proposed rule did not apply to certain types of insurance entities, such as workers' compensation carriers, and that such non-covered entities should have full access to protected health information without meeting the requirements of the rule. Other commenters argued that a complete exemption for workers' compensation carriers was inappropriate.

Response: We agree with commenters that the proposed rule did not intend to regulate workers' compensation carriers. In the final rule we have incorporated a provision that clarifies that the term "health plan" excludes "any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits as defined in section 2791(c)(1) of the PHS Act." See discussion above under the definition of "health plan" in § 164.501.

Comment: Some commenters argued that the privacy rule should defer to other laws that regulate the disclosure of information to employers and workers' compensation carriers. They commented that many states have laws that require sharing of information —without consent—between providers and employers or workers' compensation carriers.

Response: We agree that the privacy rule should permit disclosures necessary for the administration of state and other workers' compensation systems. To assure that workers' compensations systems are not disrupted, we have added a new ***82708** provisions to the final rule. The new § 164.512(l) permits covered entities to disclose protected health information as authorized by and to the extent necessary to comply with workers' compensation or other similar programs established by law that provide benefits for work-related injuries or illnesses without regard to fault. We also note that where a state or other law requires a use or disclosure of protected health information under a workers' compensation or similar scheme, the disclosure would be permitted under § 164.512(a).

Comment: Several commenters stated that if workers' compensation carriers are to receive protected health information, they should only receive the minimum necessary as required in § 164.514. The commenters argued that employers and workers' compensation carriers should not have access to the entire medical history or portions of the medical history that have nothing to do with the injury in question. Further, the covered provider and not the employer or carrier should determine minimum necessary since the provider is a covered entity and only covered entities are subject to sanctions for violations of the rule. These commenters stated that the rule should clearly indicate the ability of covered entities to refuse to disclose protected health information if it went beyond the scope of the injury. Workers' compensation carriers, on the other hand, argued that permitting providers to determine the minimum necessary was inappropriate because determining eligibility for benefits is an insurance function, not a medical function. They stated that workers' compensation carriers need access to the full range of information regarding treatment for the injury underlying the claim, the claimants' current condition, and any preexisting conditions that can either mitigate the claim or aggravate the impact of the injury.

Response: Under the final rule, covered entities must comply with the minimum necessary provisions unless the disclosure is required by law. Our review of state workers' compensation laws suggests that many of these laws address the issue of the scope of information that is available to carriers and employers. The rule permits a provider to disclose information that is authorized by such a law to the extent necessary to comply with such law. Where the law is silent, the workers' compensation carrier and covered health care provider will need to discuss what information is necessary for the carrier to administer the claim, and the health care provider may disclose that information. We note that if the workers' compensation insurer has secured an authorization from the individual for the release of protected health information, the covered entity may release the protected health information described in the authorization.

Section 164.514 Requirements for Uses and Disclosures

Section 164.514(a)-(c)—De-identification

General Approach

Comments: The comments on this topic almost unanimously supported the concept of de-identification and efforts to expand its use. Although a few comments suggested deleting one of the proposed methods or the other, most appeared to support the two method approach for entities with differing levels of statistical expertise.

Many of the comments argued that the standard for creation of de-identified information should be whether there is a "reasonable basis to believe" that the information has been de-identified. Others suggested that the "reasonable basis" standard was too vague.

A few commenters suggested that we consider information to be de-identified if all personal identifiers that directly reveal the identity of the individual or provide a direct means of identifying individuals have been removed, encrypted or replaced with a code. Essentially, this recommendation would require only removal of "direct" identifiers (e.g., name, address, and ID numbers) and allow retention of all "indirect" identifiers (e.g., zip code and birth date) in "de-identified" information. These comments did not suggest a list or further definition of what identifiers should be considered "direct" identifiers.

Some commenters suggested that the standard be modified to reflect a single standard that applies to all covered entities in the interest of reducing uncertainty and complexity. According to these comments, the standard for covered entities to meet for de-identification of protected health information should be generally accepted standards in the scientific and statistical community, rather than focusing on a specified list of identifiers that must be removed.

A few commenters believed that no record of information about an individual can be truly de-identified and that all such information should be treated and protected as identifiable because more and more information about individuals is being made available to the public, such as voter registration lists and motor vehicle and driver's license lists, that would enable someone to match (and identify) records that otherwise appear to be not identifiable.

Response: In the final rule, we reformulate the method for de-identification to more explicitly use the statutory standard of "a reasonable basis to believe that the information can be used to identify the individual"—just as information is "individually identifiable" if there is a reasonable basis to believe that it can be used to identify the individual, it is "de-identified" if there is no reasonable basis to believe it can be so used. We also define more precisely how the standard should be applied.

We did not accept comments that suggested that we allow only one method of de-identifying information. We find support for both methods in the comments but find no compelling logic for how the competing interests could be met cost-effectively with only one method.

We also disagree with the comments that advocated using a standard which required removing only the direct identifiers. Although such an approach may be more convenient for covered entities, we judged that the resulting information would often remain identifiable, and its dissemination could result in significant violations of privacy. While we encourage covered entities to remove direct identifiers whenever possible as a method of enhancing privacy, we do not believe that the resulting information is sufficiently blinded as to permit its general dissemination without the protections provided by this rule.

We agree with the comments that said that records of information about individuals cannot be truly de-identified, if that means that the probability of attribution to an individual must be absolutely zero. However, the statutory standard does not allow us to take such a position, but envisions a reasonable balance between risk of identification and usefulness of the information.

We disagree with those comments that advocated releasing only truly anonymous information (which has been changed sufficiently so that it no longer represents actual information about real individuals) and those that supported using only sophisticated statistical analysis before allowing uncontrolled disclosures. Although these approaches would provide a marginally higher level of privacy protection, they would preclude many of the laudable and valuable uses discussed in the NPRM (in § 164.506(d)) and would impose too great a burden on ***82709** less sophisticated covered entities to be justified by the small decrease in an already small risk of identification.

We conclude that compared to the alternatives advanced by the comments, the approach proposed in the NPRM, as refined and modified below in response to the comments, most closely meets the intent of the statute.

Comments: A few comments complained that the proposed standards were so strict that they would expose covered entities to liability because arguably no information could ever be de-identified.

Response: In the final rule we have modified the mechanisms by which a covered entity may demonstrate that it has complied with the standard in ways that provide greater certainty. In the standard method for de-identification, we have clarified the professional standard to be used, and anticipate issuing further guidance for covered entities to use in applying the standard. In the safe harbor method, we reduced the amount of judgment that a covered entity must apply. We believe that these mechanisms for de-identification are sufficiently well-defined to protect covered entities that follow them from undue liability.

Comments: Several comments suggested that the rule prohibit any linking of de-identified data, regardless of the probability of identification.

Response: Since our methods of de-identification include consideration of how the information might be used in combination with other information, we believe that linking de-identified information does not pose a significantly increased risk of privacy violations. In addition, since our authority extends only to the regulation of individually identifiable health information, we cannot regulate de-identified information because it no longer meets the definition of individually identifiable health information. We also have no authority to regulate entities that might receive and desire to link such information yet that are not covered entities; thus such a prohibition would have little protective effect.

Comments: Several commenters suggested that we create incentives for covered entities to use de-identified information. One commenter suggested that we mandate an assessment to see if de-identified information could be used before the use or disclosure of identified information would be allowed.

Response: We believe that this final rule establishes a reasonable mechanism for the creation of de-identified information and the fact that this de-identified information can be used without having to follow the policies, procedures, and documentation required to use individually identifiable health information should provide an incentive to encourage its use where appropriate. We disagree with the comment suggesting that we require an assessment of whether de-identified information could be used for each use or disclosure. We believe that such a requirement would be too burdensome on covered entities, particularly with respect to internal uses, where entire records are often used by medical and other personnel. For disclosures, we believe that such an assessment would add little to the protection provided by the minimum necessary requirements in this final rule.

Comments: One commenter asked if de-identification was equivalent to destruction of the protected health information (as required under several of the provisions of this final rule).

Response: The process of de-identification creates a new dataset in addition to the source dataset containing the protected health information. This process does not substitute for actual destruction of the source data.

Modifications to the Proposed Standard for De-Identification

Comments: Several commenters called for clarification of proposed language in the NPRM that would have permitted a covered entity to treat information as de-identified, even if specified identifiers were retained, as long as the probability of identifying subject individuals would be very low. Commenters expressed concern that the "very low" standard was vague. These comments expressed concern that covered entities would not have a clear and easy way to know when information meets this part of the standard.

Response: We agree with the comments that covered entities may need additional guidance on the types of analyses that they should perform in determining when the probability of re-identification of information is very low. We note that in the final rule, we reformulate the standard somewhat to require that a person with appropriate knowledge and experience apply generally accepted statistical and scientific methods relevant to the task to make a determination that the risk of re-identification is very small. In this context, we do not view the difference between a very low probability and a very small risk to be substantive. After consulting representatives of the federal agencies that routinely de-identify and anonymize information for public release[FN16] we attempt here to provide some guidance for the method of de-identification.

As requested by some commenters, we include in the final rule a requirement that covered entities (not following the safe harbor approach) apply generally accepted statistical and scientific principles and methods for rendering information not individually identifiable when determining if information is de-identified. Although such guidance will change over time to keep up with technology and the current availability of public information from other sources, as a starting point the Secretary approves the use of the following as guidance to such generally accepted statistical and scientific principles and methods:

(1) Statistical Policy Working Paper 22—Report on Statistical Disclosure Limitation Methodology (http://www.fcsm.gov/working-papers/wp22.html) (prepared by the Subcommittee on Disclosure Limitation Methodology, Federal Committee on Statistical Methodology, Office of Management and Budget); and

(2) The Checklist on Disclosure Potential of Proposed Data Releases (http:// www.fcsm.gov/docs/checklist_799.doc) (prepared by the Confidentiality and Data Access Committee, Federal Committee on Statistical Methodology, Office of Management and Budget).

We agree with commenters that such guidance will need to be updated over time and we will provide such guidance in the future.

According to the Statistical Policy Working Paper 22, the two main sources of disclosure risk for de-identified records about individuals are the existence of records with very unique characteristics (e.g., unusual occupation or very high salary or age) and the existence of external sources of records with matching data elements which can be used to link with the de-identified information and identify individuals (e.g., voter registration records or driver's license records). The risk of disclosure increases as the number of variables common to both types of records increases, as the accuracy or resolution of the data increases, and as the number of external sources increases. As outlined in Statistical Policy Working Paper 22, an expert disclosure analysis would also consider the probability that an individual who is the target of an attempt at re-identification is represented on both ***82710** files, the probability that the matching variables are recorded identically on the two types of records, the probability that the target individual is unique in the population for the matching variables, and the degree of confidence that a match would correctly identify a unique person.

Statistical Policy Working Paper 22 also describes many techniques that can be used to reduce the risk of disclosure that should be considered by an expert when de-identifying health information. In addition to removing all direct identifiers, these include the obvious choices based on the above causes of the risk; namely, reducing the number of variables on which a match might be made and limiting the distribution of the records through a “data use agreement” or “restricted access agreement” in which the recipient agrees to limits on who can use/receive the data. The techniques also include more sophisticated manipulations: recoding variables into fewer categories to provide less precise detail (including rounding of continuous variables); setting top-codes and bottom-codes to limit details for extreme values; disturbing the data by adding noise by swapping certain variables between records, replacing some variables in random records with mathematically imputed values or averages across small random groups of records, or randomly deleting or duplicating a small sample of records; and replacing actual records with synthetic records that preserve certain statistical properties of the original data.

Modifications to the “Safe Harbor”

Comments: Many commenters argued that stripping all 19 identifiers is unnecessary for purposes of de-identification. They felt that such items as zip code, city (or county), and birth date, for example, do not identify the individual and only such identifiers as name, street address, phone numbers, fax numbers, email, Social Security number, driver's license number, voter registration number, motor vehicle registration, identifiable photographs, finger prints, voice prints, web universal resource locator, and Internet protocol address number need to be removed to reasonably believe that data has been de-identified.

Other commenters felt that removing the full list of identifiers would significantly reduce the usefulness of the data. Many of these comments focused on research and, to a lesser extent, marketing and undefined “statistical analysis.” Commenters who represented various industries and research institutions expressed concern that they would not be able to continue current activities such as development of service provider networks, conducting “analysis” on behalf of the plan, studying use of medication and medical devices, community studies, marketing and strategic planning, childhood immunization initiatives, patient satisfaction surveys, and solicitation of contributions. The requirements in the NPRM to strip off zip code and date of birth were of particular concern. These commenters stated that their ability to do research and quality analysis with this data would be compromised without access to some level of information about patient age and/or geographic location.

Response: While we understand that removing the specified identifiers may reduce the usefulness of the resulting data to third parties, we remain convinced by the evidence found in the MIT study that we referred to in the preamble to the proposed rule[FN17] and the analyses discussed below that there remains a significant risk of identification of the subjects of health information from the inclusion of indirect identifiers such as birth date and zip code and that in many cases there will be a reasonable basis to believe that such information remains identifiable. We note that a covered entity not relying on the safe harbor may determine that information from which sufficient other identifiers have been removed but which retains birth date or zip code is not reasonably identifiable. As discussed above, such a determination must be made by a person with appropriate knowledge and expertise applying generally accepted statistical and scientific methods for rendering information not identifiable.

Although we have determined that all of the specified identifiers must be removed before a covered entity meets the safe harbor requirements, we made modifications in the final rule to the specified identifiers on the list to permit some information about age and geographic area to be retained in de-identified information.

For age, we specify that, in most cases, year of birth may be retained, which can be combined with the age of the subject to provide sufficient information about age for most uses. After considering current and evolving practices and consulting with federal experts on this topic, including members of the Confidentiality and Data Access Committee of the Federal Committee on Statistical Methodology, Office of Management and Budget, we concluded that in general, age is sufficiently broad to be allowed in de-identified information, although all dates that might be directly related to the subject of the information must be removed or aggregated to the level of year to prevent deduction of birth dates. Extreme ages—90 and over—must be aggregated further (to a category of 90+, for example) to avoid identification of very old individuals (because they are relatively rare). This reflects the minimum requirement of the current recommendations of the Bureau of the Census.[FN18] For research or other studies relating to young children or infants, we note that the rule would not prohibit age of an individual from being expressed as an age in months, days, or hours.

For geographic area, we specify that the initial three digits of zip codes may be retained for any three-digit zip code that contains more than 20,000 people as determined by the Bureau of the Census. As discussed more below, there are currently only 18 three-digit zip codes containing fewer than 20,000 people. We note that this number may change when information from the 2000 Decennial Census is analyzed.

In response to concerns expressed in the comments about the need for information on geographic area, we investigated the potential of allowing 5-digit zip codes or 3-digit zip codes to remain in the de-identified information. According to 1990 Census data, the populations in geographical areas delineated by 3-digit zip codes vary a great deal, from a low of 394 to a high of 3,006,997, with an average size of 282,304. There are two 3-digit zip codes containing fewer than 500 people and six 3-digit zip codes containing fewer than 10,000 people each.[FN19] Of the total of 881 3-digit zip codes, there are 18 with fewer than 20,000 people, 71 with fewer than 50,000 people, and 215 containing fewer than 100,000 population. We also looked at two-digit zip codes (the first 2 digits of the 5-digit zip code) and found that the smallest of the 98 2-digit zip codes contains 188,638 people.

We also investigated the practices of several other federal agencies which are mandated by Congress to release data ***82711** from national surveys while preserving confidentiality and which have been dealing with these issues for decades. The problems and solutions being used by these agencies are laid out in detail in the Statistical Policy Working Paper 22 cited earlier.

To protect the privacy of individuals providing information to the Bureau of Census, the Bureau has determined that a geographical region must contain at least 100,000 people.[FN20] This standard has been used by the Bureau of the Census for many years and is supported by simulation studies using Census data.[FN21] These studies showed that after a certain point, increasing the size of a geographic area does not significantly decrease the percentage of unique records (i.e., those that could be identified if sampled), but that the point of diminishing returns is dependent on the number and type of demographic variables on which matching might occur. For a small number of demographic variables (6), this point was quite low (about 20,000 population), but it rose quickly to about 50,000 for 10 variables and to about 80,000 for 15 variables. The Bureau of the Census releases sets of data to the public that it considers safe from re-identification because it limits geographical areas to those containing at least 100,000 people and limits the number and detail of the demographic variables in the data. At the point of approximately 100,000 population, 7.3% of records were unique (and therefore potentially identifiable) on 6 demographic variables from the 1990 Census Short Form: Age in years (90 categories), race (up to 180 categories), sex (2 categories), relationship to householder (14 categories), Hispanic (2 categories), and tenure (owner vs. renter in 5 categories). Using 6 variables derived from the Long Form data, age (10 categories), race (6 categories), sex (2 categories), marital status (5 categories), occupation (54 categories), and personal income (10 categories), raised the percentage to 9.8%.

We also examined the results of an NCHS simulation study using national survey data[FN22] to see if some scientific support could be found for a compromise. The study took random samples from populations of different sizes and then compared the

samples to the whole population to see how many records were identifiable, that is, matched uniquely to a unique person in the whole population on the basis of 9 demographic variables: Age (85 categories), race (4 categories), gender (2 categories), ethnicity (2 categories), marital status (3 categories), income (3 categories), employment status (2 categories), working class (4 categories), and occupation (42 categories). Even when some of the variables are aggregated or coded, from the perspective of a large statistical agency desiring to release data to the public, the study concluded that a population size of 500,000 was not sufficient to provide a reasonable guarantee that certain individuals could not be identified. About 2.5 % of the sample from the population of 500,000 was uniquely identifiable, regardless of sample size. This percentage rose as the size of the population decreased, to about 14% for a population of 100,000 and to about 25% for a population of 25,000. Eliminating the occupation variable (which is less likely to be found in health data) reduced this percentage significantly to about 0.4 %, 3%, and 10% respectively. These percentages of unique records (and thus the potentials for re-identification) are highly dependent on the number of variables (which must also be available in other databases which are identified to be considered in a disclosure risk analysis), the categorical breakdowns of those variables, and the level of geographic detail included.

With respect to how we might clarify the requirement to achieve a "low probability" that information could be identified, the Statistical Policy Working Paper 22 referenced above discusses the attempts of several researchers to define mathematical measures of disclosure risk only to conclude that "more research into defining a computable measure of risk is necessary." When we considered whether we could specify a maximum level of risk of disclosure with some precision (such as a probability or risk of identification of @0.01), we concluded that it is premature to assign mathematical precision to the "art" of de-identification.

After evaluating current practices and recognizing the expressed need for some geographic indicators in otherwise de-identified databases, we concluded that permitting geographic identifiers that define populations of greater than 20,000 individuals is an appropriate standard that balances privacy interests against desirable uses of de-identified data. In making this determination, we focused on the studies by the Bureau of Census cited above which seemed to indicate that a population size of 20,000 was an appropriate cut off if there were relatively few (6) demographic variables in the database. Our belief is that, after removing the required identifiers to meet the safe harbor standards, the number of demographic variables retained in the databases will be relatively small, so that it is appropriate to accept a relatively low number as a minimum geographic size.

In applying this provision, covered entities must replace the (currently 18) forbidden 3-digit zip codes with zeros and thus treat them as a single geographic area (with >20,000 population). The list of the forbidden 3-digit zip codes will be maintained as part of the updated Secretarial guidance referred to above. Currently, they are: 022, 036, 059, 102, 203, 555, 556, 692, 821, 823, 830, 831, 878, 879, 884, 893, 987, and 994. This will result in an average 3-digit zip code area population of 287,858 which should result in an average of about 4% unique records using the 6 variables described above from the Census Short Form. Although this level of unique records will be much higher in the smaller geographic areas, the actual risk of identification will be much lower because of the limited availability of comparable data in publically available, identified databases, and will be further reduced by the low probability that someone will expend the resources to try to identify records when the chance of success is so small and uncertain. We think this compromise will meet the current need for an easy method to identify geographic area while providing adequate protection from re-identification. If a greater level of geographical detail is required for a particular use, the information will have to be obtained through another permitted mechanism or be subjected to a specific de-identification determination as described above. We will monitor the availability of identified public data and the concomitant re-identification risks, both theoretical and actual, and adjust this safe harbor in the future as necessary.

As we stated above, we understand that many commenters would prefer a looser standard for determining when information is de-identified, both generally and with respect to the standards for identifying geographic ***82712** area. However, because public databases (such as voter records or driver's license records) that include demographic information about a geographically defined population are available, a surprisingly large percentage of records of health information that contain similar demographic information can be identified. Although the number of these databases seems to be increasing, the number of demographic variables within them still appears to be fairly limited. The number of cases of privacy violation from health records which have been identified in this way is small to date. However, the risk of identification increases with decreasing population size, with increasing amounts of demographic information (both in level of detail and number of variables), and with the uniqueness

of the combination of such information in the population. That is, an 18-year-old single white male student is not at risk of identification in a database from a large city such as New York. However, if the database were about a small town where most of the inhabitants were older, retired people of a specific minority race or ethnic group, that same person might be unique in that community and easily identified. We believe that the policy that we have articulated reaches the appropriate balance between reasonably protecting privacy and providing a sufficient level of information to make de-identified databases useful.

Comments: Some comments noted that identifiers that accompany photographic images are often needed to interpret the image and that it would be difficult to use the image alone to identify the individual.

Response: We agree that our proposed requirement to remove all photographic images was more than necessary. Many photographs of lesions, for example, which cannot usually be used alone to identify an individual, are included in health records. In this final rule, the only absolute requirement is the removal of full-face photographs, and we depend on the "catch-all" of "any other unique * * * characteristic * * * " to pick up the unusual case where another type of photographic image might be used to identify an individual.

Comments: A number of commenters felt that the proposed bar for removal had been set too high; that the removal of these 19 identifiers created a difficult standard, since some identifiers may be buried in lengthy text fields.

Response: We understand that some of the identifiers on our list for removal may be buried in text fields, but we see no alternative that protects privacy. In addition, we believe that such unstructured text fields have little or no value in a de-identified information set and would be removed in any case. With time, we expect that such identifiers will be kept out of places where they are hard to locate and expunge.

Comments: Some commenters asserted that this requirement creates a disincentive for covered entities to de-identify data and would compromise the Secretary's desire to see de-identified data used for a multitude of purposes. Others stated that the "no reason to believe" test creates an unreasonable burden on covered entities, and would actually chill the release of de-identified information, and set an impossible standard.

Response: We recognize that the proposed standards might have imposed a burden that could have prevented the widespread use of de-identified information. We believe that our modifications to the final rule discussed above will make the process less burdensome and remove some of the disincentive. However, we could not loosen the standards as far as many commenters wanted without seriously jeopardizing the privacy of the subjects of the information. As discussed above, we modify the "no reason to know" standard that was part of the safe harbor provision and replace it in the final rule with an "actual knowledge" standard. We believe that this change provides additional certainty to covered entities using the safe harbor and should eliminate any chilling effect.

Comments: Although most commenters wanted to see data elements taken off the list, there were a small number of commenters that wanted to see data items added to the list. They believed that it is also necessary to remove clinical trial record numbers, device model serial numbers, and all proper nouns from the records.

Response: In response to these requests, we have slightly revised the list of identifiers that must be removed under the safe harbor provision. Clinical trial record numbers are included in the general category of "any other unique identifying number, characteristic, or code." These record numbers cannot be included with de-identified information because, although the availability of clinical trial numbers may be limited, they are used for other purposes besides de-identification/re-identification, such as identifying clinical trial records, and may be disclosed under certain circumstances. Thus, they do not meet the criteria in the rule for use as a unique record identifier for de-identified records. Device model serial numbers are included in "any device identifier or serial number" and must be removed. We considered the request to remove all proper nouns to be very burdensome to implement for very little increase in privacy and likely to be arbitrary in operation, and so it is not included in the final rule.

Re-Identification

Comments: One commenter wanted to know if the rule requires that covered entities retain the ability to re-identify de-identified information.

Response: The rule does not require covered entities to retain the ability to re-identify de-identified information, but it does allow them to retain this ability.

Comments: A few commenters asked us to prohibit anyone from re-identifying de-identified health information.

Response: We do not have the authority to regulate persons other than covered entities, so we cannot affect attempts by entities outside of this rule to re-identify information. Under the rule, we permit the covered entity that created the de-identified information to re-identify it. However, we include a requirement that, when a unique record identifier is included in the de-identified information, such identifier must not be such that someone other than the covered entity could use it to identify the individual (such as when a derivative of the individual's name is used as the unique record identifier).

Section 164.514(d)—Minimum Necessary

Comment: A large number of commenters objected to the application of the proposed "minimum necessary" standard for uses and disclosures of protected health information to uses and disclosures for treatment purposes. Some suggested that the final regulation should establish a good faith exception or safe harbor for disclosures made for treatment.

The overwhelming majority of commenters, generally from the medical community, argued that application of the proposed standard would be contrary to sound medical practice, increase medical errors, and lead to an increase in liability. Some likened the standard to a "gag clause" in that it limited the exchange of information critical for quality patient care. They found the standard unworkable in daily treatment situations. They argued that this standard would be potentially dangerous in that it could cause practitioners to withhold information that could be essential for later care. Commenters asserted that caregivers need to be able to give and receive a ***82713** complete picture of the patient's health to make a diagnosis and develop a treatment plan.

Other commenters noted that the complexity of medicine is such that it is unreasonable to think that anyone will know the exact parameters of the information another caregiver will need for proper diagnosis and treatment or that a plan will need to support quality assurance and improvement activities. They therefore suggested that the minimum necessary standard be applied instead as an administrative requirement.

Providers also emphasized that they already have an ethical duty to limit the sharing of unnecessary medical information, and most already have well-developed guidelines and practice standards in place. Concerns were also voiced that attempts to provide the minimum necessary information in the treatment setting would lead to multiple editions of a record or creation of summaries that turn out to omit crucial information resulting in confusion and error.

Response: In response to these concerns, we substantially revise the minimum necessary requirements. As suggested by certain commenters, we provide, in § 164.502(b), that disclosures of protected health information to or requests by health care providers for treatment are not subject to the minimum necessary standard. We also modify the requirements for uses of protected health information. This final rule requires covered entities to make determinations of minimum necessary use, including use for treatment purposes, based on the role of the person or class of workforce members rather than at the level of specific uses. A covered entity must establish policies and procedures that identify the types of persons who are to have access to designated categories of information and the conditions, if any, of that access. We establish no requirements specific to a particular use of information. Covered entities are responsible for establishing and documenting these policies and procedures. This approach is consistent with the argument of many commenters that guidelines and practice standards are appropriate means for protecting the privacy of patient information.

Comment: Some commenters argued that the standard should be retained in the treatment setting for uses and disclosures pertaining to mental health information. Some of these commenters asserted that other providers do not need to know the mental status of a patient for treatment purposes.

Response: We agree that the standard should be retained for uses of mental health information in the treatment setting. However, we believe that the arguments for excepting disclosures of protected health information for treatment purposes from application of the minimum necessary standard are also persuasive with respect to mental health information. An individual's mental health can interact with proper treatment for other conditions in many ways. Psychoactive medications may have harmful interactions with drugs routinely prescribed for other purposes; an individual's mental health history may help another health care provider understand the individual's ability to abide by a complicated treatment regimen. For these reasons, it is also not reasonable to presume that, in every case, a health care provider will not need to know an individual's mental health status to provide appropriate treatment.

Providers' comments noted existing ethical duties to limit the sharing of unnecessary medical information, and well-developed guidelines and practice standards for this purpose. Under this rule, providers may use these tools to guide their discretion in disclosing health information for treatment.

Comment: Several commenters urged that covered entities should be required to conspicuously label records to show that they are not complete. They argued that absent such labeling, patient care could be compromised.

Response: We believe that the final policy to except disclosures of protected health information for treatment purposes from application of the minimum necessary standard addresses these commenters' concerns.

Comment: Some commenters argued that the audit exception to the minimum necessary requirements needs to be clarified or expanded, because “audit” and “payment” are essentially the same thing.

Response: We eliminate this exception. The proposed exclusion of disclosures to health plans for audit purposes is replaced with a general requirement that covered entities must limit requests to other covered entities for individually identifiable health information to what is reasonably necessary for the purpose intended.

Comment: Many commenters argued that the proposed standard was unworkable as applied to “uses” by a covered entity's employees, because the proposal appeared not to allow providers to create general policy as to the types of records that particular employees may have access to but instead required that each decision be made “individually,” which providers interpret as “case-by-case.” Commenters argued that the standard with regard to “uses” would be impossible to implement and prohibitively expensive, requiring both medical and legal input to each disclosure decision.

Some commenters recommended deletion of the minimum necessary standard with regard to “uses.” Other commenters specifically recommended deletion of the requirement that the standard be applied on an individual, case-by-case basis. Rather, they suggested that the covered entity be allowed to establish general policies to meet the requirement. Another commenter similarly urged that the standard not apply to internal disclosures or for internal health care operations such as quality improvement/assurance activities. The commenter recommended that medical groups be allowed to develop their own standards to ensure that these activities are carried out in a manner that best helps the group and its patients.

Other commenters expressed confusion and requested clarification as to how the standard as proposed would actually work in day-to-day operations within an entity.

Response: Commenters' arguments regarding the workability of this standard as proposed were persuasive, and we therefore make significant modification to address these comments and improve the workability of the standard. For all uses and many disclosures, we require covered entities to include in their policies and procedures (see § 164.530), which may be standard

protocols, for "minimum necessary" uses and disclosures. We require implementation of such policies in lieu of making the "minimum necessary" determination for each separate use and disclosure.

For uses, covered entities must implement policies and procedures that restrict access to and use of protected health information based on the specific professional roles of members of the covered entity's workforce. The policies and procedures must identify the persons or classes of persons in the entity's workforce who need access to protected health information to carry out their duties and the category or categories of protected health information to which such persons or classes need access. These role-based access rules must also identify the conditions, as appropriate, that would apply to such access. For example, an institutional health care provider could allow physicians access to all records under the condition that the viewing of medical records of patients not under their care is recorded and reviewed. Other health professionals' access could ***82714** be limited to time periods when they are on duty. Information available to staff who are responsible for scheduling surgical procedures could be limited to certain data. In many instances, use of order forms or selective copying of relevant portions of a record may be appropriate policies to meet this requirement.

Routine disclosures also are not subject to individual review; instead, covered entities must implement policies and procedures (which may be standard protocols) to limit the protected health information in routine disclosures to the minimum information reasonably necessary to achieve the purpose of that type of disclosure. For non-routine disclosures, a covered entity must develop reasonable criteria to limit the protected health information disclosed to the minimum necessary to accomplish the purpose for which disclosure is sought, and to implement procedures for review of disclosures on an individual basis.

We modify the proposed standard to require the covered entity to make "reasonable efforts" to meet the minimum necessary standard (not "all'reasonable efforts, as proposed). What is reasonable will vary with the circumstances. When it is practical to use order forms or selective copying of relevant portions of the record, the covered entity is required to do so. Similarly, this flexibility in the standard takes into account the ability of the covered entity to configure its record system to allow selective access to only certain fields, and the practicality of organizing systems to allow this capacity. It might be reasonable for a covered entity with a highly computerized information system to implement a system under which employees with certain functions have access to only limited fields in a patient records, while other employees have access to the complete records. Such a system might not be reasonable for a covered entity with a largely paper records system.

Covered entities' policies and procedures must provide that disclosure of an entire medical record will not be made except pursuant to policies which specifically justify why the entire medical record is needed.

We believe that these modifications significantly improve the workability of this standard. At the same time, we believe that asking covered entities to assess their practices and establish rules for themselves will lead to significant improvements in the privacy of health information. See the preamble for § 164.514 for a more detailed discussion.

Comment: The minimum necessary standard should not be applied to uses and disclosures for payment or health care operations.

Response: Commenter's arguments for exempting these uses and disclosures from the minimum necessary standard were not compelling. We believe that our modifications to application of the minimum necessary standard to internal uses of protected health information, and to routine disclosures, address many of the concerns raised, particularly the concerns about administrative burdens and the concerns about having the information necessary for day-to-day operations. We do not eliminate this standard in part because we also remain concerned that covered entities may be tempted to disclose an entire medical record when only a few items of information are necessary, to avoid the administrative step of extracting the necessary information (or redacting the unnecessary information). We also believe this standard will cause covered entities to assess their privacy practices, give the privacy interests of their patients and enrollees greater attention, and make improvements that might otherwise not have been made. For this reason, the privacy benefits of retaining the minimum necessary standard for these purposes outweigh the burdens involved. We note that the minimum necessary standard is tied to the purpose of the disclosure; thus, providers may disclose protected health information as necessary to obtain payment.

Comment: Other commenters urged us to apply a "good faith" provision to all disclosures subject to the minimum necessary standard. Commenters presented a range of options to modify the proposed provisions which, in their view, would have mitigated their liability if they failed to comply with minimum necessary standard.

Response: We believe that the modifications to this standard, described above, substantially address these commenters' concerns. In addition to allowing the covered entity to use standard protocols for routine disclosures, we modify the standard to require a covered entity to make "reasonable efforts," not "all" reasonable efforts as proposed, in making the "minimum necessary" disclosure.

Comments: Some commenters complained that language in the proposed rule was vague and provided little guidance, and should be abandoned.

Response: In the preamble for § 164.504 and these responses to comments, we provide further guidance on how a covered entity can develop its policies for the minimum necessary use and disclosure of protected health information. We do not abandon this standard for the reasons described above. We remain concerned about the number of persons who have access to identifiable health information, and believe that causing covered entities to examine their practices will have significant privacy benefits.

Comment: Some commenters asked that the minimum necessary standard should not be applied to disclosures to business partners. Many of these commenters articulated the burdens they would bear if every disclosure to a business partner was required to meet the minimum necessary standard.

Response: We do not agree. In this final rule, we minimize the burden on covered entities in the following ways: in circumstances where disclosures are made on a routine, recurring basis, such as in on-going relationships between covered entities and their business associates, individual review of each routine disclosure has been eliminated; covered entities are required only to develop standard protocols to apply to such routine disclosures made to business associates (or types of business associates). In addition, we allow covered entities to rely on the representation of a professional hired to provide professional services as to what information is the minimum necessary for that purpose.

Comment: Some commenters were concerned that applying the standard in research settings will result in providers declining to participate in research protocols.

Response: We have modified the proposal to reduce the burden on covered entities that wish to disclose protected health information for research purposes. The final rule requires covered entities to obtain documentation or statements from persons requesting protected health information for research that, among other things, describe the information necessary for the research. We allow covered entities to reasonably rely on the documentation or statements as describing the minimum necessary disclosure.

Comment: Some commenters argued that government requests should not be subject to the minimum necessary standard, whether or not they are "authorized by law."

Response: We found no compelling reason to exempt government requests from this standard, other than when a disclosure is required by law. (See preamble to § 164.512(a) for the ***82715** rationale behind this policy). When a disclosure is required by law, the minimum necessary standard does not apply, whether the recipient of the information is a government official or a private individual.

At the same time, we understand that when certain government officials make requests for protected health information, some covered entities might feel pressure to comply that might not be present when the request is from a private individuals. For

this reason, we allow (but do not require) covered entities to reasonably rely on the representations of public officials as to the minimum necessary information for the purpose.

Comment: Some commenters argued that requests under proposed § 164.510 should not be subject to the minimum necessary standard, whether or not they are "authorized by law." Others argued that for disclosures made for administrative proceedings pursuant to proposed § 164.510, the minimum necessary standard should apply unless they are subject to a court order.

Response: We found no compelling reason to exempt disclosures for purposes listed in the regulation from this standard, other than for disclosures required by law. When there is no such legal mandate, the disclosure is voluntary on the part of the covered entity, and it is therefore reasonable to expect the covered entity to make some effort to protect privacy before making such a disclosure. If the covered entity finds that redacting unnecessary information, or extracting the requested information, prior to making the disclosure, is too burdensome, it need not make the disclosure. Where there is ambiguity regarding what information is needed, some effort on the part of the covered entity can be expected in these circumstances.

We also found no compelling reason to limit the exemption for disclosures "required by law" to those made pursuant to a court order. The judgment of a state legislature or regulatory body that a disclosure is required is entitled to no less deference than the same decision made by a court. For further rationale for this policy, see the preamble to § 164.512(a).

Comment: Some commenters argued that, in cases where a request for disclosure is not required by law, covered entities should be permitted to rely on the representations by public officials, that they have requested no more than the minimum amount necessary.

Response: We agree, and retain the proposed provision which allows reasonable reliance on the representations of public officials.

Comment: Some commenters argued that it is inappropriate to require covered entities to distinguish between disclosures that are "required by law" and those that are merely "authorized by law," for the purposes of determining when the standard applies.

Response: We do not agree. Covered entities have an independent duty to be aware of their legal obligations to federal, state, local and territorial or tribal authorities. In addition, § 164.514(h) allows covered entities to reasonably rely on the oral or written representation of public officials that a disclosure is required by law.

Comment: The minimum necessary standard should not be applied to pharmacists, or to emergency services.

Response: We believe that the final rule's exemption of disclosures of protected health information to health care providers for treatment purposes from the minimum necessary standard addresses these commenters concerns about emergency services. Together with the other changes we make to the proposed standard, we believe we have also addressed most of the commenters' concerns about pharmacists. With respect to pharmacists, the comments offered no persuasive reasons to treat pharmacists differently from other health care providers. Our reasons for retaining this standard for other uses and disclosures of protected health information are explained above.

Comment: A number of commenters argued that the standard should not apply to disclosures to attorneys, because it would interfere with the professional duties and judgment of attorneys in their representation of covered entities. Commenters stated that if a layperson within a covered entity makes an improper decision as to what the minimum necessary information is in regard to a request by the entity's attorney, the attorney may end up lacking information that is vital to representation. These commenters stated that attorneys are usually going to be in a better position to determine what information is truly the minimum necessary for effective counsel and representation of the client.

Response: We found no compelling reason to treat attorneys differently from other business associates. However, to ensure that this rule does not inadvertently cause covered entities to second-guess the professional judgment of the attorneys and other professionals they hire, we modify the proposed policies to explicitly allow covered entities to rely on the representation of a professional hired to provide professional services as to what information is the minimum necessary for that purpose.

Comment: Commenters from the law enforcement community expressed concern that providers may attempt to misuse the minimum necessary standard as a means to restrict access to information, particularly with regard to disclosures for health oversight or to law enforcement officials.

Response: The minimum necessary standard does not apply to disclosures required by law. Since the disclosures to law enforcement officials to which this standard applies are all voluntary, there would be no need for a covered entity to "manipulate" the standard; it could decline to make the disclosure.

Comment: Some commenters argued that the only exception to the application of the standard should be when an individual requests access to his or her own information. Many of these commenters expressed specific concerns about victims of domestic violence and other forms of abuse.

Response: We do not agree with the general assertion that disclosure to the individual is the only appropriate exception to the minimum necessary standard. There are other, limited, circumstances in which application of the minimum necessary standard could cause significant harm. For reasons described above, disclosures of protected health information for treatment purposes are not subject to this standard. Similarly, as described in detail in the preamble to § 164.512(a), where another public body has mandated the disclosure of health information, upsetting that judgment in this regulation would not be appropriate.

The more specific concerns expressed about victims of domestic violence and other forms of abuse are addressed in a new provision regarding disclosure of protected health information related to domestic violence and abuse (see § 164.512(c)), and in new limitations on disclosures to persons involved in the individual's care (see § 164.510(b)). We believe that the limitations we place on disclosure of health information in those circumstances address the concerns of these commenters.

Comment: Some commenters argued that disclosures to next of kin should be restricted to minimum necessary protected health information, and to protected health information about only the current medical condition.

Response: In the final regulation, we change the proposed provision regarding "next of kin" to more clearly focus on the disclosures we intended to target: Disclosures to persons involved ***82716** in the individual's care. We allow such disclosure only with the agreement of the individual, or where the covered entity has offered the individual the opportunity to object to the disclosure and the individual did not object. If the opportunity to object cannot practicably be provided because of the incapacity of the individual or other emergency, we require covered entities to exercise professional judgment in the best interest of the patient in deciding whether to disclose information. In such cases, we permit disclosure only of that information directly relevant to the person's involvement with the individual's health care. (This provision also includes limited disclosure to certain persons seeking to identify or locate an individual.) See § 164.510(b).

Some additional concerns expressed about victims of domestic violence and other forms of abuse are also addressed in a new section on disclosure of protected health information related to domestic violence and abuse. See § 164.512(c). We believe that the limitations we place on disclosure of health information in these provisions address the concerns of these commenters.

Comment: Some commenters argued that covered entities should be required to determine whether de-identified information could be used before disclosing information under the minimum necessary standard.

Response: We believe that requiring covered entities' policies and procedures for minimum necessary disclosures to address whether de-identified information could be used in all instances would impose burdens on some covered entities that could

outweigh the benefits of such a requirement. There is significant variation in the sophistication of covered entities' information systems. Some covered entities can reasonably implement policies and procedures that make significant use of de-identified information; other covered entities would find such a requirement excessively burdensome. For this reason, we chose instead to require "reasonable efforts," which can vary according to the situation of each covered entity.

In addition, we believe that the fact that we allow de-identified information to be disclosed without regard to the policies, procedures, and documentation required for disclosure of identifiable health information will provide an incentive to encourage its use where appropriate.

Comment: Several commenters argued that standard transactions should not be subject to the standard.

Response: We agree that data elements that are required or situationally required in the standard transactions should not be, and are not, subject to this standard. However, in many cases, covered entities have significant discretion as to the information included in these transactions. Therefore, this standard does apply to those optional data elements.

Comment: Some commenters asked for clarification to understand how the minimum necessary standard is intended to interact with the security NPRM.

Response: The proposed Security Rule included requirements for electronic health information systems to include access management controls. Under this regulation, the covered entity's privacy policies will determine who has access to what protected health information. We will make every effort to ensure consistency prior to publishing the final Security Rule.

Comment: Many commenters, representing health care providers, argued that if the request was being made by a health plan, the health plan should be required to request only the minimum protected health information necessary. Some of these commenters stated that the requestor is in a better position to know the minimum amount of information needed for their purposes. Some of these commenters argued that the minimum necessary standard should be imposed only on the requesting entity. A few of these commenters argued that both the disclosing and the requesting entity should be subject to the minimum necessary standard, to create "internal tension" to assure the standard is honored.

Response: We agree, and in the final rule we require that a request for protected health information made by one covered entity to another covered entity must be limited to the minimum amount necessary for the purpose. As with uses and disclosures of protected health information, covered entities may have standard protocols for routine requests. Similarly, this requirement does not apply to requests made to health care providers for treatment purposes. We modify the rule to balance this provision; that is, it now applies both to disclosure of and requests for protected health information. We also allow, but do not require, the covered entity releasing the information to reasonably rely on the assertion of a requesting covered entity that it is requesting only the minimum protected health information necessary.

Comment: A few commenters suggested that there should be a process for resolving disputes between covered entities over what constitutes the "minimum necessary" information.

Response: We do not intend that this rule change the way covered entities currently handle their differences regarding the disclosure of health information. We understand that the scope of information requested from providers by health plans is a source of tension in the industry today, and we believe it would not be appropriate to use this regulation to affect that debate. As discussed above, we require both the requesting and the disclosing covered entity to take privacy concerns into account, but do not inject additional tension into the on-going discussions.

Section 164.514(e)—Marketing

Comment: Many commenters requested clarification of the boundaries between treatment, payment, health care operations, and marketing. Some of these commenters requested clarification of the apparent inconsistency between language in proposed

§ 164.506(a)(1)(i) (a covered entity is permitted to use or disclose protected health information without authorization "to carry out" treatment, payment, or health care operations) and proposed § 164.508(a)(2)(A) (a covered entity must obtain an authorization for all uses and disclosures that are not "compatible with or directly related to" treatment, payment, and health care operations). They suggested retaining the language in proposed § 164.508(a)(2)(A), which would permit a broader range of uses and disclosures without authorization, in order to engage in health promotion activities that might otherwise be considered marketing.

Response: In the final rule, we make several changes to the definitions of treatment, payment, and health care operations that are intended to clarify the uses and disclosures of protected health information that may be made for each purpose. See § 164.501 and the corresponding preamble discussion regarding the definitions of these terms. We also have added a definition of the term "marketing" to help establish the boundary between marketing and treatment, payment, and health care operations. See § 164.501. We also clarify the conditions under which authorization is or is not required for uses and disclosures of protected health information for marketing purposes. See § 164.514(e). Due to these changes, we believe it is appropriate to retain the wording from proposed § 164.506(a)(1)(i). ***82717**

Comment: We received a wide variety of suggestions with respect to authorization for uses and disclosures of protected health information for marketing purposes. Some commenters supported requiring authorization for all such uses and disclosures. Other commenters suggested permitting all such uses and disclosures without authorization.

Some commenters suggested we distinguish between marketing to benefit the covered entity and marketing to benefit a third party. For example, a few commenters suggested we should prohibit covered entities from seeking authorization for any use or disclosure for marketing purposes that benefit a third party. These commenters argued that the third parties should be required to obtain the individual's authorization directly from the individual, not through a covered entity, due to the potential for conflicts of interest.

While a few commenters suggested that we require covered entities to obtain authorization to use or disclose protected health information for the purpose of marketing its own products and services, the majority argued these types of marketing activities are vital to covered entities and their customers and should therefore be permitted to occur without authorization. For example, commenters suggested covered entities should be able to use and disclose protected health information without authorization in order to provide appointment reminders, newsletters, information about new initiatives, and program bulletins.

Finally, many commenters argued we should not require authorization for the use or disclosure of protected health information to market any health-related goods and services, even if those goods and services are offered by a third party. Some of these commenters suggested that individuals should have an opportunity to opt out of these types of marketing activities rather than requiring authorization.

Response: We have modified the final rule in ways that address a number of the issues raised in the comments. First, the final rule defines the term marketing, and excepts certain communications from the definition. See § 164.501. These exceptions include communications made by covered entities for the purpose of describing network providers or other available products, services, or benefits and communications made by covered entities for certain treatment-related purposes. These exceptions only apply to oral communications or to written communications for which the covered entity receives no third-party remuneration. The exceptions to the definition of marketing fall within the definitions of treatment and/or health care operations, and therefore uses, or disclosures to a business associate, of protected health information for these purposes are permissible under the rule without authorization.

The final rule also permits covered entities to use protected health information to market health-related products and services, whether they are the products and services of the covered entity or of a third party, subject to a number of limitations. See § 164.514(e). We permit these uses to allow entities in the health sector to inform their patients and enrollees about products that may benefit them. The final rule contains significant restrictions, including requirements that the covered entity disclose

itself as the source of a marketing communication, that it disclose any direct or indirect remuneration from third parties for making the disclosure, and that, except in the cases of general communications such as a newsletter, the communication disclose how the individual can opt-out of receiving additional marketing communications. Additional requirements are imposed if the communication is targeted based on the health status or condition of the proposed recipients.

We believe that these modifications address many of the issues raised by commenters and provide a substantial amount of flexibility as to when a covered entity may communicate about a health-related product or service to a patient or enrollee. These communications may include appointment reminders, newsletters, and information about new health products. These changes, however, do not permit a covered entity to disclose protected health information to third parties for marketing (other than to a business associate to make a marketing communication on behalf of the covered entity) without authorization under § 164.508.

Comment: A few commenters suggested we prohibit health care clearinghouses from seeking authorization for the use or disclosure of protected health information for marketing purposes.

Response: We do not prohibit clearinghouses from seeking authorizations for these purposes. We believe, however, that health care clearinghouses will almost always create or obtain protected health information in a business associate capacity. Business associates may only engage in activities involving the use or disclosure of protected health information, including seeking or acting on an authorization, to the extent their contracts allow them to do so. When a clearinghouse creates or receives protected health information other than as a business associate of a covered entity, it is permitted and required to obtain authorizations to the same extent as any other covered entity.

Comment: A few commenters suggested we require covered entities to publicly disclose, on the covered entity's website or upon request, all of their marketing arrangements.

Response: While we agree that such a requirement would provide individuals with additional information about how their information would be used, we do not feel that such a significant intrusion into the business practices of the covered entity is warranted.

Comment: Some commenters argued that if an activity falls within the scope of payment, it should not be considered marketing. Commenters strongly supported an approach which would bar an activity from being construed as “marketing” even if performing that activity would result in financial gain to the covered entity. In a similar vein, we were urged to adopt the position that if an activity was considered payment, treatment or health care operations, it could not be further evaluated to determine whether it should be excluded as marketing.

Response: We considered the approach offered by commenters but decided against it. Some activities, such as the marketing of a covered entity's own health-related products or services, are now included in the definition of health care operations, provided certain requirements are met. Other types of activities, such as the sale of a patient list to a marketing firm, would not be permitted under this rule without authorization from the individual. We do not believe that we can envision every possible disclosure of health information that would violate the privacy of an individual, so any list would be incomplete. Therefore, whether or not a particular activity is considered marketing, payment, treatment or health care operations will be a fact-based determination based on the activity's congruence with the particular definition.

Comment: Some industry groups stated that if an activity involves selling products, it is not disease management. They suggested we adopt a definition of disease management that differentiates use of information for the best interests of patient from uses undertaken for “ulterior purposes” such as advertising, marketing, or promoting separate products. ***82718**

Response: We agree in general that the sale of unrelated products to individuals is not a population-based activity that supports treatment and payment. However, in certain circumstances marketing activities are permitted as a health care operation; see the definition of “health care operations” in § 164.501 and the related marketing requirements of § 164.514.

Comment: Some commenters complained that the absence of a definition for disease management created uncertainty, in view of the proposed rule's requirement to get authorization for marketing. They expressed concern that the effect would be to require patient consent for many activities that are desirable, not practicably done if authorization is required, and otherwise classifiable as treatment, payment, or health care operations. Examples provided include reminders for appointments, reminders to get preventive services like mammograms, and information about home management of chronic illnesses. They also stated that the proposed rule would prevent many disease management and preventive health activities.

Response: We agree that the distinction in the NPRM between disease management and marketing was unclear. Rather than provide a definition of disease management, this final rule defines marketing. We note that overlap between disease management and marketing exists today in practice and they cannot be distinguished easily with a definitional label. However, for purposes of this rule, the revised language makes clear for what activities an authorization is required. We note that under this rule many of the activities mentioned by commenters will not require authorizations under most circumstances. See the discussion of disease management under the definition of "treatment" in § 164.501.

Section 164.514(f)—Fundraising

Comment: Many comments objected to the requirement that an authorization from the individual be obtained for use and disclosure of protected health information for fundraising purposes. They argued that, in the case of not-for-profit health care providers, having to obtain authorization would be time consuming and costly, and that such a requirement would lead to a decrease in charitable giving. The commenters also urged that fundraising be included within the definition of health care operations. Numerous commenters suggested that they did not need unfettered access to patient information in order to carry out their fundraising campaigns. They stated that a limited data set restricted to name, address, and telephone number would be sufficient to meet their needs. Several commenters suggested that we create a voluntary opt-out provision so people can avoid solicitations.

Response: We agree with commenters that our proposal could have adversely effected charitable giving, and accordingly make several modifications to the proposal. First, the final rule allows a covered entity to use or disclose to a business associate protected health information without authorization to identify individuals for fundraising for its own benefit. Permissible fundraising activities include appeals for money, sponsorship of events, etc. They do not include royalties or remittances for the sale of products of third parties (except auctions, rummage sales, etc).

Second, the final rule allows a covered entity to disclose protected health information without authorization to an institutionally related foundation that has as its mission to benefit the covered entity. This special provision is necessary to accommodate tax code provisions which may not allow such foundations to be business associates of their associated covered entity.

We also agree that broad access to protected health information is unnecessary for fundraising and unnecessarily intrudes on individual privacy. The final rule limits protected health information to be used or disclosed for fundraising to demographic information and the date that treatment occurred. Demographic information is not defined in the rule, but will generally include in this context name, address and other contact information, age, gender, and insurance status. The term does not include any information about the illness or treatment.

We also agree that a voluntary opt-out is an appropriate protection, and require in § 164.520 that covered entities provide information on their fundraising activities in their "Notice of Information Practices." As part of the notice and in any fundraising materials, covered entities must provide information explaining how individuals may opt out of fundraising communications.

Comment: Some commenters stated that use and disclosure of protected health information for fundraising, without authorization should be limited to not-for-profit entities. They suggested that not-for-profit entities were in greater need of charitable contributions and as such, they should be exempt from the authorization requirement while for-profit organizations should have to comply with the requirement.

Response: We do not agree that the profit status of a covered entity should determine its allowable use of protected health information for fundraising. Many for-profit entities provide the same services and have similar missions to not-for-profit entities. Therefore, the final rule does not make this distinction.

Comment: Several commenters suggested that the final rule should allow the internal use of protected health information for fundraising, without authorization, but not disclosure for fundraising. These commenters suggested that by limiting access of protected health information to only internal development offices concerns about misuse would be reduced.

Response: We do not agree. A number of commenters noted that they have related charitable foundations that raise funds for the covered entity, and we permit disclosures to such foundations to ensure that this rule does not interfere with charitable giving.

Comment: Several commenters asked us to address the content of fundraising letters. They pointed out that disease or condition-specific letters requesting contributions, if opened by the wrong person, could reveal personal information about the intended recipient.

Response: We agree that such communications raise privacy concerns. In the final rule, we limit the information that can be used or disclosed for fundraising, and exclude information about diagnosis, nature of services, or treatment.

Section 164.514(g)—Verification

Comment: A few commenters suggested that verification guidelines may need to be different as they apply to emergency clinical situations as opposed to routine data collection where delays do not threaten health.

Response: We agree, and make special provisions in §§ 164.510 and 164.512 for disclosures of protected health information by a covered entity without authorization where the individual is unable to agree or object to disclosure due to incapacity or other emergency circumstance.

For example, a health care provider may need to make disclosures to family members, close personal friends, and others involved in the individual's care in emergency situations. Similarly, a health care provider may need to respond to a request from a hospital seeking protected health information in ***82719** a circumstance described as an emergency. In each case, we require only that the covered entity exercise professional judgment, in the best interest of the patient, in deciding whether to make a disclosure. Based on the comments and our fact finding, this reflects current practice.

Comment: A few commenters stated the rules should include provisions for electronic verification of identity (such as Public Key Infrastructure (PKI)) as established in the regulations on Security and Electronic Signatures. One commenter suggested that some kind of PKI credentialing certificate should be required.

Response: This regulation does not address specific technical protocols utilized to meet the verification requirements. If the requirements of the rule are otherwise met, the mechanism for meeting them can be determined by the covered entity.

Comment: A few commenters wanted more clarification on the verification procedures. One commenter wanted to know if contract number is enough for verification. A few commenters wanted to know if a callback or authorization on a letterhead is acceptable. A few commenters wanted to know if plans are considered to “routinely do business” with all of their members.

Response: In the final rule, we modify the proposed provision and require covered entities to have policies and procedures reasonably designed to verify the identify and authority of persons requesting protected health information. Whether knowledge of a contract number is reasonable evidence of authority and identity will depend on the circumstances. Call-backs and letterhead are typically used today for verification, and are acceptable under this rule if reasonable under the circumstances. For communications with health plan members, the covered entity will already have information about each individual, collected

during enrollment, that can be used to establish identity, especially for verbal or electronic inquiries. For example, today many health plans ask for the social security or policy number of individuals seeking information or assistance by telephone. How this verification is done is left up to the covered entity.

Comment: One commenter expressed the need for consistency on verification requirements between this rule and the Security regulation.

Response: We will make every effort to ensure consistency prior to publishing the final Security Rule.

Comment: One commenter stated that the verification language in proposed § 164.518(c)(2)(ii)(B)(1) would have created a presumption that "a request for disclosure made by official legal process issued by a[n] administrative body" is reasonable legal authority to disclose the protected health information. The commenter was concerned that this provision could be interpreted to permit a state agency to demand the disclosure of protected health information merely on the basis of a letter signed by an agency representative. The commenter believed that the rule specifically should defer to state or federal law on the disclosure of protected health information pursuant to legal process.

Response: The verification provisions in this rule are minimum requirements that covered entities must meet before disclosing protected health information under this regulation. They do not mandate disclosure, nor do they preempt state laws which impose additional restrictions on disclosure. Where state law regarding disclosures is more stringent, the covered entity must adhere to state law.

Comment: A few commenters wanted the verification requirements to apply to disclosures of protected health information for treatment, payment and operations purposes.

Response: We agree. This verification requirement applies to all disclosures of protected health information permitted by this rule, including for treatment, payment and operations, where the identity of the recipient is not known to the covered entity. Routine communications between providers, where existing relationships have been established, do not require special verification procedures.

Comment: A few commenters were concerned that a verbal inquiry for next of kin verification is not consistent with the verification guidelines of this verification subsection and that verbal inquiry would create problems because anyone who purports to be a next of kin could easily obtain information under false pretenses.

Response: In the final rule in § 164.514, we require the covered entity to verify the identity and authority of persons requesting protected health information, where the identity and authority of such person is not known to the covered entity. This applies to next of kin situations. Procedures for disclosures to next of kin, other family members and persons assisting in an individual's care are also discussed in § 164.510(b), which allows the covered entity to exercise professional judgment as to whether the disclosure is in the individual's best interest when the individual is not available to agree to the disclosure or is incapacitated. Requiring written proof of identity in many of these situations, such as when a family member is seeking to locate a relative in an emergency or disaster situation, would create enormous burden without a corresponding enhancement of privacy, and could cause unnecessary delays in these situations. We therefore believe that reliance on professional judgment provides a better framework for balancing the need for privacy with the need to locate and identify individuals.

Comment: A few commenters stated that the verification requirements will provide great uncertainty to providers who receive authorizations from life, disability income and long-term care insurers in the course of underwriting and claims investigation. They are unaware of any breaches of confidentiality associated with these circumstances and believe the rule creates a solution to a non-existent problem. Another commenter stated that it is too burdensome for health care providers to verify requests that are normally received verbally or via fax.

Response: This rule requires covered health care providers to adhere to current best practices for verification. That is, when the requester is not known to the covered provider, the provider makes a reasonable effort to determine that the protected health information is being sent to the entity authorized to receive it. Our fact finding reveals that this is often done by sending the information to a recognizable organizational address or if being transmitted by fax or phone by calling the requester back through the main organization switchboard rather than through a direct phone number. We agree that these procedures seem to work reasonably well in current practice and are sufficient to meet the relevant requirements in the final rule.

Comments: One comment suggested requiring a form of photo identification such as a driver's license or certain personal information such as date of birth to verify the identity of the individual.

Response: These are exactly the types of standard procedures for verifying the identity of individuals that are envisioned by the final rule. Most health care entities already conduct such procedures successfully. However, it is unwise to prescribe specific means of verification for all situations. Instead, we require policies and procedures reasonably designed for purposes of verification.

Comment: One professional association said that the example procedure described in the NPRM for asking questions to verify that an adult ***82720** acting for a young child had the requisite relationship to the child would be quite complex and difficult in practice. The comment asked for specific guidance as to what questions would constitute an adequate attempt to verify such a relationship.

Response: The final rule requires the covered entity to implement policies and procedures that are reasonably designed to comply with the verification requirement in § 164.514. It would not be possible to create the requested specific guidance which could deal with the infinite variety of situations that providers must face, especially the complex ones such as that described by the commenter. As with many of the requirements of this final rule, health care providers are given latitude and expected to make decisions regarding disclosures, based on their professional judgment and experience with common practice, in the best interest of the individual.

Comment: One commenter asserted that ascertaining whether a requestor has the appropriate legal authority is beyond the scope of the training or expertise of most employees in a physician's office. They believe that health care providers must be able to reasonably rely on the authority of the requestor.

Response: In the final regulation we require covered entities to have policies and procedures reasonably designed to verify the identify and authority of persons requesting health information. Where the requester is a public official and legal authority is at issue, we provide detailed descriptions of the acceptable methods for such verification in the final rule. For others, the covered entity must implement policies and procedures that are reasonably designed to comply with the requirement to verify the identity and authority of a requestor, but only if the requestor is unknown to the covered entity. As described above, we expect these policies and procedures to document currently used best practices and reliance on professional judgment in the best interest of the individual.

Comment: One commenter expressed concern that the verification/identification procedures may eliminate or significantly reduce their ability to utilize medical records copy services. As written, they believe the NPRM provides the latitude to set up copy service arrangements, but any change that would add restrictions would adversely affect their ability to process an individual's disability claim.

Response: The covered entity can establish reasonable policies and procedures to address verification in routine disclosures under business associate agreements, with, for example, medical records copy services. Nothing in the verification provisions would preclude those activities, nor have we significantly modified the NPRM provision on this issue.

Section 164.520—Notice of Privacy Practices for Protected Health Information

Comment: Many commenters supported the proposal to require covered entities to produce a notice of information practices. They stated that such notice would improve individuals' understanding of how their information may be used and disclosed and would help to build trust between individuals and covered entities. A few comments, however, argued that the notice requirement would be administratively burdensome and expensive without providing significant benefit to individuals.

Response: We retain the requirement for covered health care providers and health plans to produce a notice of information practices. We additionally require health care clearinghouses that create or receive protected health information other than as a business associate of another covered entity to produce a notice. We believe the notice will provide individuals with a clearer understanding of how their information may be used and disclosed and is essential to inform individuals of their privacy rights. The notice will focus individuals on privacy issues, and prompt individuals to have discussions about privacy issues with their health plans, health care providers, and other persons.

The importance of providing individuals with notice of the uses and disclosures of their information and of their rights with respect to that information is well supported by industry groups, and is recognized in current state and federal law. The July 1977 Report of the Privacy Protection Study Commission recommended that "each medical-care provider be required to notify an individual on whom it maintains a medical record of the disclosures that may be made of information in the record without the individual's express authorization."[FN23] The Commission also recommended that "an insurance institution * * * notify (an applicant or principal insured) as to: * * * the types of parties to whom and circumstances under which information about the individual may be disclosed without his authorization, and the types of information that may be disclosed; [and] * * * the procedures whereby the individual may correct, amend, delete, or dispute any resulting record about himself."[FN24] The Privacy Act (5 U.S.C. 552a) requires government agencies to provide notice of the routine uses of information the agency collects and the rights individuals have with respect to that information. In its report "Best Principles for Health Privacy," the Health Privacy Working Group stated, "Individuals should be given notice about the use and disclosure of their health information and their rights with regard to that information."[FN25] The National Association of Insurance Commissioners' Health Information Privacy Model Act requires carriers to provide a written notice of health information policies, standards, and procedures, including a description of the uses and disclosures prohibited and permitted by the Act, the procedures for authorizing and limiting disclosures and for revoking authorizations, and the procedures for accessing and amending protected health information.

Some states require additional notice. For example, Hawaii requires health care providers and health plans, among others, to produce a notice of confidentiality practices, including a description of the individual's privacy rights and a description of the uses and disclosures of protected health information permitted under state law without the individual's authorization. (HRS section 323C-13)

Today, health plan hand books and evidences of coverage include some of what is required to be in the notice. Industry and standard-setting organizations have also developed notice requirements. The National Committee for Quality Assurance accreditation guidelines state that an accredited managed care organization "communicates to prospective members its policies and practices regarding the collection, use, and disclosure of medical information [and] * * * informs members * * * of its policies and procedures on * * * allowing members access to their medical records."[FN26] Standards of the American Society for Testing and Materials state, ***82721** "Organizations and individuals who collect, process, handle, or maintain health information should provide individuals and the public with a notice of information practices." They recommend that the notice include, among other elements, "a description of the rights of individuals, including the right to inspect and copy information and the right to seek amendments [and] a description of the types of uses and disclosures that are permitted or required by law without the individual's authorization."[FN27] We build on this well-established principle in this final rule.

Comment: We received many comments on the model notice provided in the proposed rule. Some commenters argued that patients seeing similar documents would be less likely to become disoriented when examining a new notice. Other commenters, however, opposed the inclusion of a model notice or expressed concern about particular language included in the model. They maintained that a uniform model notice would never capture the varying practices of covered entities. Many commenters

opposed requirements for a particular format or specific language in the notice. They stated that covered entities should be afforded maximum flexibility in fashioning their notices. Other commenters requested inclusion of specific language as a header to indicate the importance of the notice. A few commenters recommended specific formatting requirements, such as font size or type.

Response: On the whole, we found commenters' arguments for flexibility in the regulation more persuasive than those arguing for more standardization. We agree that a uniform notice would not capture the wide variation in information practices across covered entities. We therefore do not include a model notice in the final rule, and do not require inclusion of specific language in the notice (except for a standard header). We also do not require particular formatting. We do, however, require the notice to be written in plain language. (See above for guidance on writing documents in plain language.) We also agree with commenters that the notice should contain a standard header to draw the individual's attention to the notice and facilitate the individual's ability to recognize the notice across covered entities.

We believe that post-publication guidance will be a more effective mechanism for helping covered entities design their notices than the regulation itself. After the rule is published, we can provide guidance on notice content and format tailored to different types of health plans and providers. We believe such specially designed guidance will be more useful than a one-size-fits-all model notice we might publish with this regulation.

Comment: Commenters suggested that the rule should require that the notice regarding privacy practices include specific provisions related to health information of unemancipated minors.

Response: Although we agree that minors and their parents should be made aware of practices related to confidentiality of protected health information of unemancipated minors, we do not require covered entities that treat minors or use their protected health information to include provisions in their notice that are not required of other covered entities. In general, the content of notice requirements in § 164.520(b) do not vary based on the status of the individual being served. We have decided to maintain consistency by declining to prescribe specific notice requirements for minors. The rule does permit a covered entity to provide individuals with notice of its policies and procedures with respect to anticipated uses and disclosures of protected health information (§ 164.520(b)(2)), and providers are encouraged to do so.

Comment: Some commenters argued that covered entities should not be required to distinguish between those uses and disclosures that are required by law and those that are permitted by law without authorization, because these distinctions may not always be clear and will vary across jurisdictions. Some commenters maintained that simply stating that the covered entity would make all disclosures required by law would be sufficient. Other comments suggested that covered entities should be able to produce very broadly stated notices so that repeated revisions and mailings of those revisions would not be necessary.

Response: While we believe that covered entities have an independent duty to understand the laws to which they are subject, we also recognize that it could be difficult to convey such legal distinctions clearly and concisely in a notice. We therefore eliminate the proposed requirement for covered entities to distinguish between those uses and disclosures that are required by and those that are permitted by law. We instead require that covered entities describe each purpose for which they are permitted or required to use or disclose protected health information under this rule and other applicable law without individual consent or authorization. Specifically, covered entities must describe the types of uses and disclosures they are permitted to make for treatment, payment, and health care operations. They must also describe each of the purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written consent or authorization (even if they do not plan to make a permissive use or disclosure). We believe this requirement provides individuals with sufficient information to understand how information about them can be used and disclosed and to prompt them to ask for additional information to obtain a clearer understanding, while minimizing covered entities' burden.

A notice that stated only that the covered entity would make all disclosures required by law, as suggested by some of these commenters, would fail to inform individuals of the uses and disclosures of information about them that are permitted, but not

required, by law. We clarify that each and every disclosure required by law need not be listed on the notice. Rather, the covered entity can include a general statement that disclosures required by law will be made.

Comment: Some comments argued that the covered entity should not have to provide notice about uses and disclosures that are permitted under the rule without authorization. Other comments suggested that the notice should inform individuals about all of the uses and disclosures that may be made, with or without the individual's authorization.

Response: When the individual's permission is not required for uses and disclosures of information, we believe providing the required notice is the most effective means of ensuring that individuals are aware of how information about them may be shared. The notice need not describe uses and disclosures for which the individual's permission is required, because the individual will be informed of these at the time permission to use or disclose the information is requested.

We additionally require covered entities, even those required to obtain the individual's consent for use and disclosure of protected health information for treatment, payment, and health care operations, to describe those uses and disclosures in their notice. (See § 164.506 and the corresponding preamble discussion regarding consent requirements.) We require these uses ***82722** and disclosures to be described in the notice in part in order to reduce the administrative burden on covered providers that are required to obtain consent. Rather than obtaining a new consent each time the covered provider's information policies and procedures are materially revised, covered providers may revise and redistribute their notice. We also expect that the description of how information may be used to carry out treatment, payment, and health care operations in the notice will be more detailed than in the more general consent document.

Comment: Some commenters argued that covered entities should not be required to provide notice of the right to request restrictions, because doing so would be burdensome to the covered entity and distracting to the individual; because individuals have the right whether they are informed of such right or not; and because the requirement would be unlikely to improve patient care.

Response: We disagree. We believe that the ability of an individual to request restrictions is an important privacy right and that informing people of their rights improves their ability to exercise those rights. We do not believe that adding a sentence to the notice is burdensome to covered entities.

Comment: We received comments supporting inclusion of a contact point in the notice, so that individuals will not be forced to make multiple calls to find someone who can assist them with the issues in the notice.

Response: We retain the requirement, but clarify that the title of the contact person is sufficient. A person's name is not required.

Comment: Some commenters argued that we could facilitate compliance by requiring the notice to include the proposed requirement that covered entities use and disclose only the minimum necessary protected health information.

Response: We do not agree that adding such a requirement would strengthen the notice. The purpose of the notice is to inform individuals of their privacy rights, and of the purposes for which protected health information about them may be used or disclosed. Informing individuals that covered entities may use and disclose only the minimum necessary protected health information for a purpose would not increase individuals' understanding of their rights or the purposes for which information may be used or disclosed.

Comment: A few commenters supported allowing covered entities to apply changes in their information practices to protected health information obtained prior to the change. They argued that requiring different protections for information obtained at different times would be inefficient and extremely difficult to administer. Some comments supported requiring covered entities to state in the notice that the information policies and procedures are subject to change.

Response: We agree. In the final rule, we provide a mechanism by which covered entities may revise their privacy practices and apply those revisions to protected health information they already maintain. We permit, but do not require, covered entities to reserve the right to change their practices and apply the revised practices to information previously created or obtained. If a covered entity wishes to reserve this right, it must make a statement to that effect in its notice. If it does not make such a statement, the covered entity may still revise its privacy practices, but it may apply the revised practices only to protected health information created or obtained after the effective date of the notice in which the revised practices are reflected. See § 164.530(i) and the corresponding preamble discussion of requirements regarding changes to information policies and procedures.

Comment: Some commenters requested clarification of the term "material changes" so that entities will be comfortable that they act properly after making changes to their information practices. Some comments stated that entities should notify individuals whenever a new category of disclosures to be made without authorization is created.

Response: The concept of "material change" appears in other notice laws, such as the ERISA requirements for summary plan descriptions. We therefore retain the "materiality" condition for revision of notices, and encourage covered entities to draw on the concept as it has developed through those other laws. We agree that the addition of a new category of use or disclosure of health information that may be made without authorization would likely qualify as a material change.

Comment: We proposed to permit covered entities to implement revised policies and procedures without first revising the notice if a compelling reason existed to do so. Some commenters objected to this proposal because they were concerned that the "compelling reason" exception would give covered entities broad discretion to engage in post hoc violations of its own information practices.

Response: We agree and eliminate this provision. Covered entities may not implement revised information policies and procedures before properly documenting the revisions and updating their notice. See § 164.530(i). Because in the final rule we require the notice to include all disclosures that may be made, not only those the covered entity intends to make, we no longer need this provision to accommodate emergencies.

Comment: Some comments suggested that we require covered entities to maintain a log of all past notices, with changes from the previous notice highlighted. They further suggested we require covered entities to post this log on their web sites.

Response: In accordance with § 164.530(j)(2), a covered entity must retain for six years a copy of each notice it issues. We do not require highlighting of changes to the notice or posting of prior notices, due to the associated administrative burdens and the complexity such a requirement would build into the notice over time. We encourage covered entities, however, to make such materials available upon request.

Comment: Several commenters requested clarification about when, relative to the compliance date, covered entities are required to produce their notice. One commenter suggested that covered entities be allowed a period not less than 180 days after adoption of the final rule to develop and distribute the notice. Other comments requested that the notice compliance date be consistent with other HIPAA regulations.

Response: We require covered entities to have a notice available upon request as of the compliance date of this rule (or the compliance date of the covered entity if such date is later). See § 164.534 and the corresponding preamble discussion of the compliance date.

Comment: Some commenters suggested that covered entities, particularly covered health care providers, should be required to discuss the notice with individuals. They argued that posting a notice or otherwise providing the notice in writing may not achieve the goal of informing individuals of how their information will be handled, because some individuals may not be literate or able to function at the reading level used in the notice. Others argued that entities should have the flexibility to choose alternative modes of communicating the information in the notice, including voice disclosure. In contrast, some commenters

were concerned that requirements to provide the notice in plain language or in languages other than English would be overly burdensome. ***82723**

Response: We require covered entities to write the notice in plain language so that the average reader will be able to understand the notice. We encourage, but do not require, covered entities to consider alternative means of communicating with certain populations. We note that any covered entity that is a recipient of federal financial assistance is generally obligated under Title VI of the Civil Rights Act of 1964 to provide material ordinarily distributed to the public in the primary languages of persons with limited English proficiency in the recipients' service areas. While we believe the notice will prompt individuals to initiate discussions with their health plans and health care providers about the use and disclosure of health information, we believe this should be a matter left to each individual and that requiring covered entities to initiate discussions with each individual would be overly burdensome.

Comment: Some commenters suggested that covered entities, particularly health plans, should be permitted to distribute their notice in a newsletter or other communication with individuals.

Response: We agree, so long as the notice is sufficiently separate from other important documents. We therefore prohibit covered entities from combining the notice in a single document with either a consent (§ 164.506) or an authorization (§ 164.508), but do not otherwise prohibit covered entities from including the notice in or with other documents the covered entity shares with individuals.

Comment: Some comments suggested that covered entities should not be required to respond to requests for the notice from the general public. These comments indicated that the requirement would place an undue burden on covered entities without benefitting individuals.

Response: We proposed that the notice be publicly available so that individuals may use the notice to compare covered entities' privacy practices and to select a health plan or health care provider accordingly. We therefore retain the proposed requirement for covered entities to provide the notice to any person who requests a copy, including members of the general public.

Comment: Many commenters argued that the distribution requirements for health plans should be less burdensome. Some suggested requiring distribution upon material revision, but not every three years. Some suggested that health plans should only be required to distribute their notice annually or upon re-enrollment. Some suggested that health plans should only have to distribute their notice upon initial enrollment, not re-enrollment. Other commenters supported the proposed approach.

Response: We agree that the notice distribution requirements for health plans can be less burdensome than in the NPRM while still being effective. In the final rule, we reduce health plans' distribution burden in several ways. First, we require health plans to remind individuals every three years of the availability of the notice and of how to obtain a copy of the notice, rather than requiring the notice to be distributed every three years as proposed. Second, we clarify that health plans only have to distribute the notice to new enrollees on enrollment, not to current members of the health plan upon re-enrollment. Third, we specifically allow all covered entities to distribute the notice electronically in accordance with § 164.520(c)(3).

We retain the requirement for health plans to distribute the notice within 60 days of a material revision. We believe the revised distribution requirements will ensure that individuals are adequately informed of health plans' information practices and any changes to those procedures, without unduly burdening health plans.

Comment: Many commenters argued that health plans should not be required to distribute their notice to every person covered by the plan. They argued that distributing the notice to every family member would be unnecessarily duplicative, costly, and difficult to administer. They suggested that health plans only be required to distribute the notice to the primary participant or to each household with one or more insured individuals.

Response: We agree, and clarify in the final rule that a health plan may satisfy the distribution requirement by providing the notice to the named insured on behalf of the dependents of that named insured. For example, a group health plan may satisfy its notice requirement by providing a single notice to each covered employee of the plan sponsor. We do not require the group health plan to distribute the notice to each covered employee and to each covered dependent of those employees.

Comment: Many comments requested clarification about health plans' ability to distribute the notice via other entities. Some commenters suggested that group health plans should be able to satisfy the distribution requirement by providing copies of the notice to plan sponsors for delivery to employees. Others requested clarification that covered health care providers are only required to distribute their own notice and that health plans should be prohibited from using their affiliated providers to distribute the health plan's notice.

Response: We require health plans to distribute their notice to individuals covered by the health plan. Health plans may elect to hire or otherwise arrange for others, including group health plan sponsors and health care providers affiliated with the health plan, to carry out this distribution. We require covered providers to distribute only their own notices, and neither require nor prohibit health plans and health care providers from devising whatever arrangements they find suitable to meet the requirements of this rule. However, if a covered entity arranges for another person or entity to distribute the covered entity's notice on its behalf and individuals do not receive such notice, the covered entity would be in violation of the rule.

Comment: Some comments stated that covered providers without direct patient contact, such as clinical laboratories, might not have sufficient patient contact information to be able to mail the notice. They suggested we require or allow such providers to form agreements with referring providers or other entities to distribute notices on their behalf or to include their practices in the referring entity's own notice.

Response: We agree with commenters' concerns about the potential administrative and financial burdens of requiring covered providers that have indirect treatment relationships with individuals, such as clinical laboratories, to distribute the notice. Therefore, we require these covered providers to provide the notice only upon request. In addition, these covered providers may elect to reach agreements with other entities distribute their notice on their behalf, or to participate in an organized health care arrangement that produces a joint notice. See § 164.520(d) and the corresponding preamble discussion of joint notice requirements.

Comment: Some commenters requested that covered health care providers be permitted to distribute their notice prior to an individual's initial visit so that patients could review the information in advance of the visit. They suggested that distribution in advance would reduce the amount of time covered health care providers' staff would have to spend explaining the notice to patients in the office. Other comments argued that providers should ***82724** distribute their notice to patients at the time the individual visits the provider, because providers lack the administrative infrastructure necessary to develop and distribute mass communications and generally have difficulty identifying active patients.

Response: In the final rule, we clarify that covered providers with direct treatment relationships must provide the notice to patients no later than the first service delivery to the patient after the compliance date. For the reasons identified by these commenters, we do not require covered providers to send their notice to the patient in advance of the patient's visit. We do not prohibit distribution in advance, but only require distribution to the patient as of the time of the visit. We believe this flexibility will allow each covered provider to develop procedures that best meet its and its patients' needs.

Comment: Some comments suggested that covered providers should be required to distribute the notice as of the compliance date. They noted that if the covered provider waited to distribute the notice until first service delivery, it would be possible (pursuant to the rule) for a use or disclosure to be made without the individual's authorization, but before the individual receives the notice.

Response: Because health care providers generally lack the administrative infrastructure necessary to develop and distribute mass communications and generally have difficulty identifying active patients, we do not require covered providers to distribute the notice until the first service delivery after the compliance date. We acknowledge that this policy allows uses and disclosure of health information without individuals' consent or authorization before the individual receives the notice. We require covered entities, including covered providers, to have the notice available upon request as of the compliance date of the rule. Individuals may request a copy of the notice from their provider at any time.

Comment: Many commenters were concerned with the requirement that covered providers post their notice. Some commenters suggested that covered hospital-based providers should be able to satisfy the distribution requirements by posting their notice in multiple locations at the hospital, rather than handing the notice to patients—particularly with respect to distribution after material revisions have been made. Some additionally suggested that these covered providers should have copies of the notice available on site. Some commenters emphasized that the notice must be clear and conspicuous to give individuals meaningful and effective notice of their rights. Other commenters noted that posting the notice will not inform former patients who no longer see the provider.

Response: We clarify in the final rule that the requirement to post a notice does not substitute for the requirement to give individuals a notice or make notices available upon request. Covered providers with direct treatment relationships, including covered hospitals, must give a copy of the notice to the individual as of first service delivery after the compliance date. After giving the individual a copy of the notice as of that first visit, the covered provider has no other obligation to actively distribute the notice. We believe it is unnecessarily burdensome to require covered providers to mail the notice to all current and former patients each time the notice is revised, because unlike health plans, providers may have a difficult time identifying active patients. All individuals, including those who no longer see the covered provider, have the right to receive a copy of the notice on request.

If the covered provider maintains a physical delivery site, it must also post the notice (including revisions to the notice) in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered provider to be able to read the notice. The covered provider must also have the notice available on site for individuals to be able to request and take with them.

Comment: Some comments requested clarification about the distribution requirements for a covered entity that is a health plan and a covered health care provider.

Response: Under § 164.504(g), discussed above, covered entities that conduct multiple types of covered functions, such as the kind of entities described in the above comments, are required to comply with the provisions applicable to a particular type of health care function when acting in that capacity. Thus, in the example described above, the covered entity is required by § 164.504(g) to follow the requirements for health plans with respect to its actions as a health plan and to follow the requirements for health care providers with respect to its actions as a health care provider.

Comment: We received many comments about the ability of covered entities to distribute their notices electronically. Many commenters suggested that we permit covered entities to distribute the notice electronically, either via a web site or e-mail. They argued that covered entities are increasingly using electronic technology to communicate with patients and otherwise administer benefits. They also noted that other regulations permit similar documents, such as ERISA-required summary plan descriptions, to be delivered electronically. Some commenters suggested that electronic distribution should be permitted unless the individual specifically requests a hard copy or lacks electronic access. Some argued that entities should be able to choose a least-cost alternative that allows for periodic changes without excessive mailing costs. A few commenters suggested requiring covered entities to distribute notices electronically.

Response: We clarify in the final rule that covered entities may elect to distribute their notice electronically, provided the individual agrees to receiving the notice electronically and has not withdrawn such agreement. We do not require any particular

form of agreement. For example, a covered provider could ask an individual at the time the individual requests a copy of the notice whether she prefers to receive it in hard copy or electronic form. A health plan could ask an individual applying for coverage to provide an e-mail address where the health plan can send the individual information. If the individual provides an e-mail address, the health plan can infer agreement to obtain information electronically.

An individual who has agreed to receive the notice electronically, however, retains the right to request a hard copy of the notice. This right must be described in the notice. In addition, if the covered entity knows that electronic transmission of the notice has failed, the covered entity must produce a hard copy of the notice. We believe this provision allows covered entities flexibility to provide the notice in the form that best meets their needs without compromising individuals' right to adequate notice of covered entities' information practices.

We note that covered entities may also be subject to the Electronic Signatures in Global and National Commerce Act. This rule is not intended to alter covered entities' requirements under that Act.

Comment: Some commenters were concerned that covered providers with “face-to-face” patient contact would have a competitive disadvantage against covered internet-based providers, because the face-to-face providers would be required to distribute the notice in hard copy while internet-based providers could satisfy the requirement ***82725** by requiring review of the notice on the web site before processing an order. They suggested allowing face-to-face covered providers to satisfy the distribution requirement by asking patients to review the notice posted on site.

Response: We clarify in the final rule that covered health care providers that provide services to individuals over the internet have direct treatment relationships with those individuals. Covered internet-based providers, therefore, must distribute the notice at the first service delivery after the compliance date by automatically and contemporaneously providing the notice electronically in response to the individual's first request for service, provided the individual agrees to receiving the notice electronically.

Even though we require all covered entity web sites to post the entity's notice prominently, we note that such posting is not sufficient to meet the distribution requirements. A covered internet-based provider must send the notice electronically at the individual's first request for service, just as other covered providers with direct treatment relationships must give individuals a copy of the notice as of the first service delivery after the compliance date.

We do not intend to create competitive advantages among covered providers. A web-based and a non-web-based covered provider each have the same alternatives available for distribution of the notice. Both types of covered providers may provide either a paper copy or an electronic copy of the notice.

Comment: We received several comments suggesting that some covered entities should be exempted from the notice requirement or permitted to combine notices with other covered entities. Many comments argued that the notice requirement would be burdensome for hospital-based physicians and result in numerous, duplicative notices that would be meaningless or confusing to patients. Other comments suggested that multiple health plans offered through the same employer should be permitted to produce a single notice.

Response: We retain the requirement for all covered health care providers and health plans to produce a notice of information practices. Health care clearinghouses are required to produce a notice of information practices only to the extent the clearinghouse creates or receives protected health information other than as a business associate of a covered entity. See § 164.500(b)(2). Two other types of covered entities are not required to produce a notice: a correctional institution that is a covered entity and a group health plan that provides benefits only through one or more contracts of insurance with health insurance issuers or HMOs.

We clarify in § 164.504(d), however, that affiliated covered entities under common ownership or control may designate themselves as a single covered entity for purposes of this rule. An affiliated covered entity is only required to produce a single notice.

In addition, covered entities that participate in an organized health care arrangement—which could include hospitals and their associated physicians—may choose to produce a single, joint notice, if certain requirements are met. See § 164.501 and the corresponding preamble discussion of organized health care arrangements.

We clarify that each covered entity included in a joint notice must meet the applicable distribution requirements. If any one of the covered entities, however, provides the notice to a given individual, the distribution requirement with respect to that individual is met for all of the covered entities included in the joint notice. For example, a covered hospital and its attending physicians may elect to produce a joint notice. When an individual is first seen at the hospital, the hospital must provide the individual with a copy of the joint notice. Once the hospital has done so, the notice distribution requirement for all of the attending physicians that provide treatment to the individual at the hospital and that are included in the joint notice is satisfied.

Comment: We solicited and received comments on whether to require covered entities to obtain the individual's signature on the notice. Some commenters suggested that requiring a signature would convey the importance of the notice, would make it more likely that individuals read the notice, and could have some of the same benefits of a consent. They noted that at least one state already requires entities to make a reasonable effort to obtain a signed notice. Other comments noted that the signature would be useful for compliance and risk management purposes because it would document that the individual had received the notice.

The majority of commenters on this topic, however, argued that a signed acknowledgment would be administratively burdensome, inconsistent with the intent of the Administrative Simplification requirements of HIPAA, impossible to achieve for incapacitated individuals, difficult to achieve for covered entities that do not have direct contact with patients, inconsistent with other notice requirements under other laws, misleading to individuals who might interpret their signature as an agreement, inimical to the concept of permitting uses and disclosures without authorization, and an insufficient substitute for authorization.

Response: We agree with the majority of commenters and do not require covered entities to obtain the individual's signed acknowledgment of receipt of the notice. We believe that we satisfied most of the arguments in support of requiring a signature with the new policy requiring covered health care providers with direct treatment relationships to obtain a consent for uses and disclosures of protected health information to carry out treatment, payment, and health care operations. See § 164.506 and the corresponding preamble discussion of consent requirements. We note that this rule does not preempt other applicable laws that require a signed notice and does not prohibit a covered entity from requesting an individual to sign the notice.

Comment: Some commenters supported requiring covered entities to adhere to their privacy practices, as described in their notice. They argued that the notice is meaningless if a covered entity does not actually have to follow the practices contained in its notice. Other commenters were concerned that the rule would prevent a covered entity from using or disclosing protected health information in otherwise lawful and legitimate ways because of an intentional or inadvertent omission from its published notice. Some of these commenters suggested requiring the notice to include a description of some or all disclosures that are required or permitted by law. Some commenters stated that the adherence requirement should be eliminated because it would generally inhibit covered entities' ability to innovate and would be burdensome.

Response: We agree that the value of the notice would be significantly diminished absent a requirement that covered entities adhere to the statements they make in their notices. We therefore retain the requirement for covered entities to adhere to the terms of the notice. See § 164.502(i).

Many of these commenters' concerns regarding a covered entity's inability to use or disclose protected health information due to an intentional or inadvertent omission from the notice are addressed in our revisions to the proposed content requirements for the notice. Rather than require covered entities to describe only those uses and ***82726** disclosures they anticipate making,

as proposed, we require covered entities to describe all uses and disclosures they are required or permitted to make under the rule without the individual's consent or authorization. We permit a covered entity to provide a statement that it will disclose protected health information that is otherwise required by law, as permitted in § 164.512(a), without requiring them to list all state laws that may require disclosure. Because the notice must describe all legally permissible uses and disclosures, the notice will not generally preclude covered entities from making any uses or disclosures they could otherwise make without individual consent or authorization. This change will also ensure that individuals are aware of all possible uses and disclosures that may occur without their consent or authorization, regardless of the covered entity's current practices.

We encourage covered entities, however, to additionally describe the more limited uses and disclosures they actually anticipate making in order to give individuals a more accurate understanding of how information about them will be shared. We expect that certain covered entities will want to distinguish themselves on the basis of their privacy protections. We note that a covered entity that chooses to exercise this option must clearly state that, at a minimum, the covered entity may make disclosures that are required by law and that are necessary to avert a serious and imminent threat to health or safety.

Section 164.522—Rights To Request Privacy Protection for Protected Health Information

Section 164.522(a)—Right of an Individual To Request Restriction of Uses and Disclosures

Comment: Several commenters supported the language in the NPRM regarding the right to request restrictions. One commenter specifically stated that this is a balanced approach that addresses the needs of the few who would have reason to restrict disclosures without negatively affecting the majority of individuals. At least one commenter explained that if we required consent or authorization for use and disclosure of protected health information for treatment, payment, and health care operations then we must also have a right to request restrictions of such disclosure in order to make the consent meaningful.

Many commenters requested that we delete this provision, claiming it would interfere with patient care, payment, and data integrity. Most of the commenters that presented this position asserted that the framework of giving patients control over the use or disclosure of their information is contrary to good patient care because incomplete medical records may lead to medical errors, misdiagnoses, or inappropriate treatment decisions. Other commenters asserted that covered entities need complete data sets on the populations they serve to effectively conduct research and quality improvement projects and that restrictions would hinder research, skew findings, impede quality improvement, and compromise accreditation and performance measurement.

Response: We acknowledge that widespread restrictions on the use and disclosure of protected health information could result in some difficulties related to payment, research, quality assurance, etc. However, in our efforts to protect the privacy of health information about individuals, we have sought a balance in determining the appropriate level of individual control and the smooth operation of the health care system. In the final rule, we require certain covered providers and permit all covered entities to obtain consent from individuals for use and disclosure of protected health information for treatment, payment, and health care operations (see § 164.506). In order to give individuals some control over their health information for uses and disclosures of protected health information for treatment, payment, and health care operations, we provide individuals with the opportunity to request restrictions of such uses and disclosures.

Because the right to request restrictions encourages discussions about how protected health information may be used and disclosed and about an individual's concerns about such uses and disclosures, it may improve communications between a provider and patient and thereby improve care. According to a 1999 survey on the Confidentiality of Medical Records by the California HealthCare Foundation, one out of every six people engage in behavior to protect themselves from unwanted disclosures of health information, such as lying to providers or avoiding seeking care. This indicates that, without the ability to request restrictions, individuals would have incentives to remain silent about important health information that could have an effect on their health and health care, rather than consulting a health care provider.

Further, this policy is not a dramatic change from the status quo. Today, many state laws restrict disclosures for certain types of health information without patient's authorization. Even if there is no mandated requirement to restrict disclosures of health

information, providers may agree to requests for restrictions of disclosures when a patient expresses particular sensitivity and concern for the disclosure of health information.

We agree that there may be instances in which a restriction could negatively affect patient care. Therefore, we include protections against this occurrence. First, the right to request restrictions is a right of individuals to make the request. A covered entity may refuse to restrict uses and disclosures or may agree only to certain aspects of the individual's request if there is concern for the quality of patient care in the future. For example, if a covered provider believes that it is not in the patient's best medical interest to have such a restriction, the provider may discuss the request for restriction with the patient and give the patient the opportunity to explain the concern for disclosure. Also, a covered provider who is concerned about the implications on future treatment can agree to use and disclose sensitive protected health information for treatment purposes only and agree not to disclose information for payment and operation purposes. Second, a covered provider need not comply with a restriction that has been agreed to if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment. This exception should limit the harm to health that may otherwise result from restricting the use or disclosure of protected health information. We encourage covered providers to discuss with individuals that the information may be used or disclosed in emergencies. We require that the covered entity that discloses restricted protected health information in an emergency request that the health care provider that receives such information not further use or re-disclose the information.

Comment: Some health plans stated that an institutionalized right to restrict can interfere with proper payment and can make it easier for unscrupulous providers or patients to commit fraud on insurance plans. They were concerned that individuals could enter into restrictions with providers to withhold information to insurance companies so that the insurance company would not know about certain conditions when underwriting a policy. ***82727**

Response: This rule does not enhance the ability of unscrupulous patients or health care providers to engage in deceptive or fraudulent withholding of information. This rule grants a right to request a restriction, not an absolute right to restrict. Individuals can make such requests today. Other laws criminalize insurance fraud; this regulation does not change those laws.

Comment: One commenter asserted that patients cannot anticipate the significance that one aspect of their medical information will have on treatment of other medical conditions, and therefore, allowing them to restrict use or disclosure of some information is contrary to the patient's best interest.

Response: We agree that patients may find it difficult to make such a calculus, and that it is incumbent on health care providers to help them do so. Health care providers may deny requests for or limit the scope of the restriction requested if they believe the restriction is not in the patient's best interest.

Comment: One commenter asked whether an individual's restriction to disclosure of information will be a bar to liability for misdiagnosis or failure to diagnose by a covered entity who can trace its error back to the lack of information resulting from such restriction.

Response: Decisions regarding liability and professional standards are determined by state and other law. This rule does not establish or limit liability for covered entities under those laws. We expect that the individual's request to restrict the disclosure of their protected health information would be considered in the decision of whether or not a covered entity is liable.

Comment: One commenter requested that we allow health plans to deny coverage or reimbursement when a covered health care provider's agreement to restrict use or disclosure prevents the plan from getting the information that is necessary to determine eligibility or coverage.

Response: In this rule, we do not modify insurers' rules regarding information necessary for payment. We recognize that restricting the disclosure of information may result in a denial of payment. We expect covered providers to explain this possibility

to individuals when considering their requests for restrictions and to make alternative payment arrangements with individuals if necessary.

Comment: Some commenters discussed the administrative burden and cost of the requirement that individuals have the right to request restrictions and that trying to segregate certain portions of information for protection may be impossible. Others stated that the administrative burden would make providers unable to accommodate restrictions, and would therefore give patients false expectations that their right to request restrictions may be acted upon. One commenter expressed concern that large covered providers would have a particularly difficult time establishing a policy whereby the covered entity could agree to restrictions and would have an even more difficult time implementing the restrictions since records may be kept in multiple locations and accessed by multiple people within the organization. Still other commenters believed that the right to request restrictions would invite argument, delay, and litigation.

Response: We do not believe that this requirement is a significant change from current practice. Providers already respond to requests by patients regarding sensitive information, and are subject to state law requirements not to disclose certain types of information without authorization. This right to request is permissive so that covered entities can balance the needs of particular individuals with the entity's ability to manage specific accommodations.

Comment: Some commenters were concerned that a covered entity would agree to a restriction and then realize later that the information must be disclosed to another caregiver for important medical care purposes.

Response: Some individuals seek treatment only on the condition that information about that treatment will not be shared with others. We believe it is necessary and appropriate, therefore, that when a covered provider agrees to such a restriction, the individual must be able to rely on that promise. We strongly encourage covered providers to consider future treatment implications of agreeing to a restriction. We encourage covered entities to inform others of the existence of a restriction when appropriate, provided that such notice does not amount to a de facto disclosure of the restricted information. If the covered provider subject to the restriction believes that disclosing the protected health information that was created or obtained subject to the restriction is necessary to avert harm (and it is not for emergency treatment), the provider must ask the individual for permission to terminate or modify the restriction. If the individual agrees to the termination of the restriction, the provider must document this termination by noting this agreement in the medical record or by obtaining a written agreement of termination from the individual and may use or disclose the information for treatment. If the individual does not agree to terminate or modify the restriction, however, the provider must continue to honor the restriction with respect to protected health information that was created or received subject to the restriction. We note that if the restricted protected health information is needed to provide emergency treatment to the individual who requested the restriction, the covered entity may use or disclose such information for such treatment.

Comment: Commenters asked that we require covered entities to keep an accounting of the requests for restrictions and to report this information to the Department in order for the Department to determine whether covered entities are showing “good faith” in dealing with these requests.

Response: We require that covered entities that agree to restrictions with individuals document such restrictions. A covered entity must retain such documentation for six years from the date of its creation or the date when it last was in effect, whichever is later. We do not require covered entities to keep a record of all requests made, including those not agreed to, nor that they report such requests to the Department. The decision to agree to restrictions is that of the covered entity. Because there is no requirement to agree to a restriction, there is no reason to impose the burden to document requests that are denied. Any reporting requirement could undermine the purpose of this provision by causing the sharing, or appearance of sharing, of information for which individuals are seeking extra protection.

Comment: One commenter asserted that providers that currently allow such restrictions will choose not to do so under the rule based on the guidance of legal counsel and loss prevention managers, and suggested that the Secretary promote competition among providers with respect to privacy by developing a third-party ranking mechanism.

Response: We believe that providers will do what is best for their patients, in accordance with their ethics codes, and will continue to find ways to accommodate requested restrictions when they believe that it is in the patients' best interests. We anticipate that providers who find such action to be of commercial benefit will notify consumers of their willingness to be responsive to such requests. Involving third parties could undermine the purpose of this provision, by causing the sharing, or appearance of sharing, of information for which individuals are seeking extra protection. ***82728**

Comment: One commenter said that any agreement regarding patient-requested restrictions should be in writing before a covered provider would be held to standards for compliance.

Response: We agree that agreed to restrictions must be documented in writing, and we require that covered entities that agree to restrictions document those restrictions in accordance with § 164.530(j). The writing need not be formal; a notation in the medical record will suffice. We disagree with the request that an agreed to restriction be reduced to writing in order to be enforced. If we adopted the requested policy, a covered entity could agree to a restriction with an individual, but avoid being held to this agreed to restriction under the rule by failing to document the restriction. This would give a covered entity the opportunity to agree to a restriction and then, at its sole discretion, determine if it is enforceable by deciding whether or not to make a note of the restriction in the record about the individual. Because the covered entity has the ability to agree or fail to agree to a restriction, we believe that once the restriction is agreed to, the covered entity must honor the agreement. Any other result would be deceptive to the individual and could lead an individual to disclose health information under the assumption that the uses and disclosures will be restricted. Under § 164.522, a covered entity could be found to be in violation of the rule if it fails to put an agreed-upon restriction in writing and also if it uses or discloses protected health information inconsistent with the restriction.

Comment: Some commenters said that the right to request restrictions should be extended to some of the uses and disclosures permitted without authorization in § 164.510 of the NPRM, such as disclosures to next of kin, for judicial and administrative proceedings, for law enforcement, and for governmental health data systems. Other commenters said that these uses and disclosures should be preserved without an opportunity for individuals to opt out.

Response: We have not extended the right to request restrictions under this rule to disclosures permitted in § 164.512 of the final rule. However, we do not preempt other law that would enforce such agreed-upon restrictions. As discussed in more detail, above, we have extended the right to request restrictions to disclosures to persons assisting in the individual's care, such as next of kin, under § 164.510(b). Any restriction that a covered entity agrees to with respect to persons assisting in the individual's care in accordance with the rule will be enforceable under the rule.

Comment: A few commenters raised the question of the effect of a restriction agreed to by one covered entity that is part of a larger covered entity, particularly a hospital. Commenters were also concerned about who may speak on behalf of the covered entity.

Response: All covered entities are required to establish policies and procedures for providing individuals the right to request restrictions, including policies for who may agree to such restrictions on the covered entity's behalf. Hospitals and other large entities that are concerned about employees agreeing to restrictions on behalf of the organization will have to make sure that their policies are communicated appropriately to those employees. The circumstances under which members of a covered entity's workforce can bind the covered entity are a function of other law, not of this regulation.

Comment: Commenters expressed confusion about the intended effect of any agreed-upon restrictions on downstream covered entities. They asserted that it would be extremely difficult for a requested restriction to be followed through the health care

system and that it would be unfair to hold covered entities to a restriction when they did not agree to such restriction. Specifically, commenters asked whether a covered provider that receives protected health information in compliance with this rule from a physician or medical group that has agreed to limit certain uses of the information must comply with the original restriction. Other commenters expressed concern that not applying a restriction to downstream covered entities is a loophole and that all downstream covered providers and health plans should be bound by the restrictions.

Response: Under the final rule, a restriction that is agreed to between an individual and a covered entity is only binding on the covered entity that agreed to the restriction and not on downstream entities. It would also be binding on any business associate of the covered entity since a business associate can not use or disclose protected health information in any manner that a covered entity would not be permitted to use or disclose such information. We realize that this may limit the ability of an individual to successfully restrict a use or disclosure under all circumstances, but we take this approach for two reasons. First, we allow covered entities to refuse individuals' requests for restrictions. Requiring downstream covered entities to abide by a restriction would be tantamount to forcing them to agree to a request to which they otherwise may not have agreed. Second, some covered entities have information systems which will allow them to accommodate such requests, while others do not. If the downstream provider is in the latter category, the administrative burden of such a requirement would be unmanageable.

We encourage covered entities to explain this limitation to individuals when they agree to restrictions, so individuals will understand that they need to ask all their health plans and providers for desired restrictions. We also require that a covered entity that discloses protected health information to a health care provider for emergency treatment, in accordance with § 164.522(a)(iii), to request that the recipient not further use or disclose the information.

Comment: One commenter requested that agreed-to restrictions of a covered entity not be applied to business associates.

Response: As stated in § 164.504(e)(2), business associates are acting on behalf of, or performing services for, the covered entity and may not, with two narrow exceptions, use or disclose protected health information in a manner that would violate this rule if done by the covered entity. Business associates are agents of the covered entity with respect to protected health information they obtain through the business relationship. If the covered entity agrees to a restriction and, therefore, is bound to such restriction, the business associate will also be required to comply with the restriction. If the covered entity has agreed to a restriction, the satisfactory assurances from the business associate, as required in § 164.504(e), must include assurances that protected health information will not be used or disclosed in violation of an agreed to restriction.

Comment: One commenter requested clarification that the right to request restrictions cannot be used to restrict the creation of de-identified information.

Response: We found no reason to treat the use of protected health information to create de-identified information different from other uses of protected health information. The right to request restriction applies to any use or disclosure of protected health information to carry out treatment, payment, or health care operations. If the covered entity uses protected health information to create de-identified information, the covered entity need not agree to a restriction of this use. ***82729**

Comment: Some commenters stated that individuals should be given a true right to restrict uses and disclosures of protected health information in certain defined circumstances (such as for sensitive information) rather than a right to request restrictions.

Response: We are concerned that a right to restrict could create conflicts with the professional ethical obligations of providers and others. We believe it is better policy to allow covered entities to refuse to honor restrictions that they believe are not appropriate and leave the individual with the option of seeking service from a different covered entity. In addition, many covered entities have information systems that would make it difficult or impossible to accommodate certain restrictions.

Comment: Some commenters requested that self-pay patients have additional rights to restrict protected health information. Others believed that this policy would result in de facto discrimination against those patients that could not afford to pay out-of-pocket.

Response: Under the final rule, the decision whether to tie an agreement to restrict to the way the individual pays for services is left to each covered entity. We have not provided self-pay patients with any special rights under the rule.

Comment: Some commenters suggested that we require restrictions to be clearly noted so that insurers and other providers would be aware that they were not being provided with complete information.

Response: Under the final rule, we do not require or prohibit a covered entity to note the existence of an omission of information. We encourage covered entities to inform others of the existence of a restriction, in accordance with professional practice and ethics, when appropriate to do so. In deciding whether or not to disclose the existence of a restriction, we encourage the covered entity to carefully consider whether disclosing the existence is tantamount to disclosure of the restricted protected health information so as to not violate the agreed to restriction.

Comment: A few commenters said that covered entities should have the right to modify or revoke an agreement to restrict use or disclosure of protected health information.

Response: We agree that, as circumstances change, covered entities should be able to revisit restrictions to which they had previously agreed. At the same time, individuals should be able to rely on agreements to restrict the use or disclosure of information that they believe is particularly sensitive. If a covered entity would like to revoke or modify an agreed-upon restriction, the covered entity must renegotiate the agreement with the individual. If the individual agrees to modify or terminate the restriction, the covered entity must get written agreement from the individual or must document the oral agreement. If the individual does not agree to terminate or modify the restriction, the covered entity must inform the individual that it is modifying or terminating its agreement to the restriction and any modification or termination would apply only with respect to protected health information created or received after the covered entity informed the individual of the termination. Any protected health information created or received during the time between when the restriction was agreed to and when the covered entity informed the individual or such modification or termination remains subject to the restriction.

Comment: Many commenters advocated for stronger rights to request restrictions, particularly that victims of domestic violence should have an absolute right to restrict disclosure of information.

Response: We address restrictions for disclosures in two different ways, the right to request restrictions (§ 164.522(a)) and confidential communications (§ 164.522(b)). We have provided all individuals with a right to request restrictions on uses or disclosures of treatment, payment, and health care operations. This is not an absolute right to restrict. Covered entities are not required to agree to requested restrictions; however, if they do, the rule would require them to act in accordance with the restrictions. (See the preamble regarding § 164.522 for a more comprehensive discussion of the right to request restrictions.)

In the final rule, we create a new provision that provides individuals with a right to confidential communications, in response to these comments. This provision grants individuals with a right to restrict disclosures of information related to communications made by a covered entity to the individual, by allowing the individual to request that such communications be made to the person at an alternative location or by an alternative means. For example, a woman who lives with an abusive man and is concerned that his knowledge of her health care treatment may lead to additional abuse can request that any mail from the provider be sent to a friend's home or that telephone calls by a covered provider be made to her at work. Other reasonable accommodations may be requested as well, such as requesting that a covered provider never contact the individual by a phone, but only contact her by electronic mail. A provider must accommodate an individual's request for confidential communications, under this section, without requiring an explanation as to the reason for the request as a condition of accommodating the request. The individual does not need to be in an abusive situation to make such requests of a covered provider. The only conditions that a covered

provider may place on an individual is that the request be reasonable with respect to the administrative burden on the provider, the request to be in writing, the request specify an alternative address or other method of contact, and that (where relevant) the individual provide information about how payment will be handled. What is reasonable may vary by the size or type of covered entity; however, additional modest cost to the provider would not be unreasonable.

An individual also has a right to restrict communications from a health plan. The right is the same as with covered providers except it is limited to cases where the disclosure of information could endanger the individual. A health plan may require an individual to state this fact as a condition of accommodating the individual's request for confidential communications. This would provide victims of domestic violence the right to control such disclosures.

Comment: Commenters opposed the provision of the NPRM (§ 164.506(c)(1)(ii)(B)) stating that an individual's right to request restrictions on use or disclosure of protected health information would not apply in emergency situations as set forth in proposed § 164.510(k). Commenters asserted that victims who have been harmed by violence may first turn to emergency services for help and that, in such situations, the victim should be able to request that the perpetrator not be told of his or her condition or whereabouts.

Response: We agree with some of the commenters' concerns. In the final rule, the right to request restrictions is available to all individuals regardless of the circumstance or the setting in which the individual is obtaining care. For example, an individual that seeks care in an emergency room has the same right to request a restriction as an individual seeking care in the office of a covered physician.

However, we continue to permit a covered entity to disclose protected health information to a health care ***82430** provider in an emergency treatment situation if the restricted protected health information is needed to provide the emergency treatment or if the disclosure is necessary to avoid serious and imminent threats to public health and safety. Although we understand the concern of the commenters, we believe that these exceptions are limited and will not cause a covered entity to disclose information to a perpetrator of a crime. We are concerned that a covered provider would be required to delay necessary care if a covered entity had to determine if a restriction exists at the time of such emergency. Even if a covered entity knew that there was a restriction, we permitted this limited exception for emergency situations because, as we had stated in the preamble for § 164.506 of the NPRM, an emergency situation may not provide sufficient opportunity for a patient and health care provider to discuss the potential implications of restricting use and disclosure of protected health information on that emergency. We also believe that the importance of avoiding serious and imminent threats to health and safety and the ethical and legal obligations of covered health care providers' to make disclosures for these purposes is so significant that it is not appropriate to apply the right to request restrictions on such disclosures.

We note that we have included other provisions in the final rule intended to avoid or minimize harm to victims of domestic violence. Specifically, we include provisions in the final rule that allow individuals to opt out of certain types of disclosures and require covered entities to use professional judgment to determine whether disclosure of protected health information is in a patient's best interest (see § 164.510(a) on use and disclosure for facility directories and § 164.510(b) on uses and disclosures for assisting in an individual's care and notification purposes). Although an agreed to restriction under § 164.522 would apply to uses and disclosures for assisting in an individual's care, the opt out provision in § 164.510(b) can be more helpful to a person who is a victim of domestic violence because the individual can opt out of such disclosure without obtaining the agreement of the covered provider. We permit a covered entity to elect not to treat a person as a personal representative (see § 164.502(g)) or to deny access to a personal representative (see § 164.524(a)(3)(iii)) where there are concerns related to abuse. We also include a new § 164.512(c) which recognizes the unique circumstances surrounding disclosure of protected health information about victims of abuse, neglect, and domestic violence.

Section 164.522(b)—Confidential Communications Requirements

Comment: Several commenters requested that we add a new section to prevent disclosure of sensitive health care services to members of the patient's family through communications to the individual's home, such as appointment notices, confirmation

or scheduling of appointments, or mailing a bill or explanation of benefits, by requiring covered entities to agree to correspond with the patient in another way. Some commenters stated that this is necessary in order to protect inadvertent disclosure of sensitive information and to protect victims of domestic violence from disclosure to an abuser. A few commenters suggested that a covered entity should be required to obtain an individual's authorization prior to communicating with the individual at the individual's home with respect to health care relating to sensitive subjects such as reproductive health, sexually transmissible diseases, substance abuse or mental health.

Response: We agree with commenters' concerns regarding covered entities' communications with individuals. We created a new provision, § 164.522(b), to address confidential communications by covered entities. This provision gives individuals the right to request that they receive communications from covered entities at an alternative address or by an alternative means, regardless of the nature of the protected health information involved. Covered providers are required to accommodate reasonable requests by individuals and may not require the individual to explain the basis for the request as a condition of accommodation. Health plans are required to accommodate reasonable requests by individuals as well; however, they may require the individual to provide a statement that disclosure of the information could endanger the individual, and they may condition the accommodation on the receipt of such statement.

Under the rule, we have required covered providers to accommodate requests for communications to alternative addresses or by alternative means, regardless of the reason, to limit risk of harm. Providers have more frequent one-on-one communications with patients, making the safety concerns from an inadvertent disclosure more substantial and the need for confidential communications more compelling. We have made the requirement for covered providers absolute and not contingent on the reason for the request because we wanted to make it relatively easy for victims of domestic violence, who face real safety concerns by disclosures of health information, to limit the potential for such disclosures.

The standard we created for health plans is different from the requirement for covered providers, in that we only require health plans to make requested accommodations for confidential communications when the individual asserts that disclosure could be dangerous to the individual. We address health plan requirements in this way because health plans are often issued to a family member (the employee), rather than to each individual member of a family, and therefore, health plans tend to communicate with the named insured rather than with individual family members. Requiring plans to accommodate a restriction for one individual could be administratively more difficult than it is for providers that regularly communicate with individuals. However, in the case of domestic violence or potential abuse, the level of harm that can result from a disclosure of protected health information tips the balance in favor of requiring such restriction to prevent inadvertent disclosure. We have adopted the policy recommended by the National Association of Insurance Commissioners in the Health Information Policy Model Act (1998) as this best reflects the balance of the appropriate level of regulation of the industry compared with the need to protect individuals from harm that may result from inadvertent disclosure of information. This policy is also consistent with recommendations made in the Family Violence Prevention Fund's publication “Health Privacy Principles for Protecting Victims of Domestic Violence” (October 2000). Of course, health plans may accommodate requests for confidential communications without requiring a statement that the individual would be in danger from disclosure of protected health information.

Comment: One commenter requested that we create a standard that all information from a health plan be sent to the patient and not the policyholder or subscriber.

Response: We require health plans to accommodate certain requests that information not be sent to a particular location or by particular means. A health plan must accommodate reasonable requests by individuals that protected health information about them be sent directly to them and not to a policyholder or subscriber, if the ***82731** individual states that he or she may be in danger from disclosure of such information. We did not generally require health plans to send information to the patient and not the policyholder or subscriber because we believed it would be administratively burdensome and because the named insured may have a valid need for such information to manage payment and benefits.

Sensitive Subjects

Comment: Many commenters requested that additional protections be placed on sensitive information, including information regarding HIV/AIDS, sexually transmitted diseases, mental health, substance abuse, reproductive health, and genetics. Many requested that we ensure the regulation adequately protects victims of domestic violence. They asserted that the concern for discrimination or stigma resulting from disclosure of sensitive health information could dissuade a person from seeking needed treatment. Some commenters noted that many state laws provide additional protections for various types of information. They requested that we develop federal standards to have consistent rules regarding the protection of sensitive information to achieve the goals of cost savings and patient protection. Others requested that we require patient consent or special authorization before certain types of sensitive information was disclosed, even for treatment, payment, and health care operations, and some thought we should require a separate request for each disclosure. Some commenters requested that the right to request restrictions be replaced with a requirement for an authorization for specific types of sensitive information. There were recommendations that we require covered entities to develop internal policies to address sensitive information.

Other commenters argued that sensitive information should not be segregated from the record because it may limit a future provider's access to information necessary for treatment of the individual and it could further stigmatize a patient by labeling him or her as someone with sensitive health care issues. These commenters further maintained that segregation of particular types of information could negatively affect analysis of community needs, research, and would lead to higher costs of health care delivery.

Response: We generally do not differentiate among types of protected health information, because all health information is sensitive. The level of sensitivity varies not only with the type of information, but also with the individual and the particular situation faced by the individual. This is demonstrated by the different types of information that commenters singled out as meriting special protection, and in the great variation among state laws in defining and protecting sensitive information. Most states have a law providing heightened protection for some type of health information. However, even though most states have considered the issue of sensitive information, the variation among states in the type of information that is specially protected and the requirements for permissible disclosure of such information demonstrates that there is no national consensus.

Where, as in this case, most states have acted and there is no predominant rule that emerges from the state experience with this issue, we have decided to let state law predominate. The final rule only provides a floor of protection for health information and does not preempt state laws that provide greater protection than the rule. Where states have decided to treat certain information as more sensitive than other information, we do not preempt those laws.

To address the variation in the sensitivity of protected health information without defining specially sensitive information, we incorporate opportunities for individuals and covered entities to address specific sensitivities and concerns about uses and disclosures of certain protected health information that the patient and provider believe are particularly sensitive, as follows:

- Covered entities are required to provide individuals with notice of their privacy practices and give individuals the opportunity to request restrictions of the use and disclosure of protected health information by the covered entity. (See § 164.522(a) regarding right to request restrictions.)

- Individuals have the right to request, and in some cases require, that communications from the covered entity to them be made to an alternative address or by an alternative means than the covered entity would otherwise use. (See § 164.522(b) regarding confidential communications.)

- Covered entities have the opportunity to decide not to treat a person as a personal representative when the covered entity has a reasonable belief that an individual has been subjected to domestic violence, abuse, or neglect by such person or that treating such person as a personal representative could endanger the individual. (See § 164.502(g)(5) regarding personal representatives.)

- Covered entities may deny access to protected health information when there are concerns that the access may result in varying levels of harm. (See § 164.524(a)(3) regarding denial of access.)

- Covered health care providers may, in some circumstances and consistent with any known prior preferences of the individual, exercise professional judgment in the individual's best interest to not disclose directory information. (See § 164.510(a) regarding directory information.)

- Covered entities may, in some circumstances, exercise professional judgment in the individual's best interest to limit disclosure to persons assisting in the individual's care. (See § 164.510(b) regarding persons assisting in the individual's care.)

This approach allows for state law and personal variation in this area.

The only type of protected health information that we treat with heightened protection is psychotherapy notes. We provide a different level of protection because they are unique types of protected health information that typically are not used or required for treatment, payment, or health care operations other than by the mental health professional that created the notes. (See § 164.508(a)(2) regarding psychotherapy notes.)

Section 164.524—Access of Individuals to Protected Health Information

Comment: Some commenters recommended that there be no access to disease registries.

Response: Most entities that maintain disease registries are not covered entities under this regulation; examples of such non-covered entities are public health agencies and pharmaceutical companies. If, however, a disease registry is maintained by a covered entity and is used to make decisions about individuals, this rule requires the covered entity to provide access to information about a requesting individual unless one of the rule's conditions for denial of access is met. We found no persuasive reasons why disease registries should be given special treatment compared with other information that may be used to make decisions about an individual.

Comment: Some commenters stated that covered entities should be held accountable for access to information held by business partners so that individuals would not have the burden of tracking down their protected health information from a business partner. Many commenters, including insurers ***82732** and academic medical centers, recommended that, to reduce burden and duplication, only the provider who created the protected health information should be required to provide individuals access to the information. Commenters also asked that other entities, including business associates, the Medicare program, and pharmacy benefit managers, not be required to provide access, in part because they do not know what information the covered entity already has and they may not have all the information requested. A few commenters also argued that billing companies should not have to provide access because they have a fiduciary responsibility to their physician clients to maintain the confidentiality of records.

Response: A general principle in responding to all of these points is that a covered entity is required to provide access to protected health information in accordance with the rule regardless of whether the covered entity created such information or not. Thus, we agree with the first point: in order to meet its requirements for providing access, a covered entity must not only provide access to such protected health information it holds, but must also provide access to such information in a designated record set of its business associate, pursuant to its business associate contract, unless the information is the same as information maintained directly by the covered entity. We require this because an individual may not be aware of business associate relationships. Requiring an individual to track down protected health information held by a business associate would significantly limit access. In addition, we do not permit a covered entity to limit its duty to provide access by giving protected health information to a business associate.

We disagree with the second point: if the individual directs an access request to a covered entity that has the protected health information requested, the covered entity must provide access (unless it may deny access in accordance with this rule). In order to assure that an individual can exercise his or her access rights, we do not require the individual to make a separate request to

each originating provider. The originating provider may no longer be in business or may no longer have the information, or the non-originating provider may have the information in a modified or enhanced form.

We disagree with the third point: other entities must provide access only if they are covered entities or business associates of covered entities, and they must provide access only to protected health information that they maintain (or that their business associates maintain). It would not be efficient to require a covered entity to compare another entity's information with that of the entity to which the request was addressed. (See the discussion regarding covered entities for information about whether a pharmacy benefit manager is a covered entity.)

We disagree with the fourth point: a billing company will be required by its business associate contract only to provide the requested protected health information to its physician client. This action will not violate any fiduciary responsibility. The physician client would in turn be required by the rule to provide access to the individual.

Comment: Some commenters asked for clarification that the clearinghouse function of turning non-standardized data into standardized data does not create non-duplicative data and that "duplicate" does not mean "identical." A few commenters suggested that duplicated information in a covered entity's designated record set be supplied only once per request.

Response: We consider as duplicative information the same information in different formats, media, or presentations, or which have been standardized. Business associates who have materially altered protected health information are obligated to provide individuals access to it. Summary information and reports, including those of lab results, are not the same as the underlying information on which the summaries or reports were based. A clean document is not a duplicate of the same document with notations. If the same information is kept in more than one location, the covered entity has to produce the information only once per request for access.

Comment: A few commenters suggested requiring covered entities to disclose to third parties without exception at the requests of individuals. It was argued that this would facilitate disability determinations when third parties need information to evaluate individuals' entitlement to benefits. Commenters argued that since covered entities may deny access to individuals under certain circumstances, individuals must have another method of providing third parties with their protected health information.

Response: We allow covered entities to forward protected health information about an individual to a third party, pursuant to the individual's authorization under § 164.508. We do not require covered entities to disclose information pursuant to such authorizations because the focus of the rule is privacy of protected health information. Requiring disclosures in all circumstances would be counter to this goal. In addition, a requirement of disclosing protected health information to a third party is not a necessary substitute for the right of access to individuals, because we allow denial of access to individuals under rare circumstances. However, if the third party is a personal representative of the individual in accordance with § 164.502(g) and there is no concern regarding abuse or harm to the individual or another person, we require the covered entity to provide access to that third party on the individual's behalf, subject to specific limitations. We note that a personal representative may obtain access on the individual's behalf in some cases where covered entity may deny access to the individual. For example, an inmate may be denied a copy of protected health information, but a personal representative may be able to obtain a copy on the individual's behalf. See § 164.502(g) and the corresponding preamble discussion regarding the ability of a personal representative to act on an individual's behalf.

Comment: The majority of commenters supported granting individuals the right to access protected health information for as long as the covered entity maintains the protected health information; commenters argued that to do otherwise would interfere with existing record retention laws. Some commenters advocated for limiting the right to information that is less than one or two years old. A few commenters explained that frequent changes in technology makes it more difficult to access stored data. The commenters noted that the information obtained prior to the effective date of the rule should not be required to be accessible.

Response: We agree with the majority of commenters and retain the proposal to require covered entities to provide access for as long as the entity maintains the protected health information. We do not agree that information created prior to the effective date of the rule should not be accessible. The reasons for granting individuals access to information about them do not vary with the date the information was created.

Comment: A few commenters argued that there should be no grounds for denying access, stating that individuals should always have the right to inspect and copy their protected health information. ***82733**

Response: While we agree that in the vast majority of instances individuals should have access to information about them, we cannot agree that a blanket rule would be appropriate. For example, where a professional familiar with the particular circumstances believes that providing such access is likely to endanger a person's life or physical safety, or where granting such access would violate the privacy of other individuals, the benefits of allowing access may not outweigh the harm. Similarly, we allow denial of access where disclosure would reveal the source of confidential information because we do not want to interfere with a covered entity's ability to maintain implicit or explicit promises of confidence.

We create narrow exceptions to the rule of open access, and we expect covered entities to employ these exceptions rarely, if at all. Moreover, we require covered entities to provide access to any protected health information requested after excluding only the information that is subject to a denial. The categories of permissible denials are not mandatory, but are a means of preserving the flexibility and judgment of covered entities under appropriate circumstances.

Comment: Many commenters supported our proposal to allow covered entities to deny an individual access to protected health information if a professional determines either that such access is likely to endanger the life or physical safety of a person or, if the information is about another person, access is reasonably likely to cause substantial harm to such person.

Some commenters requested that the rule also permit covered entities to deny a request if access might be reasonably likely to cause psychological or mental harm, or emotional distress. Other commenters, however, were particularly concerned about access to mental health information, stating that the lack of access creates resentment and distrust in patients.

Response: We disagree with the comments suggesting that we expand the grounds for denial of access to an individual to include a likelihood of psychological or mental harm of the individual. We did not find persuasive evidence that this is a problem sufficient to outweigh the reasons for providing open access. We do allow a denial for access based on a likelihood of substantial psychological or mental harm, but only if the protected health information includes information about another person and the harm may be inflicted on such other person or if the person requesting the access is a personal representative of the individual and the harm may be inflicted on the individual or another person.

We generally agree with the commenters concerns that denying access specifically to mental health records could create distrust. To balance this concern with other commenters' concerns about the potential for psychological harm, however, we exclude psychotherapy notes from the right of access. This is the only distinction we make between mental health information and other types of protected health information in the access provisions of this rule. Unlike other types of protected health information, these notes are not widely disseminated through the health care system. We believe that the individual's privacy interests in having access to these notes, therefore, are outweighed by the potential harm caused by such access. We encourage covered entities that maintain psychotherapy notes, however, to provide individuals access to these notes when they believe it is appropriate to do so.

Comment: Some commenters believed that there is a potential for abuse of the provision allowing denial of access because of likely harm to self. They questioned whether there is any experience from the Privacy Act of 1974 to suggest that patients who requested and received their records have ever endangered themselves as a result.

Response: We are unaware of such problems from access to records that have been provided under the Privacy Act but, since these are private matters, such problems might not come to our attention. We believe it is more prudent to preserve the flexibility and judgment of health care professionals familiar with the individuals and facts surrounding a request for records than to impose the blanket rule suggested by these commenters.

Comment: Commenters asserted that the NPRM did not adequately protect vulnerable individuals who depend on others to exercise their rights under the rule. They requested that the rule permit a covered entity to deny access when the information is requested by someone other than the subject of the information and, in the opinion of a licensed health care professional, access to the information could harm the individual or another person.

Response: We agree with the commenters that such protection is warranted and add a provision in § 164.524(a)(3), which permits a covered health care provider to deny access if a personal representative of the individual is making the request for access and a licensed health care professional has determined, in the exercise of professional judgment, that providing access to such personal representative could result in substantial harm to the individual or another person. Access can be denied even if the potential harm may be inflicted by someone other than the personal representative.

This provision is designed to strike a balance between the competing interests of ensuring access to protected health information and protecting the individual or others from harm. The "substantial harm" standard will ensure that a covered entity cannot deny access in cases where the harm is de minimus.

The amount of discretion that a covered entity has to deny access to a personal representative is generally greater than the amount of discretion that a covered entity has to deny access to an individual. Under the final rule, a covered entity may deny access to an individual if a licensed health care professional determines that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person. In this case, concerns about psychological or emotional harm would not be sufficient to justify denial of access. We establish a relatively high threshold because we want to assure that individuals have broad access to health information about them, and due to the potential harm that comes from denial of access, we believe denials should be permitted only in limited circumstances.

The final rule grants covered entities greater discretion to deny access to a personal representative than to an individual in order to provide protection to those vulnerable people who depend on others to exercise their rights under the rule and who may be subjected to abuse or neglect. This provision applies to personal representatives of minors as well as other individuals. The same standard for denial of access on the basis of potential harm that applies to personal representatives also applies when an individual is seeking access to his or her protected health information, and the information makes reference to another person. Under these circumstances, a covered entity may deny a request for access if such access is reasonably likely to cause substantial harm to such other person. The standard for this provision and for the provision regarding access by personal representatives is the same because both circumstances involve one person obtaining information about another person, and in both cases the covered entity is balancing the right of access of one person against the right of ***82734** a second person not to be harmed by the disclosure.

Under any of these grounds for denial of access to protected health information, the covered entity is not required to deny access to a personal representative under these circumstances, but has the discretion to do so.

In addition to denial of access rights, we also address the concerns raised by abusive or potentially abusive situations in the section regarding personal representatives by giving covered entities discretion to not recognize a person as a personal representative of an individual if the covered entity has a reasonable belief that the individual has been subjected to domestic violence, abuse, or neglect by or would be in danger from a person seeking to act as the personal representative. (See § 164.502(g))

Comment: A number of commenters were concerned that this provision would lead to liability for covered entities if the release of information results in harm to individuals. Commenters requested a "good faith" standard in this provision to relieve covered entities of liability if individuals suffer harm as a result of seeing their protected health information or if the information is found to be erroneous. A few commenters suggested requiring providers (when applicable) to include with any disclosure to a third party a statement that, in the provider's opinion, the information should not be disclosed to the patient.

Response: We do not intend to create a new duty to withhold information nor to affect other laws on this issue. Some state laws include policies similar to this rule, and we are not aware of liability arising as a result.

Comment: Some commenters suggested that both the individual's health care professional and a second professional in the relevant field of medicine should review each request. Many commenters suggested that individuals have a right to have an independent review of any denial of access, e.g., review by a health care professional of the individual's choice.

Response: We agree with the commenters who suggest that denial on grounds of harm to self or others should be determined by a health professional, and retain this requirement in the final rule. We disagree, however, that all denials should be reviewed by a professional of the individual's choice. We are concerned that the burden such a requirement would place on covered entities would be significantly greater than any benefits to the individual. We believe that any health professional, not just one of the individual's choice, will exercise appropriate professional judgment. To address some of these concerns, however, we add a provision for the review of denials requiring the exercise of professional judgment. If a covered entity denies access based on harm to self or others, the individual has the right to have the denial reviewed by another health care professional who did not participate in the original decision to deny access.

Comment: A few commenters objected to the proposal to allow covered entities to deny a request for access to health information if the information was obtained from a confidential source that may be revealed upon the individual's access. They argued that this could be subject to abuse and the information could be inherently less reliable, making the patient's access to it even more important.

Response: While we acknowledge that information provided by confidential sources could be inaccurate, we are concerned that allowing unfettered access to such information could undermine the trust between a health care provider and patients other than the individual. We retain the proposed policy because we do not want to interfere with a covered entity's ability to obtain important information that can assist in the provision of health care or to maintain implicit or explicit promises of confidence, which may be necessary to obtain such information. We believe the concerns raised about abuse are mitigated by the fact that the provision does not apply to promises of confidentiality made to a health care provider. We note that a covered entity may provide access to such information.

Comment: Some commenters were concerned that the NPRM did not allow access to information unrelated to treatment, and thus did not permit access to research information.

Response: In the final rule, we eliminate the proposed special provision for "research information unrelated to treatment." The only restriction on access to research information in this rule applies where the individual agrees in advance to denial of access when consenting to participate in research that includes treatment. In this circumstance, the individual's right of access to protected health information created in the course of the research may be suspended for as long as the research is in progress, but access rights resume after such time. In other instances, we make no distinction between research information and other information in the access provisions in this rule.

Comment: A few commenters supported the proposed provision temporarily denying access to information obtained during a clinical trial if participants agreed to the denial of access when consenting to participate in the trial. Some commenters believed there should be no access to any research information. Other commenters believed denial should occur only if the trial would be compromised. Several recommended conditioning the provision. Some recommended that access expires upon completion

of the trial unless there is a health risk. A few commenters suggested that access should be allowed only if it is included in the informed consent and that the informed consent should note that some information may not be released to the individual, particularly research information that has not yet been validated. Other commenters believed that there should be access if the research is not subject to IRB or privacy board review or if the information can be disclosed to third parties.

Response: We agree with the commenters that support temporary denial of access to information from research that includes treatment if the subject has agreed in advance, and with those who suggested that the denial of access expire upon completion of the research, and retain these provisions in the final rule. We disagree with the commenters who advocate for further denial of this information. These comments did not explain why an individual's interest in access to health information used to make decisions about them is less compelling with respect to research information. Under this rule, all protected health information for research is subject either to privacy board or IRB review unless a specific authorization to use protected health information for research is obtained from the individual. Thus, this is not a criterion we can use to determine access rights.

Comment: A few commenters believed that it would be “extremely disruptive of and dangerous” to patients to have access to records regarding their current care and that state law provides sufficient protection of patients' rights in this regard.

Response: We do not agree. Information about current care has immediate and direct impact on individuals. Where a health care professional familiar with the circumstances believes that it is reasonably likely that access to records would endanger the life or physical safety of the individual or another ***82735** person, the regulation allows the professional to withhold access.

Comment: Several commenters requested clarification that a patient not be denied access to protected health information because of failure to pay a bill. A few commenters requested clarification that entities may not deny requests simply because producing the information would be too burdensome.

Response: We agree with these comments, and confirm that neither failure to pay a bill nor burden are lawful reasons to deny access under this rule. Covered entities may deny access only for the reasons provided in the rule.

Comment: Some commenters requested that the final rule not include detailed procedural requirements about how to respond to requests for access. Others made specific recommendations on the procedures for providing access, including requiring written requests, requiring specific requests instead of blanket requests, and limiting the frequency of requests. Commenters generally argued against requiring covered entities to acknowledge requests, except under certain circumstances, because of the potential burden on entities.

Response: We intend to provide sufficient procedural guidelines to ensure that individuals have access to their protected health information, while maintaining the flexibility for covered entities to implement policies and procedures that are appropriate to their needs and capabilities. We believe that a limit on the frequency of requests individuals may make would arbitrarily infringe on the individual's right of access and have, therefore, not included such a limitation. To limit covered entities' burden, we do not require covered entities to acknowledge receipt of the individuals' requests, other than to notify the individual once a decision on the request has been made. We also permit a covered entity to require an individual to make a request for access in writing and to discuss a request with an individual to clarify which information the individual is actually requesting. If individuals agree, covered entities may provide access to a subset of information rather than all protected health information in a designated record set. We believe these changes provide covered entities with greater flexibility without compromising individuals' access rights.

Comment: Commenters offered varying suggestions for required response time, ranging from 48 hours because of the convenience of electronic records to 60 days because of the potential burden. Others argued against a finite time period, suggesting the response time be based on mutual convenience of covered entities and individuals, reasonableness, and exigencies. Commenters also varied on suggested extension periods, from one 30-day extension to three 30-day extensions to one 90-day extension, with special provisions for off-site records.

Response: We are imposing a time limit because individuals are entitled to know when to expect a response. Timely access to protected health information is important because such information may be necessary for the individual to obtain additional health care services, insurance coverage, or disability benefits, and the covered entity may be the only source for such information. To provide additional flexibility, we eliminate the requirement that access be provided as soon as possible and we lengthen the deadline for access to off-site records. For on-site records, covered entities must act on a request within 30 days of receipt of the request. For off-site records, entities must complete action within 60 days. We also permit covered entities to extend the deadline by up to 30 days if they are unable to complete action on the request within the standard deadline. These time limits are intended to be an outside deadline rather than an expectation. We expect covered entities to be attentive to the circumstances surrounding each request and respond in an appropriate time frame.

Comment: A few commenters suggested that, upon individuals' requests, covered entities should be required to provide protected health information in a format that would be understandable to a patient, including explanations of codes or abbreviations. The commenters suggested that covered entities be permitted to provide summaries of pertinent information instead of full copies of records; for example, a summary may be more helpful for the patient's purpose than a series of indecipherable billing codes.

Response: We agree with these commenters' point that some health information is difficult to interpret. We clarify, therefore, that the covered entity may provide summary information in lieu of the underlying records. A summary may only be provided if the covered entity and the individual agree, in advance, to the summary and to any fees imposed by the covered entity for providing such summary. We similarly permit a covered entity to provide an explanation of the information. If the covered entity charges a fee for providing an explanation, it must obtain the individual's agreement to the fee in advance.

Comment: Though there were recommendations that fees be limited to the costs of copying, the majority of commenters on this topic requested that covered entities be able to charge a reasonable, cost-based fee. Commenters suggested that calculation of access costs involve factors such as labor costs for verification of requests, labor and software costs for logging of requests, labor costs for retrieval, labor costs for copying, expense costs for copying, capital cost for copying, expense costs for mailing, postal costs for mailing, billing and bad-debt expenses, and labor costs for refiling. Several commenters recommended specific fee structures.

Response: We agree that covered entities should be able to recoup their reasonable costs for copying of protected health information, and include such provision in the regulation. We are not specifying a set fee because copying costs could vary significantly depending on the size of the covered entity and the form of such copy (e.g., paper, electronic, film). Rather, covered entities are permitted to charge a reasonable, cost-based fee for copying (including the costs of supplies and labor), postage, and summary or explanation (if requested and agreed to by the individual) of information supplied. The rule limits the types of costs that may be imposed for providing access to protected health information, but does not preempt applicable state laws regarding specific allowable fees for such costs. The inclusion of a copying fee is not intended to impede the ability of individuals to copy their records.

Comment: Many commenters stated that if a covered entity denies a request for access because the entity does not hold the protected health information requested, the covered entity should provide, if known, the name and address of the entity that holds the information. Some of these commenters additionally noted that the Uniform Insurance Information and Patient Protection Act, adopted by 16 states, already imposes this notification requirement on insurance entities. Some commenters also suggested requiring providers who leave practice or move offices to inform individuals of that fact and of how to obtain their records.

Response: We agree that, when covered entities deny requests for access because they do not hold the protected health information requested, they should inform individuals of the holder of the information, if known; we include this provision in the final rule. We do not require health care providers to ***82736** notify all patients when they move or leave practice, because the volume of such notifications would be unduly burdensome.

Section 164.526—Amendment of Protected Health Information

Comment: Many commenters strongly encouraged the Secretary to adopt “appendment” rather than “amendment and correction” procedures. They argued that the term “correction” implies a deletion of information and that the proposed rule would have allowed covered entities to remove portions of the record at their discretion. Commenters indicated that appendment rather than correction procedures will ensure the integrity of the medical record and allow subsequent health care providers access to the original information as well as the appended information. They also indicated appendment procedures will protect both individuals and covered entities since medical records are sometimes needed for litigation or other legal proceedings.

Response: We agree with commenters' concerns about the term “correction.” We have revised the rule and deleted “correction” from this provision in order to clarify that covered entities are not required by this rule to delete any information from the designated record set. We do not intend to alter medical record retention laws or current practice, except to require covered entities to append information as requested to ensure that a record is accurate and complete. If a covered entity prefers to comply with this provision by deleting the erroneous information, and applicable record retention laws allow such deletion, the entity may do so. For example, an individual may inform the entity that someone else's X-rays are in the individual's medical record. If the entity agrees that the X-ray is inaccurately filed, the entity may choose to so indicate and note where in the record the correct X-ray can be found. Alternatively, the entity may choose to remove the X-ray from the record and replace it with the correct X-ray, if applicable law allows the entity to do so. We intend the term “amendment” to encompass either action.

We believe this approach is consistent with well-established privacy principles, with other law, and with industry standards and ethical guidelines. The July 1977 Report of the Privacy Protection Study Commission recommended that health care providers and other organizations that maintain medical-record information have procedures for individuals to correct or amend the information.[FN28] The Privacy Act (5 U.S.C. 552a) requires government agencies to permit individuals to request amendment of any record the individual believes is not accurate, relevant, timely, or complete. In its report “Best Principles for Health Privacy,” the Health Privacy Working Group recommended, “An individual should have the right to supplement his or her own medical record. Supplementation should not be implied to mean deletion or alteration of the medical record.”[FN29] The National Association of Insurance Commissioners' Health Information Privacy Model Act establishes the right of an individual who is the subject of protected health information to amend protected health information to correct any inaccuracies. The National Conference of Commissioners on Uniform State Laws' Uniform Health Care Information Act states, “Because accurate health-care information is not only important to the delivery of health care, but for patient applications for life, disability and health insurance, employment, and a great many other issues that might be involved in civil litigation, this Act allows a patient to request an amendment in his record.”

Some states also establish a right for individuals to amend health information about them. For example, Hawaii law (HRS section 323C-12) states, “An individual or the individual's authorized representative may request in writing that a health care provider that generated certain health care information append additional information to the record in order to improve the accuracy or completeness of the information; provided that appending this information does not erase or obliterate any of the original information.” Montana law (MCA section 50-16-543) states, “For purposes of accuracy or completeness, a patient may request in writing that a health care provider correct or amend its record of the patient's health care information to which he has access.” Connecticut, Georgia, and Maine provide individuals a right to request correction, amendment, or deletion of recorded personal information about them maintained by an insurance institution. Many other states have similar provisions.

Industry and standard-setting organizations have also developed policies for amendment of health information. The National Committee for Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations issued recommendations stating, “The opportunity for patients to review their records will enable them to correct any errors and may provide them with a better understanding of their health status and treatment. Amending records does not erase the original information. It inserts the correct information with a notation about the date the correct information was available and any explanation about the reason for the error.”[FN30] Standards of the American Society for Testing and Materials state, “An individual has a right to amend by adding information to his or her record or database to correct inaccurate information in his or her patient record and in secondary records and databases which contain patient identifiable health information.”[FN31] We build on this well-established principle in this final rule.

Comment: Some commenters supported the proposal to allow individuals to request amendment for as long as the covered provider or plan maintains the information. A few argued that the provision should be time-limited, e.g., that covered entities should not have to amend protected health information that is more than two years old. Other comments suggested that the provision should only be applied to protected health information created after the compliance date of the regulation.

Response: The purpose of this provision is to create a mechanism whereby individuals can ensure that information about them is as accurate as possible as it travels through the health care system and is used to make decisions, including treatment decisions, about them. To achieve this result, individuals must have the ability to request amendment for as long as the information used to make decisions about them exists. We therefore retain the proposed approach. For these reasons, we also require covered entities to address requests for amendment of all protected health information within designated record sets, including information created or obtained prior to ***82737** the compliance date, for as long as the entity maintains the information.

Comment: A few commenters were concerned that the proposal implied that the individual is in control of and may personally change the medical record. These commenters opposed such an approach.

Response: We do not give individuals the right to alter their medical records. Individuals may request amendment, but they have no authority to determine the final outcome of the request and may not make actual changes to the medical record. The covered entity must review the individual's request and make appropriate decisions. We have clarified this intent in § 164.526(a)(1) by stating that individuals have a right to have a covered entity amend protected health information and in § 164.526(b)(2) by stating that covered entities must act on an individual's request for amendment.

Comment: Some comments argued that there is no free-text field in some current transaction formats that would accommodate the extra text required to comply with the amendment provisions (e.g., sending statements of disagreement along with all future disclosures of the information at issue). Commenters argued that this provision will burden the efficient transmission of information, contrary to HIPAA requirements.

Response: We believe that most amendments can be incorporated into the standard transactions as corrections of erroneous data. We agree that some of the standard transactions cannot currently accommodate additional material such as statements of disagreement and rebuttals to such statements. To accommodate these rare situations, we modify the requirements in § 164.526(d)(iii). The provision now states that if a standard transaction does not permit the inclusion of the additional material required by this section, the covered entity may separately transmit the additional material to the recipient of the standard transaction. Commenters interested in modifying the standard transactions to allow the incorporation of additional materials may also bring the issue up for resolution through the process established by the Transactions Rule and described in its preamble.

Comment: The NPRM proposed to allow amendment of protected health information in designated record sets. Some commenters supported the concept of a designated record set and stated that it appropriately limits the type of information available for amendment to information directly related to treatment. Other commenters were concerned about the burden this provision will create due to the volume of information that will be available for amendment. They were primarily concerned with the potential for frivolous, minor, or technical requests. They argued that for purposes of amendment, this definition should be limited to information used to make medical or treatment decisions about the individual. A few commenters requested clarification that individuals do not have a right to seek amendment unless there is verifiable information to support their claim or they can otherwise convince the entity that the information is inaccurate or incomplete.

Response: We believe that the same information available for inspection should also be subject to requests for amendment, because the purpose of these provisions is the same: To give consumers access to and the chance to correct errors in information that may be used to make decisions that affect their interests. We thus retain use of the “designated record set” in this provision. However, we share commenters” concerns about the potential for minor or technical requests. To address this concern, we have

clarified that covered entities may deny a request for amendment if the request is not in writing and does not articulate a reason to support the request, as long as the covered entity informs the individual of these requirements in advance.

Comment: Many commenters noted the potentially negative impact of the proposal to allow covered entities to deny a request for amendment if the covered entity did not create the information at issue. Some commenters pointed out that the originator of the information may no longer exist or the individual may not know who created the information in question. Other commenters supported the proposal that only the originator of the information is responsible for amendments to it. They argued that any extension of this provision requiring covered entities to amend information they have not created is administratively and financially burdensome.

Response: In light of the comments, we modify the rule to require the holder of the information to consider a request for amendment if the individual requesting amendment provides a reasonable basis to believe that the originator of the information is no longer available to act on a request. For example, if a request indicates that the information at issue was created by a hospital that has closed, and the request is not denied on other grounds, then the entity must amend the information. This provision is necessary to preserve an individual's right to amend protected health information about them in certain circumstances.

Comment: Some commenters stated that the written contract between a covered entity and its business associate should stipulate that the business associate is required to amend protected health information in accordance with the amendment provisions. Otherwise, these commenters argued, there would be a gap in the individual's right to have erroneous information corrected, because the covered entity could deny a request for amendment of information created by a business associate.

Response: We agree that information created by the covered entity or by the covered entity's business associates should be subject to amendment. This requirement is consistent with the requirement to make information created by a business associate available for inspection and copying. We have revised the rule to require covered entities to specify in the business associate contract that the business associate will make protected health information available for amendment and will incorporate amendments accordingly. (See § 164.504(e).)

Comment: One commenter argued that covered entities should be required to presume information must be corrected where an individual informs the entity that an adjudicative process has made a finding of medical identity theft.

Response: Identity theft is one of many reasons why protected health information may be inaccurate, and is one of many subjects that may result in an adjudicative process relevant to the accuracy of protective health information. We believe that this provision accommodates this situation without a special provision for identity theft.

Comment: Some commenters asserted that the proposed rule's requirement that action must be taken on individuals' requests within 60 days of the receipt of the request was unreasonable and burdensome. A few commenters proposed up to three 30-day extensions for “extraordinary” (as defined by the entity) requests.

Response: We agree that 60 days will not always be a sufficient amount of time to adequately respond to these requests. Therefore, we have revised this provision to allow covered entities the option of a 30-day extension to deal with requests that require additional response time. However, we expect that 60 days will be adequate for most cases.

Comment: One commenter questioned whether a covered entity could ***82738** appropriately respond to a request by amending the record, without indicating whether it believes the information at issue is accurate and complete.

Response: An amendment need not include a statement by the covered entity as to whether the information is or is not accurate and complete. A covered entity may choose to amend a record even if it believes the information at issue is accurate and complete. If a request for amendment is accepted, the covered entity must notify the individual that the record has been amended.

This notification need not include any explanation as to why the request was accepted. A notification of a denied request, however, must contain the basis for the denial.

Comment: A few commenters suggested that when an amendment is made, the date should be noted. Some also suggested that the physician should sign the notation.

Response: We believe such a requirement would create a burden that is not necessary to protect individuals' interests, and so have not accepted this suggestion. We believe that the requirements of § 164.526(c) regarding actions a covered entity must take when accepting a request will provide an adequate record of the amendment. A covered entity may date and sign an amendment at its discretion.

Comment: The NPRM proposed that covered entities, upon accepting a request for amendment, make reasonable efforts to notify those persons the individual identifies, and other persons whom the covered entity knows have received the erroneous or incomplete information and who may have relied, or could foreseeably rely, on such information to the detriment of the individual. Many commenters argued that this notification requirement was too burdensome and should be narrowed. They expressed concern that covered entities would have to notify anyone who might have received the information, even persons identified by the individual with whom the covered entity had no contact. Other commenters also contended that this provision would require covered entities to determine the reliance another entity might place on the information and suggested that particular part of the notification requirements be removed. Another commenter suggested that the notification provision be eliminated entirely, believing that it was unnecessary.

Response: Although there is some associated administrative burden with this provision, we believe it is a necessary requirement to effectively communicate amendments of erroneous or incomplete information to other parties. The negative effects of erroneous or incomplete medical information can be devastating. This requirement allows individuals to exercise some control in determining recipients they consider important to be notified, and requires the covered entity to communicate amendments to other persons that the covered entity knows have the erroneous or incomplete information and may take some action in reliance on the erroneous or incomplete information to the detriment of the individual. We have added language to clarify that the covered entity must obtain the individual's agreement to have the amendment shared with the persons the individual and covered entity identifies. We believe these notification requirements appropriately balance covered entities' burden and individuals' interest in protecting the accuracy of medical information used to make decisions about them. We therefore retain the notification provisions substantially as proposed.

Comment: Some commenters argued against the proposed provision requiring a covered entity that receives a notice of amendment to notify its business associates, “as appropriate,” of necessary amendments. Some argued that covered entities should only be required to inform business associates of these changes if the amendment could affect the individual's further treatment, citing the administrative and financial burden of notifying all business associates of changes that may not have a detrimental effect on the patient. Other commenters suggested that covered entities should only be required to inform business associates whom they reasonably know to be in possession of the information.

Response: We agree with commenters that clarification is warranted. Our intent is that covered entities must meet the requirements of this rule with respect to protected health information they maintain, including protected health information maintained on their behalf by their business associates. We clarify this intent by revising the definition of designated record set (see § 164.501) to include records maintained “by or for” a covered entity. Section 164.526(e) requires a covered entity that is informed of an amendment made by another covered entity to incorporate that amendment into designated record sets, whether the designated record set is maintained by the covered entity or for the covered entity by a business associate. If a business associate maintains the record at issue on the covered entity's behalf, the covered entity must fulfill its requirement by informing the business associate of the amendment to the record. The contract with the business associate must require the business associate to incorporate any such amendments. (See § 164.504(e).)

Comment: Some commenters supported the proposal to require covered entities to provide notification of the covered entity's statement of denial and the individual's statement of disagreement in any subsequent disclosures of the information to which the dispute relates. They argued that we should extend this provision to prior recipients of disputed information who have relied on it. These commenters noted an inconsistency in the proposed approach, since notification of accepted amendments is provided to certain previous recipients of erroneous health information and to recipients of future disclosures. They contended there is not a good justification for the different treatment and believed that the notification standard should be the same, regardless of whether the covered entity accepts the request for amendment.

These commenters also recommended that the individual be notified of the covered entity's intention to rebut a statement of disagreement. They suggested requiring covered entities to send a copy of the statement of rebuttal to the individual.

Response: Where a request for amendment is accepted, the covered entity knows that protected health information about the individual is inaccurate or incomplete or the amendment is otherwise warranted; in these circumstances, it is reasonable to ask the covered entity to notify certain previous recipients of the information that reliance on such information could be harmful. Where, however, the request for amendment is denied, the covered entity believes that the relevant information is accurate and complete or the amendment is otherwise unacceptable. In this circumstance, the burden of prior notification outweighs the potential benefits. We therefore do not require notification of prior recipients.

We agree, however, that individuals should know how a covered entity has responded to their requests, and therefore add a requirement that covered entities also provide a copy of any rebuttal statements to the individual.

***82739 Section 164.528—Accounting of Disclosures of Protected Health Information**

Comment: Many commenters expressed support for the concept of the right to receive an accounting of disclosures. Others opposed even the concept. One commenter said that it is likely that some individuals will request an accounting of disclosures from each of his or her health care providers and payors merely to challenge the disclosures that the covered entity made.

Some commenters also questioned the value to the individual of providing the right to an accounting. One commenter stated that such a provision would be meaningless because those who deliberately perpetrate an abuse are unlikely to note their breach in a log.

Response: The final rule retains the right of an individual to receive an accounting of disclosures of protected health information. The provision serves multiple purposes. It provides a means of informing the individual as to which information has been sent to which recipients. This information, in turn, enables individuals to exercise certain other rights under the rule, such as the rights to inspection and amendment, with greater precision and ease. The accounting also allows individuals to monitor how covered entities are complying with the rule. Though covered entities who deliberately make disclosures in violation of the rule may be unlikely to note such a breach in the accounting, other covered entities may document inappropriate disclosures that they make out of ignorance and not malfeasance. The accounting will enable the individual to address such concerns with the covered entity.

We believe this approach is consistent with well-established privacy principles, with other law, and with industry standards and ethical guidelines. The July 1977 Report of the Privacy Protection Study Commission recommended that a health care provider should not disclose individually-identifiable information for certain purposes without the individual's authorization unless “an accounting of such disclosures is kept and the individual who is the subject of the information being disclosed can find out that the disclosure has been made and to whom.”[FN32] With certain exceptions, the Privacy Act (5 U.S.C. 552a) requires government agencies to “keep an accurate accounting of * * * the date, nature, and purpose of each disclosure of a record to any person or to another agency * * * and * * * the name and address of the person or agency to whom the disclosure is made.” The National Association of Insurance Commissioners' Health Information Privacy Model Act requires carriers to provide to individuals on request “information regarding disclosure of that individual's protected health information that is sufficient to exercise the right to amend the information.” We build on these standards in this final rule.

Comment: Many commenters disagreed with the NPRM's exception for treatment, payment, and health care operations. Some commenters wanted treatment, payment, and health care operations disclosures to be included in an accounting because they believed that improper disclosures of protected health information were likely to be committed by parties within the entity who have access to protected health information for treatment, payment, and health care operations related purposes. They suggested that requiring covered entities to record treatment, payment, and health care operations disclosures would either prevent improper disclosures or enable transgressions to be tracked.

One commenter reasoned that disclosures for treatment, payment, and health care operations purposes should be tracked since these disclosures would be made without the individual's consent. Others argued that if an individual's authorization is not required for a disclosure, then the disclosure should not have to be tracked for a future accounting to the individual.

One commenter requested that the provision be restated so that no accounting is required for disclosures "compatible with or directly related to" treatment, payment or health care operations. This comment indicated that the change would make § 164.515(a)(1) of the NPRM consistent with § 164.508(a)(2)(i)(A) of the NPRM.

Response: We do not accept the comments suggesting removing the exception for disclosures for treatment, payment, and health care operations. While including all disclosures within the accounting would provide more information to individuals about to whom their information has been disclosed, we believe that documenting all disclosures made for treatment, payment, and health care operations purposes would be unduly burdensome on entities and would result in accountings so voluminous as to be of questionable value. Individuals who seek treatment and payment expect that their information will be used and disclosed for these purposes. In many cases, under this final rule, the individual will have consented to these uses and disclosures. Thus, the additional information that would be gained from including these disclosures would not outweigh the added burdens on covered entities. We believe that retaining the exclusion of disclosures to carry out treatment, payment, and health care operations makes for a manageable accounting both from the point of view of entities and of individuals. We have conformed the language in this section with language in other sections of the rule regarding uses and disclosures to carry out treatment, payment, and health care operations. See § 164.508 and the corresponding preamble discussion regarding our decision to use this language.

Comments: A few commenters called for a record of all disclosures, including a right of access to a full audit trail where one exists. Some commenters stated while audit trails for paper records are too expensive to require, the privacy rule should not discourage audit trails, at least for computer-based records. They speculated that an important reason for maintaining a full audit trail is that most abuses are the result of activity by insiders. On the other hand, other commenters pointed out that an enormous volume of records would be created if the rule requires recording all accesses in the manner of a full audit trail.

One commenter supported the NPRM's reference to the proposed HIPAA Security Rule, agreeing that access control and disclosure requirements under this rule should be coordinated with the final HIPAA Security Rule. The commenter recommended that HHS add a reference to the final HIPAA Security Rule in this section and keep specific audit log and reporting requirements generic in the privacy rule.

Response: Audit trails and the accounting of disclosures serve different functions. In the security field, an audit trail is typically a record of each time a sensitive record is altered, how it was altered and by whom, but does not usually record each time a record is used or viewed. The accounting required by this rule provides individuals with information about to whom a disclosure is made. An accounting, as described in this rule, would not capture uses. To the extent that an audit trail would capture uses, consumers reviewing an audit trail may not be able to distinguish between ***82740** accesses of the protected health information for use and accesses for disclosure. Further, it is not clear the degree to which the field is technologically poised to provide audit trails. Some entities could provide audit trails to individuals upon their request, but we are concerned that many could not.

We agree that it is important to coordinate this provision of the privacy rule with the Security Rule when it is issued as a final rule.

Comments: We received many comments from researchers expressing concerns about the potential impact of requiring an accounting of disclosures related to research. The majority feared that the accounting provision would prove so burdensome that many entities would decline to participate in research. Many commenters believed that disclosure of protected health information for research presents little risk to individual privacy and feared that the accounting requirement could shut down research.

Some commenters pointed out that often only a few data elements or a single element is extracted from the patient record and disclosed to a researcher, and that having to account for so singular a disclosure from what could potentially be an enormous number of records imposes a significant burden. Some said that the impact would be particularly harmful to longitudinal studies, where the disclosures of protected health information occur over an extended period of time. A number of commenters suggested that we not require accounting of disclosures for research, registries, and surveillance systems or other databases unless the disclosure results in the actual physical release of the patient's entire medical record, rather than the disclosure of discrete elements of information contained within the record.

We also were asked by commenters to provide an exclusion for research subject to IRB oversight or research that has been granted a waiver of authorization pursuant to proposed § 164.510, to exempt "in-house" research from the accounting provision, and to allow covered entities to describe the type of disclosures they have made to research projects, without specifically listing each disclosure. Commenters suggested that covered entities could include in an accounting a listing of the various research projects in which they participated during the time period at issue, without regard to whether a particular individual's protected health information was disclosed to the project.

Response: We disagree with suggestions from commenters that an accounting of disclosures is not necessary for research. While it is possible that informing individuals about the disclosures made of their health information may on occasion discourage worthwhile activities, we believe that individuals have a right to know who is using their health information and for what purposes. This information gives individuals more control over their health information and a better base of knowledge from which to make informed decisions.

For the same reasons, we also do not believe that IRB or privacy board review substitutes for providing individuals the right to know how their information has been disclosed. We permit IRBs or privacy boards to determine that a research project would not be feasible if authorization were required because we understand that it could be virtually impossible to get authorization for archival research involving large numbers of individuals or where the location of the individuals is not easy to ascertain. While providing an accounting of disclosures for research may entail some burden, it is feasible, and we do not believe that IRBs or privacy boards would have a basis for waiving such a requirement. We also note that the majority of comments that we received from individuals supported including more information in the accounting, not less.

We understand that requiring covered entities to include disclosures for research in the accounting of disclosures entails some burden, but we believe that the benefits described above outweigh the burden.

We do not agree with commenters that we should exempt disclosures where only a few data elements are released or in the case of data released without individuals' names. We recognize that information other than names can identify an individual. We also recognize that even a few data elements could be clues to an individual's identity. The actual volume of information released is not an appropriate indicator of whether an individual could have a concern about privacy.

We disagree with comments that suggested that it would be sufficient to provide individuals with a general list of research projects to which information has been disclosed by the covered entity. We believe that individuals are entitled to a level of specificity about disclosures of protected health information about them and should know to which research projects their protected health information has been disclosed, rather than to which projects protected health information may have been disclosed. However, we have added a provision allowing for a summary accounting of recurrent disclosures. For multiple disclosures to the same recipient pursuant to a single authorization or for a single purpose permitted under the rule without authorization, the covered entity may provide a summary accounting addressing the series of disclosures rather than a detailed

accounting of each disclosure in the series. This change is designed to ease the burden on covered entities involved in longitudinal projects.

With regard to the suggestion that we exempt "in-house" research from the accounting provision, we note that only disclosures of protected health information must appear in an accounting.

Comments: Several commenters noted that disclosures for public health activities may be of interest to individuals, but add to the burden imposed on entities. Furthermore, some expressed fear that priority public health activities would be compromised by the accounting provision. One commenter from a health department said that covered entities should not be required to provide an accounting to certain index cases, where such disclosures create other hazards, such as potential harm to the reporting provider. This commenter also speculated that knowing protected health information had been disclosed for these public health purposes might cause people to avoid treatment in order to avoid being reported to the public health department.

A provider association expressed concern about the effect that the accounting provision might have on a non-governmental, centralized disease registry that it operates. The provider organization feared that individuals might request that their protected health information be eliminated in the databank, which would make the data less useful.

Response: As in the discussion of research above, we reject the contention that we should withhold information from individuals about where their information has been disclosed because informing them could occasionally discourage some worthwhile activities. We also believe that, on balance, individuals' interest in having broad access to this information outweighs concerns about the rare instances in which providing this information might raise concerns about harm to the person who made the disclosure. As we stated above, we believe that individuals have ***82741** a right to know who is using their health information and for what purposes. This information gives individuals more control over their health information and a better base of knowledge from which to make informed decisions.

Comment: We received many comments about the proposed time-limited exclusion for law enforcement and health oversight. Several commenters noted that it is nearly impossible to accurately project the length of an investigation, especially during its early stages. Some recommended we permit a deadline based on the end of an event, such as conclusion of an investigation. One commenter recommended amending the standard such that covered entities would never be required to give an accounting of disclosures to health oversight or law enforcement agencies. The commenter noted that there are public policy reasons for limiting the extent to which a criminal investigation is made known publicly, including the possibility that suspects may destroy or falsify evidence, hide assets, or flee. The commenter also pointed out that disclosure of an investigation may unfairly stigmatize a person or entity who is eventually found to be innocent of any wrongdoing.

On the other hand, many commenters disagreed with the exemption for recording disclosures related to oversight activities and law enforcement. Many of these commenters stated that the exclusion would permit broad exceptions for government purposes while holding disclosures for private purposes to a more burdensome standard.

Some commenters felt that the NPRM made it too easy for law enforcement to obtain an exception. They suggested that law enforcement should not be excepted from the accounting provision unless there is a court order. One commenter recommended that a written request for exclusion be dated, signed by a supervisory official, and contain a certification that the official is personally familiar with the purpose of the request and the justification for exclusion from accounting.

Response: We do not agree with comments suggesting that we permanently exclude disclosures for oversight or law enforcement from the accounting. We believe generally that individuals have a right to know who is obtaining their health information and for what purposes.

At the same time, we agree with commenters that were concerned that an accounting could tip off subjects of investigations. We have retained a time-limed exclusion period similar to that proposed in the NPRM. To protect the integrity of investigations,

in the final rule we require covered entities to exclude disclosures to a health oversight agency or law enforcement official for the time specified by that agency or official, if the agency or official states that including the disclosure in an accounting to the individual would be reasonably likely to impede the agency or official's activities. We require the statement from the agency or official to provide a specific time frame for the exclusion. For example, pursuant to a law enforcement official's statement, a covered entity could exclude a law enforcement disclosure from the accounting for a period of three months from the date of the official's statement or until a date specified in the statement.

In the final rule, we permit the covered entity to exclude the disclosure from an accounting to an individual if the agency or official makes the statement orally and the covered entity documents the statement and the identify of the agency or official that made the statement. We recognize that in urgent situations, agencies and officials may not be able to provide statements in writing. If the agency or official's statement is made orally, however, the disclosure can be excluded from an accounting to the individual for no longer than 30 days from the oral statement. For exclusions longer than 30 days, a covered entity must receive a written statement.

We believe these requirements appropriately balance individuals' rights to be informed of the disclosures of protected health information while recognizing the public's interest in maintaining the integrity of health oversight and law enforcement activities.

Comment: One commenter stated that under Minnesota law, providers who are mandated reporters of abuse are limited as to whom they may reveal the report of abuse (generally law enforcement authorities and other providers only). This is because certain abusers, such as parents, by law may have access to a victim's (child's) records. The commenter requested clarification as to whether these disclosures are exempt from the accounting requirement or whether preemption would apply.

Response: While we do not except mandatory disclosures of abuse from the accounting for disclosure requirement, we believe the commenter's concerns are addressed in several ways. First, nothing in this regulation invalidates or limits the authority or procedures established under state law providing for the reporting of child abuse. Thus, with respect to child abuse the Minnesota law's procedures are not preempted even though they are less stringent with respect to privacy. Second, with respect to abuse of persons other than children, we allow covered entities to refuse to treat a person as an individual's personal representative if the covered entity believes that the individual has been subjected to domestic violence, abuse, or neglect from the person. Thus, the abuser would not have access to the accounting. We also note that a covered entity must exclude a disclosure, including disclosures to report abuse, from the accounting for specified period of time if the law enforcement official to whom the report is made requests such exclusion.

Comment: A few comments noted the lack of exception for disclosures made to intelligence agencies.

Response: We agree with the comments and have added an exemption for disclosures made for national security or intelligence purposes under § 164.512(k)(2). Individuals do not have a right to an accounting of disclosures for these purposes.

Comment: Commenters noted that the burden associated with this provision would, in part, be determined by other provisions of the rule, including the definitions of “individually identifiable,” “treatment,” and “health care operations.” They expressed concern that the covered entity would have to be able to organize on a patient by patient basis thousands of disclosures of information, which they described as “routine.” These commenters point to disclosures for patient directory information, routine banking and payment processes, uses and disclosures in emergency circumstances, disclosures to next of kin, and release of admissions statistics to a health oversight agency.

Response: We disagree with the commenters that ambiguity in other areas of the rule increase the burden associated with maintaining an accounting. The definitions of treatment, payment, and health operations are necessarily broad and there is no accounting required for disclosures for these purposes. These terms cover the vast majority of routine disclosures for health care purposes. (See § 164.501 and the associated preamble for a discussion of changes made to these definitions.)

The disclosures permitted under § 164.512 are for national priority purposes, and determining whether a disclosure fits within the section is necessary before the disclosure can be ***82742** made. There is no additional burden, once such a determination is made, in determining whether it must be included in the accounting.

We agree with the commenters that there are areas where we can reduce burden by removing additional disclosures from the accounting requirement, without compromising individuals' rights to know how their information is being disclosed. In the final rule, covered entities are not required to include the following disclosures in the accounting: disclosures to the individual, disclosures for facility directories under § 164.510(a), or disclosures to persons assisting in the individual's care or for other notification purposes under § 164.510(b). For each of these types of disclosures, the individual is likely to already know about the disclosure or to have agreed to the disclosure, making the inclusion of such disclosures in the accounting less important to the individual and unnecessarily burdensome to the covered entity.

Comment: Many commenters objected to requiring business partners to provide an accounting to covered entities upon their request. They cited the encumbrance associated with re-contracting with the various business partners, as well as the burden associated with establishing this type of record keeping.

Response: Individuals have a right to know to whom and for what purpose their protected health information has been disclosed by a covered entity. The fact that a covered entity uses a business associate to carry out a function does not diminish an individual's right to know.

Comments: One commenter requested clarification as to how far a covered entity's responsibility would extend, asking whether an entity had to track only their direct disclosures or subsequent re-disclosures.

Response: Covered entities are required to account for their disclosures, as well as the disclosures of their business associates, of protected health information. Because business associates act on behalf of covered entities, it is essential that their disclosures be included in any accounting that an individual requests from a covered entity. Covered entities are not responsible, however, for the actions of persons who are not their business associates. Once a covered entity has accounted for a disclosure to any person other than a business associate, it is not responsible for accounting for any further uses or disclosures of the information by that other person.

Comments: Some commenters said that the accounting provision described in the NPRM was ambiguous and created uncertainty as to whether it addresses disclosures only, as the title would indicate, or whether it includes accounting of uses. They urged that the standard address disclosures only, and not uses, which would make implementation far more practicable and less burdensome.

Response: The final rule requires disclosures, not uses, to be included in an accounting. See § 164.501 for definitions of “use” and “disclosure.”

Comments: We received many comments from providers and other representatives of various segments of the health care industry, expressing the view that a centralized system of recording disclosures was not possible given the complexity of the health care system, in which disclosures are made by numerous departments within entities. For example, commenters stated that a hospital medical records department generally makes notations regarding information it releases, but that these notations do not include disclosures that the emergency department may make. Several commenters proposed that the rule provide for patients to receive only an accounting of disclosures made by medical records departments or some other central location, which would relieve the burden of centralizing accounting for those entities who depend on paper records and tracking systems.

Response: We disagree with commenters' arguments that covered entities should not be held accountable for the actions of their subdivisions or workforce members. Covered entities are responsible for accounting for the disclosures of protected health

information made by the covered entity, in accordance with this rule. The particular person or department within the entity that made the disclosure is immaterial to the covered entity's obligation. In the final rule, we require covered entities to document each disclosure that is required to be included in an accounting. We do not, however, require this documentation to be maintained in a central registry. A covered hospital, for example, could maintain separate documentation of disclosures that are made from the medical records department and the emergency department. At the time an individual requests an accounting, this documentation could be integrated to provide a single accounting of disclosures made by the covered hospital. Alternatively, the covered hospital could centralize its processes for making and documenting disclosures. We believe this provision provides covered entities with sufficient flexibility to meet their business needs without compromising individuals' rights to know how information about them is disclosed.

Comments: Commenters stated that the accounting requirements placed undue burden on covered entities that use paper, rather than electronic, records.

Response: We do not agree that the current reliance on paper records makes the accounting provision unduly burdensome. Covered entities must use the paper records in order to make a disclosure, and have the opportunity when they do so to make a notation in the record or in a separate log. We require an accounting only for disclosures for purposes other than treatment, payment, and health care operations. Such disclosures are not so numerous that they cannot be accounted for, even if paper records are involved.

Comments: The exception to the accounting provision for disclosures of protected health information for treatment, payment, and health care operations purposes was viewed favorably by many respondents. However, at least one commenter stated that since covered entities must differentiate between disclosures that require documentation and those that do not, they will have to document each instance when a patient's medical record is disclosed to determine the reason for the disclosure. This commenter also argued that the administrative burden of requiring customer services representatives to ask in which category the information falls and then to keep a record that they asked the question and record the answer would be overwhelming for plans. The commenter concluded that the burden of documentation on a covered entity would not be relieved by the stipulation that documentation is not required for treatment, payment, and health care operations.

Response: We disagree. Covered entities are not required to document every disclosure in order to differentiate those for treatment, payment, and health care operations from those for purposes for which an accounting is required. We require that, when a disclosure is made for which an accounting is required, the covered entity be able to produce an accounting of those disclosures upon request. We do not require a covered entity to be able to account for every disclosure. In addition, we believe that we have addressed many of the commenters' concerns by clarifying in the final rule that disclosures to the ***82743** individual, regardless of the purpose for the disclosure, are not subject to the accounting requirement.

Comments: An insurer explained that in the context of underwriting, it may have frequent and multiple disclosures of protected health information to an agent, third party medical provider, or other entity or individual. It requested we reduce the burden of accounting for such disclosures.

Response: We add a provision allowing for a summary accounting of recurrent disclosures. For multiple disclosures to the same recipient pursuant to a single authorization or for a single purpose permitted under the rule without authorization, the covered entity may provide a summary accounting addressing the series of disclosures rather than a detailed accounting of each disclosure in the series.

Comment: Several commenters said that it was unreasonable to expect covered entities to track disclosures that are requested by the individual. They believed that consumers should be responsible for keeping track of their own requests.

Other commenters asked that we specify that entities need not retain and provide copies of the individual's authorization to disclose protected health information. Some commenters were particularly concerned that if they maintain all patient information on a computer system, it would be impossible to link the paper authorization with the patient's electronic records.

Another commenter suggested we allow entities to submit copies of authorizations after the 30-day deadline for responding to the individual, as long as the accounting itself is furnished within the 30-day window.

Response: In the final rule we do not require disclosures to the individual to be included in the accounting. Other disclosures requested by the individual must be included in the accounting, unless they are otherwise excepted from the requirement. We do not agree that individuals should be required to track these disclosures themselves. In many cases, an authorization may authorize a disclosure by more than one entity, or by a class of entities, such as all physicians who have provided medical treatment to the individual. Absent the accounting, the individual cannot know whether a particular covered entity has acted on the authorization.

We agree, however, that it is unnecessarily burdensome to require covered entities to provide the individual with a copy of the authorization. We remove the requirement. Instead, we require the accounting to contain a brief statement describing the purpose for which the protected health information was disclosed. The statement must be sufficient to reasonably inform the individual of the basis for the disclosure. Alternatively, the covered entity may provide a copy of the authorization or a copy of the written request for disclosure, if any, under §§ 164.502(a)(2)(ii) or 164.512.

Comments: We received many comments regarding the amount of information required in the accounting. A few commenters requested that we include additional elements in the accounting, such as the method of transmittal and identity of the employee who accessed the information.

Other commenters, however, felt that the proposed requirements went beyond what is necessary to inform the individual of disclosures. Another commenter stated that if the individual's right to obtain an accounting extends to disclosures that do not require a signed authorization, then the accounting should be limited to a disclosure of the manner and purpose of disclosures, as opposed to an individual accounting of each entity to whom the protected health information was disclosed. An insurer stated that this section of the proposed rule should be revised to provide more general, rather than detailed, guidelines for accounting of disclosures. The commenter believed that its type of business should be allowed to provide general information regarding the disclosure of protected health information to outside entities, particularly with regard to entities with which the insurer maintains an ongoing, standard relationship (such as a reinsurer).

Response: In general, we have retained the proposed approach, which we believe strikes an appropriate balance between the individual's right to know to whom and for what purposes their protected health information has been disclosed and the burden placed on covered entities. In the final rule, we clarify that the accounting must include the address of the recipient only if the address is known to the covered entity. As noted above, we also add a provision allowing for a summary accounting of recurrent disclosures. We note that some of the activities of concern to commenters may fall under the definition of health care operations (see § 164.501 and the associated preamble).

Comment: A commenter asked that we limit the accounting to information pertaining to the medical record itself, as opposed to protected health information more generally. Similarly, commenters suggested that the accounting be limited to release of the medical record only.

Response: We disagree. Protected health information exists in many forms and resides in many sources. An individual's right to know to whom and for what purposes his or her protected health information has been disclosed would be severely limited if it pertained only to disclosure of the medical record, or information taken only from the record.

Comment: A commenter asked that we make clear that only disclosures external to the organization are within the accounting requirement.

Response: We agree. The requirement only applies to disclosures of protected health information, as defined in § 164.501.

Comment: Some commenters requested that we establish a limit on the number of times an individual could request an accounting. One comment suggested we permit individuals to request one accounting per year; another suggested two accountings per year, except in "emergency situations." Others recommended that we enable entities to recoup some of the costs associated with implementation by allowing the entity to charge for an accounting.

Response: We agree that covered entities should be able to defray costs of excessive requests. The final rule provides individuals with the right to receive one accounting without charge in a twelve-month period. For additional requests by an individual within a twelve-month period, the covered entity may charge a reasonable, cost-based fee. If it imposes such a fee, the covered entity must inform the individual of the fee in advance and provide the individual with an opportunity to withdraw or modify the request to avoid or reduce the fee.

Comment: In the NPRM, we solicited comments on the appropriate duration of the individual's right to an accounting. Some commenters supported the NPRM's requirement that the right exist for as long as the covered entities maintains the protected health information. One commenter, however, noted that most audit control systems do not retain data on activity for indefinite periods of time.

Other commenters noted that laws governing the length of retention of clinical records vary by state and by provider type and suggested that entities be allowed to adhere to state laws or policies established by professional organizations or accrediting bodies. Some commenters suggested that the ***82744** language be clarified to state that whatever minimum requirements are in place for the record should also guide covered entities in retaining their capacity to account for disclosures over that same time, but no longer.

Several commenters asked us to consider specific time limits. It was pointed out that proposed § 164.520(f)(6) of the NPRM set a six-year time limit for retaining certain information including authorization forms and contracts with business partners. Included in this list was the accounting of disclosures, but this requirement was inconsistent with the more open-ended language in § 164.515. Commenters suggested that deferring to this six-year limit would make this provision consistent with other record retention provisions of the standard and might relieve some of the burden associated with implementation. Other specific time frames suggested were two years, three years, five years, and seven years.

Another option suggested by commenters was to keep the accounting record for as long as entities have the information maintained and "active" on their systems. Information permanently taken off the covered entity's system and sent to "dead storage" would not be covered. One commenter further recommended that we not require entities to maintain records or account for prior disclosures for members who have "disenrolled."

Response: We agree with commenters who suggested we establish a specific period for which an individual may request an accounting. In the final rule, we provide that individuals have a right to an accounting of the applicable disclosures that have been made in the six-year period prior to a request for an accounting. We adopt this time frame to conform with the other documentation retention requirements in the rule. We also note that an individual may request, and a covered entity may then provide, an accounting of disclosures for a period of time less than six years from the date of the request. For example, an individual could request an accounting only of disclosures that occurred during the year prior to the request. In addition, we note that covered entities do not have to account for disclosures that occurred prior to the compliance date of this rule.

Comments: Commenters asked that we provide more time for entities to respond to requests for accounting. Suggestions ranged from 60 days to 90 days. Another writer suggested that entities be able to take up to three 30-day extensions from the original

30-day deadline. Commenters raised concerns about the proposed requirement that a covered health care provider or health plan act as soon as possible.

Response: We agree with concerns raised by commenters and in the final rule, covered entities are required to provide a requested accounting no later than 60 days after receipt of the request. We also provide for one 30 day extension if the covered entity is unable to provide the accounting within the standard time frame. We eliminate the requirement for a covered entity to act as soon as possible.

We recognize that circumstances may arise in which an individual will request an accounting on an expedited basis. We encourage covered entities to implement procedures for handling such requests. The time limitation is intended to be an outside deadline, rather than an expectation. We expect covered entities always to be attentive to the circumstances surrounding each request and to respond in an appropriate time frame.

Comment: A commenter asked that we provide an exemption for disclosures related to computer upgrades, when protected health information is disclosed to another entity solely for the purpose of establishing or checking a computer system.

Response: This activity falls within the definition of health care operations and is, therefore, excluded from the accounting requirement.

Section 164.530—Administrative Requirements

Section 164.530(a)—Designation of a Privacy Official and Contact Person

Comment: Many of the commenters on this topic objected to the cost of establishing a privacy official, including the need to hire additional staff, which might need to include a lawyer or other highly paid individual.

Response: We believe that designation of a privacy official is essential to ensure a central point of accountability within each covered entity for privacy-related issues. The privacy official is charged with developing and implementing the policies and procedures for the covered entity, as required throughout the regulation, and for compliance with the regulation generally. While the costs for these activities are part of the costs of compliance with this rule, not extra costs associated with the designation of a privacy official, we do anticipate that there will be some cost associated with this requirement. The privacy official role may be an additional responsibility given to an existing employee in the covered entity, such as an office manager in a small entity or an information officer or compliance official in a larger institution. Cost estimates for the privacy official are discussed in detail in the overall cost analysis.

Comment: A few commenters argued for more flexibility in meeting the requirement for accountability. One health care provider maintained that covered entities should be able to establish their own system of accountability. For example, most physician offices already have the patient protections incorporated in the proposed administrative requirements—the commenter urged that the regulation should explicitly promote the application of flexibility and scalability. A national physician association noted that, in small offices, in particular, responsibility for the policies and procedures should be allowed to be shared among several people. A major manufacturing corporation asserted that mandating a privacy official is unnecessary and that it would be preferable to ask for the development of policies that are designed to ensure that processes are maintained to assure compliance.

Response: We believe that a single focal point is needed to achieve the necessary accountability. At the same time, we recognize that covered entities are organized differently and have different information systems. We therefore do not prescribe who within a covered entity must serve as the privacy official, nor do we prohibit combining this function with other duties. Duties may be delegated and shared, so long as there is one point of accountability for the covered entity's policies and procedures and compliance with this regulation.

Comment: Some commenters echoed the proposal of a professional information management association that the regulation establish formal qualifications for the privacy official, suggesting that this should be a credentialed information management professional with specified minimum training standards. One commenter emphasized that the privacy official should be sufficiently high in management to have influence.

Response: While there may be some advantages to establishing formal qualifications, we concluded the disadvantages outweigh the advantages. Since the job of privacy official will differ substantially among organizations of varying size and function, specifying a single set of qualifications would sacrifice flexibility and scalability in implementation. ***82745**

Comment: A few commenters suggested that we provide guidance on the tasks of the privacy official. One noted that this would reduce the burden on covered entities to clearly identify those tasks during the initial HIPAA implementation phase.

Response: The regulation itself outlines the tasks of the privacy official, by specifying the policies and procedures required, and otherwise explaining the duties of covered entities. Given the wide variation in the function and size of covered entities, providing further detail here would unnecessarily reduce flexibility for covered entities. We will, however, provide technical assistance in the form of guidance on the various provisions of the regulation before the compliance date.

Comment: Some comments expressed concern that the regulation would require a company with subsidiaries to appoint a privacy official within each subsidiary. Instead they argued that the corporate entity should have the option of designating a single corporate official rather than one at each subsidiary.

Response: In the final regulation, we give covered entities with multiple subsidiaries that meet the definition of covered entities under this rule the flexibility to designate whether such subsidiaries are each a separate covered entity or are together a single covered entity. (See § 164.504(b) for the rules requiring such designation.) If only one covered entity is designated for the subsidiaries, only one privacy officer is needed. Further, we do not prohibit the privacy official of one covered entity from serving as the privacy official of another covered entity, so long as all the requirements of this rule are met for each such covered entity.

Section 164.530(b)—Training

Comment: A few commenters felt that the proposed provision was too stringent, and that the content of the training program should be left to the reasonable discretion of the covered entity.

Response: We clarify that we do not prescribe the content of the required training; the nature of the training program is left to the discretion of the covered entity. The scenarios in the NPRM preamble of potential approaches to training for different sized covered entities were intended as examples of the flexibility and scalability of this requirement.

Comment: Most commenters on this provision asserted that recertification/retraining every three years is excessive, restrictive, and costly. Commenters felt that retraining intervals should be left to the discretion of the covered entity. Some commenters supported retraining only in the event of a material change. Some commenters supported the training requirement as specified in the NPRM.

Response: For the reasons cited by the commenters, we eliminate the triennial recertification requirements in the final rule. We also clarify that retraining is not required every three years. Retraining is only required in the case of material changes to the privacy policies and procedures of the covered entity.

Comment: Several commenters objected to the burden imposed by required signatures from employees after they are trained. Many commenters suggested that electronic signatures be accepted for various reasons. Some felt that it would be less costly than manually producing, processing, and retaining the hard copies of the forms. Some suggested sending out the notice to the personal workstation via email or some other electronic format and having staff reply via email. One commenter suggested that the covered entity might opt to give web based training instead of classroom or some other type. The commenter indicated that

with web based training, the covered entity could record whether or not an employee had received his or her training through the use of a guest book or registration form on the web site. Thus, a physical signature should not be required.

Response: We agree that there are many appropriate mechanisms by which covered entities can implement their training programs, and therefore remove this requirement for signature. We establish only a general requirement that covered entities document compliance with the training requirement.

Comment: Some commenters were concerned that there was no proposed requirement for business associates to receive training and/or to train their employees. The commenters believed that if the business associate violated any privacy requirements, the covered entity would be held accountable. These commenters urged the Secretary to require periodic training for appropriate management personnel assigned outside of the component unit of the covered entity, including business associates. Other commenters felt that it would not be fair to require covered entities to impose training requirements on business associates.

Response: We do not have the statutory authority directly to require business associates to train their employees. We also believe it would be unnecessarily burdensome to require covered entities to monitor business associates' establishment of specific training requirements. Covered entities' responsibility for breaches of privacy by their business associates is described in §§ 164.504(e) and 164.530(f). If a covered entity believes that including a training requirement in one or more of its business associate contracts is an appropriate means of protecting the health information provided to the business associate, it is free to do so.

Comments: Many commenters argued that training, as well as all of the other administrative requirements, are too costly for covered entities and that small practices would not be able to bear the added costs. Commenters also suggested that HHS should provide training materials at little, or no, cost to the covered entity.

Response: For the final regulation, we make several changes to the proposed provisions. We believe that these changes address the issue of administrative cost and burden to the greatest extent possible, consistent with protecting the privacy of health information. In enforcing the privacy rule, we expect to provide general training materials. We also hope to work with professional associations and other groups that target classes of providers, plans and patients, in developing specialized material for these groups.

We note that, under long-standing legal principles, entities are generally responsible for the actions of their workforce. The requirement to train workforce members to implement the covered entity's privacy policies and procedures, and do such things as pass evidence of potential problems to those responsible, is in line with these principles. For example, the comments and our fact finding indicate that, today, many hospitals require their workforce members to sign a confidentiality agreement, and include confidentiality matters in their employee handbooks.

Section 164.530(c)—Safeguards

Comments: A few comments assert that the rule requires some institutions that do not have adequate resources to develop costly physical and technical safeguards without providing a funding mechanism to do so. Another comment said that the vague definitions of adequate and appropriate safeguards could be interpreted by HHS to require the purchase of new computer systems and reprogram many old ones. A few other comments suggested that the safeguards language was vague and asked for more specifics.

Response: We require covered entities to maintain safeguards adequate for their operations, but do not require that ***82746** specific technologies be used to do so. Safeguards need not be expensive or high-tech to be effective. Sometimes, it is an adequate safeguard to put a lock on a door and only give the keys to those who need access. As described in more detail in the preamble discussion of § 164.530, we do not require covered entities to guarantee the safety of protected health information against all assaults. This requirement is flexible and scalable to allow implementation of required safeguards at a reasonable cost.

Comments: A few commenters noted that once protected health information becomes non-electronic, by being printed for example, it escapes the protection of the safeguards in the proposed Security Rule. They asked if this safeguards requirement is intended to install similar security protections for non-electronic information.

Response: This provision is not intended to incorporate the provisions in the proposed Security regulation into this regulation, or to otherwise require application of those provisions to paper records.

Comments: Some commenters said that it was unclear what "appropriate" safeguards were required by the rule and who establishes the criteria for them. A few noted that the privacy safeguards were not exactly the same as the security safeguards, or that the "other safeguards" section was too vague to implement. They asked for more clarification of safeguards requirements and flexible solutions.

Response: In the preamble discussion of § 164.530, we provide examples of types of safeguards that can be appropriate to satisfy this requirement. Other sections of this regulation require specific safeguards for specific circumstances. The discussion of the requirements for "minimum necessary" uses and disclosures of protected health information includes related guidance for developing role-based access policies for a covered entity's workforce. The requirements for "component entities" include requirements for firewalls to prevent access by unauthorized persons. The proposed Security Rule included further details on what safeguards would be appropriate for electronic information systems. The flexibility and scalability of these rules allows covered entities to analyze their own needs and implement solutions appropriate for their own environment.

Comments: A few comments asked for a requirement for a firewall between a health care component and the rest of a larger organization as another appropriate safeguard.

Response: We agree, and have incorporated such a requirement in § 164.504.

Comments: One commenter agreed with the need for administrative, physical, and technical safeguards, but took issue with our specification of the type of documentation or proof that the covered entity is taking action to safeguard protected health information.

Response: This privacy rule does not require specific forms of proof for safeguards.

Comments: A few commenters asked that, for the requirement for a signed certification of training and the requirements for verification of identity, we consider the use of electronic signatures that meet the requirements in the proposed security regulation to meet the requirements of this rule.

Response: In this final rule, we drop the requirements for signed certifications of training. Signatures are required elsewhere in this regulation, for example, for a valid authorization. In the relevant sections we clarify that electronic signatures are sufficient provided they meet standards to be adopted under HIPAA. In addition, we do not intend to interfere with the application of the Electronic Signature in Global and National Commerce Act.

Comments: A few commenters requested that the privacy requirements for appropriate administrative, technical, and physical safeguards be considered to have been met if the requirements of the proposed Security Rule have been met. Others requested that the safeguards requirements of the final Privacy Rule mirror or be harmonized with the final Security Rule so they do not result in redundant or conflicting requirements.

Response: Unlike the proposed regulation, the final regulation covers all protected health information, not just information that had at some point been electronic. Thus, these commenters' assumption that the proposed Privacy Rule and the proposed Security Rule covered the same information is not the case, and taking the approach suggested by these comments would leave

a significant number of health records unprotected. The safeguards required by this regulation are appropriate for both paper and electronic information. We will take care to ensure that the final Security Rule works in tandem with these requirements.

Comments: One commenter requested that the final privacy rule be published before the final Security Rule, recognizing that the privacy policies must be in place before the security technology used to implement them could be worked out. Another commenter asked that the final Security Rule be published immediately and not wait for an expected delay while privacy policies are worked out.

Response: Now that this final privacy rule has been published in a timely manner, the final Security Rule can be harmonized with it and published soon.

Comments: Several commenters echoed an association recommendation that, for those organizations that have implemented a computer based patient record that is compliant with the requirements of the proposed Security Rule, the minimum necessary rule should be considered to have been met by the implementation of role-based access controls.

Response: The privacy regulation applies to paper records to which the proposed Security Rule does not apply. Thus, taking the approach suggested by these comments would leave a significant number of health records unprotected. Further, since the final Security Rule is not yet published and the number of covered entities that have implemented this type of computer-based patient record systems is still small, we cannot make a blanket statement. We note that this regulation requires covered entities to develop role-based access rules, in order to implement the requirements for "minimum necessary" uses and disclosures of protected health information. Thus, this regulation provides a foundation for the type of electronic system to which these comments refer.

Section 164.530(d)*—*Complaints to the Covered Entity

Comment: Several commenters felt that some form of due process is needed when it comes to internal complaints. Specifically, they wanted to be assured that the covered entity actually hears the complaints made by the individual and that the covered entity resolves the complaint within a reasonable time frame. Without due process the commenters felt that the internal complaint process is open ended. Some commenters wanted the final rule to include an appeals process for individuals if a covered entity's determination in regards to the complaint is unfavorable to the individual.

Response: We do not require covered entities to implement any particular due process or appeals process for complaints, because we are concerned about the burden this could impose on covered entities. We provide individuals with an alternative to take their complaints to the Secretary. We believe that this provides incentives for ***82747** covered entities to implement a complaint process that resolves complaints to individuals' satisfaction.

Comment: Some commenters felt that the individual making the complaint should exhaust all other avenues to resolve their issues before filing a complaint with the Secretary. A number of commenters felt that any complaint being filed with the Secretary should include documentation of the reviews done by the covered entity.

Response: We reject these suggestions, for two reasons. First, we want to avoid establishing particular process requirements for covered entities' complaint programs. Also, this rule does not require the covered entity to share any information with the complainant, only to document the receipt of the complaint and the resolution, if any. Therefore, we cannot expect the complainant to have this information available to submit to the Secretary. Second, we believe the individual making the complaint should have the right to share the complaint with the Secretary at any point in time. This approach is consistent with existing civil rights enforcement programs for which the Department is responsible. Based on that experience, we believe that most complaints will come first to covered entities for disposition.

Comment: Some commenters wanted the Department to prescribe a minimum amount of time before the covered entity could dispose of the complaints. They felt that storing these complaints indefinitely would be cumbersome and expensive.

Response: We agree, and in the final rule require covered entities to keep all items that must be documented, including complaints, for at least six years from the date of creation.

Comments: Some commenters objected to the need for covered entities to have at least one employee, if not more, to deal with complaints. They felt that this would be costly and is redundant in light of the designation of a contact person to receive complaints.

Response: We do not require assignment of dedicated staff to handle complaints. The covered entity can determine staffing based on its needs and business practices. We believe that consumers need one clear point of contact for complaints, in order that this provision effectively inform consumers how to lodge complaints and so that the compliant will get to someone who knows how to respond. The contact person (or office) is for receipt of complaints, but need not handle the complaints.

Section 164.530(e)—Sanctions

Comment: Commenters argued that most covered entities already have strict sanctions in place for violations of a patient's privacy, either due to current laws, contractual obligations, or good operating practices. Requiring covered entities to create a formal sanctioning process would be superfluous.

Response: We believe it is important for the covered entity to have these sanction policies and procedures documented so that employees are aware of what actions are prohibited and punishable. For entities that already have sanctions policies in place, it should not be problematic to document those policies. We do not define the particular sanctions that covered entities must impose.

Comment: Several commenters agreed that training should be provided and expectations should be clear so that individuals are not sanctioned for doing things that they did not know were wrong or inappropriate. A good faith exception should be included in the final rule to protect these individuals.

Response: We agree that employees should be trained to understand the covered entity's expectations and understand the consequences of any violation. This is why we are requiring each covered entity to train its workforce. However, we disagree that a good faith exception is explicitly needed in the final rule. We leave the details of sanctions policies to the discretion of the covered entity. We believe it is more appropriate to leave this judgment to the covered entity that will be familiar with the circumstances of the violation, rather than to specify such requirements in the regulation.

Comment: Some commenters felt that the sanctions need to reach business partners as well, not just employees of the covered entities. These commenters felt all violators should be sanctioned, including government officials and agencies.

Response: All members of a covered entity's workforce are subject to sanctions for violations, including government officials who are part of a covered entity's workforce. Requirements for addressing privacy violations by business associates are discussed in §§ 164.504(e) and 164.530(f).

Comments: Many commenters appreciated the flexibility left to the covered entities to determine sanctions. However, some were concerned that the covered entity would need to predict each type of violation and the associated sanction. They argue that, if the Department could not determine this in the NPRM, then the covered entities should be allowed to come up with sanctions as appropriate at the time of the violation. Some commenters wanted a better explanation and understanding of what HHS' expectation is of when is it appropriate to apply sanctions. Some commenters felt that the sanctioning requirement is nebulous and requires independent judgment of compliance; as a result it is hard to enforce. Offending individuals may use the vagueness of the standard as an defense.

Response: We agree with the commenters that argue that covered entities should be allowed to determine the specific sanctions as appropriate at the time of the violation. We believe it is more appropriate to leave this judgment to the covered entity, because the covered entity will be familiar with the circumstances of the violation and the best way to improve compliance.

Comment: A commenter felt that the self-imposition of this requirement is an inadequate protection, as there is an inherent conflict of interest when an entity must sanction one of its own.

Response: We believe it is in the covered entity's best interests to appropriately sanction those individuals who do not follow the outlined policies and procedures. Allowing violations to go unpunished may lead bigger problems later, and result in complaints being registered with the Department by aggrieved parties and/or an enforcement action.

Comment: This provision should cover all violations, not just repeat violations.

Response: We do not limit this requirement to repeat offenses.

Section 164.530(f)—Duty To Mitigate

Comments: A few commenters felt that any duty to mitigate would be onerous, especially for small entities. One commenter supported an affirmative duty to mitigate for employees of the covered entity, as long as there is no prescribed mitigation policy. One commenter stated that a requirement for mitigation is unnecessary because any prudent entity would do it.

Some practitioner organizations as well as a health plan, expressed concern about the obligation to mitigate in the context of the business associate relationship. Arguing that it is unnecessary for the regulation to explicitly extend the duty to mitigate to business associates, commenters noted that: Any prudent entity would discipline a vendor or employee that violates a regulation; that the matter is best left to the terms of the contract, and that it is difficult and expensive for a ***82748** business associate to have a separate set of procedures on mitigation for each client/provider. One commenter suggested that the federal government should fund the monitoring needed to administer the requirement.

Response: Eliminating the requirement to mitigate harm would undermine the purposes of this rule by reducing covered entities' accountability to their patients for failure to protect their confidential data. To minimize burden, we do not prescribe what mitigation policies and procedures must be implemented. We require only that the covered entity mitigate harm. We also assume that violations will be rare, and so the duty to mitigate harm will rarely be triggered. To the extent a covered entity already has methods for mitigating harm, this rule will not pose significant burden, since we don't require the covered entity to follow any prescribed method or set of rules.

We also modify the NPRM to impose the duty to mitigate only where the covered entity has actual knowledge of harm. Further reducing burden, the rule requires mitigation “to the extent practicable.” It does not require the covered entity to eliminate the harm unless that is practicable. For example, if protected health information is advertently provided to a third party without authorization in a domestic abuse situation, the covered entity would be expected to promptly contact the patient as well as appropriate authorities and apprize them of the potential danger.

The harm to the individual is the same, whether the privacy breach was caused by a member of the covered entity's workforce, or by a contractor. We believe the cost of this requirement to be minimal for covered entities that engage in prudent business practices for exchanging protected health information with their business associates.

Comment: A few commenters noted that it is difficult to determine whether a violation has resulted in a deleterious effect, especially as the entity cannot know all places to which information has gone and uses that have been made of it. Consequently, there should be a duty to mitigate even if a deleterious effect cannot be shown, because the individual has no other redress.

Response: As noted above, this provision only applies if the covered entity has actual knowledge of the harm, and requires mitigation "to the extent practicable." The covered entity is expected to take reasonable steps based on knowledge of where the information has been disclosed, how it might be used to cause harm to the patient or another individual, and what steps can actually have a mitigating effect in that specific situation.

Comments: Commenters stated that the language of the regulation was in some places vague and imprecise thus providing covered entities with insufficient guidance and allowing variation in interpretation. Commenters also noted that this could result in inconsistency in implementation as well as permitting such inconsistency to be used as a defense by an offending entity. Particular language for which at least one commenter requested clarification included "reasonable steps" and what is entailed in the duty to mitigate.

Response: We considered ways in which we might increase specificity, including defining "to the extent practicable" and "reasonable steps" and relating the mitigating action to the deleterious impact. While this approach could remove from the covered entity the burden of decision-making about actions that need to be taken, we believe that other factors outweighed this potential benefit. Not only would there be a loss of desirable flexibility in implementation, but it would not be possible to define "to the extent practicable" in a way that makes sense for all types of covered entities. We believe that allowing flexibility and judgment by those familiar with the circumstances to dictate the approach is the best approach to mitigating harm.

Section 164.530(g)—Refraining From Intimidating or Retaliatory Acts

Comment: Several commenters stated that the regulation should prohibit covered entities from engaging in intimidating or retaliatory acts against any person, not just against the "individual," as proposed. They suggested adding "or other person or entity" after "any individual."

Response: We agree, and allow any person to file a compliant with the Secretary. "Person" is not limited to natural persons, but includes any type of organization, association or group such as other covered entities, health oversight agencies and advocacy groups.

Comment: A few commenters suggested deleting this provision in its entirety. One commenter indicated that the whistleblower and retaliation provisions could be inappropriately used against a hospital and that the whistleblower's ability to report numerous violations will result in a dangerous expansion of liability. Another commenter stated that covered entities could not take action against an employee who had violated the employer's privacy provisions if this employee files a complaint with the Secretary.

Several commenters suggested deleting "in any manner" and "or opposing any act or practice made unlawful by this subpart" in § 164.522(d)(4). The commenters indicated that, as proposed, the rule would make it difficult to enforce compliance within the workforce. One commenter stated that the proposed 164.522(d)(4) "is extremely broad and may allow an employee to reveal protected health information to fellow employees, the media and others (e.g., an employee may show a medical record to a friend or relative before filing a complaint with the Department). This commenter further stated that covered entities will "absolutely be prevented from prohibiting such conduct." One commenter suggested adding that a covered entity may take disciplinary action against any member of its work force or any business partner who uses or discloses individually identifiable health information in violation of this subpart in any manner other than through the processes set forth in the regulation.

Response: To respond to these comments, we make several changes to the proposed provision.

First, where the activity does not involve the filing of a complaint under § 160.306 of this part or participation in an investigation or proceeding initiated by the government under the rule, we delete the phrase "in any manner" and add a requirement that the individual's opposition to "any act or practice" made unlawful by this subpart be in good faith, and that the expression of that opposition must be reasonable. Second, we add a requirement that the individual's opposition to "any act or practice" made unlawful by this subpart must not involve a disclosure of protected health information that is in violation of this subpart. Thus, the employee who discloses protected health information to the media or friends is not protected. In providing interpretations

of the retaliation provision, we will consider existing interpretations of similar provisions such as the guidance issued by EEOC in this regard.

Section 164.530(h)—Waiver of Rights

There are no comments directly about this section because it was not included in the proposed rule.

Section 164.530(i)—Policies and Procedures and § 164.530(j)—Documentation Requirements

Comments: Many of the comments to this provision addressed the costs and ***82749** complexity of the regulation as a whole, not the additional costs of documenting policies and procedures per se. Some did, either implicitly or explicitly, object to the need to develop and document policies and procedures as creating excessive administrative burden. Many of these commenters also asserted that there is a contradiction between the administrative burden of this provision and one of the statutory purposes of this section of the HIPAA to reduce costs through administrative simplification. Suggested alternatives were generally reliance on existing regulations and ethical standards, or on current business practices.

Response: A specific discussion of cost and burden is found in the Regulatory Impact Analysis of this final rule.

We do not believe there is a contradiction between the administrative costs of this provision and of the goal of administrative simplification. In the Administrative Simplification provisions of the HIPAA, Congress combined a mandate to facilitate the efficiencies and cost savings for the health care industry that the increasing use of electronic technology affords, with a mandate to improve privacy and confidentiality protections. Congress recognized, and we agree, that the benefits of electronic commerce can also cause increased vulnerability to inappropriate access and use of medical information, and so must be balanced with increased privacy protections. By including the mandate for privacy standards in section 264 of the HIPAA, Congress determined that existing regulations and ethical standards, and current business practices were insufficient to provide the necessary protections.

Congress mandated that the total benefits associated with administrative simplification must outweigh its costs, including the costs of implementing the privacy regulation. We are well within this mandate.

Comments: Several commenters suggested that the documentation requirements not be established as a standard under the regulation, because standards are subject to penalties. They recommend we delete the documentation standards and instead provide specific guidance and technical assistance. Several commenters objected to the suggestion in the NPRM that professional associations assist their members by developing appropriate policies for their membership. Several commentators representing professional associations believed this to be an onerous and costly burden for the associations, and suggested instead that we develop specific models which might require only minor modification. Some of these same associations were also concerned about liability issues in developing such guidelines. One commenter argued that sample forms, procedures, and policies should be provided as part of the Final Rule, so that practitioners would not be overburdened in meeting the demands of the regulations. They urged us to apply this provision only to larger entities.

Response: The purpose of requiring covered entities to develop policies and procedures for implementing this regulation is to ensure that important decisions affecting individuals' rights and privacy interests are made thoughtfully, not on an ad hoc basis. The purpose of requiring covered entities to maintain written documentation of these policies is to facilitate workforce training, and to facilitate creation of the required notice of information practices. We further believe that requiring written documentation of key decisions about privacy will enhance accountability, both within the covered entity and to the Department, for compliance with this regulation.

We do not include more specific guidance on the content of the required policies and procedures because of the vast difference in the size of covered entities and types of covered entities' businesses. We believe that covered entities should have the flexibility to design the policies and procedures best suited to their business and information practices. We do not exempt smaller entities,

because the privacy of their patients is no less important than the privacy of individuals who seek care from large providers. Rather, to address this concern we ensure that the requirements of the rule are flexible so that smaller covered entities need not follow detailed rules that might be appropriate for larger entities with complex information systems.

We understand that smaller covered entities may require some assistance, and intend to provide such technical assistance after publication of this rule. We hope to work with professional associations and other groups that target classes of providers, plans and patients, in developing specialized material for these groups. Our discussions with several such organizations indicate their intent to work on various aspects of model documentation, including forms. Because the associations' comments regarding concerns about liability did not provide sufficient details, we cannot address them here.

Comment: Many commenters discussed the need for a recognition of scalability of the policies and procedures of an entity based on size, capabilities, and needs of the participants. It was noted that the actual language of the draft regulations under § 164.520 did not address scalability, and suggested that some scalability standard be formally incorporated into the regulatory language and not rely solely on the NPRM introductory commentary.

Response: In § 164.530(i)(1) of the final rule, we specify that we require covered entities to implement policies and procedures that take into account the size of the covered entity and the types of activities that relate to protected health information undertaken by the covered entity.

Comment: One commenter objected to our proposal to allow covered entities to make uses or disclosures not permitted by their current notice if a compelling reason exists to make the use or disclosure and the entity documents the reasons and changes its policies within 30 days of the use or disclosure. The commenter argued that the subjective language of the regulation might give entities the ability to engage in post hoc justifications for violations of their own information practices and policies. The commenter suggested that there should be an objective standard for reviewing the covered entity's reasons before allowing the covered entity to amend its policies.

Response: We eliminate this provision from the final rule. The final rule requires each covered entity to include in its notice of information practices a statement of all permitted uses under this rule, not just those in which the covered entity actually engages in at the time of that notice.

Comment: Some commenters expressed concern that the required retention period in the NPRM applied to the retention of medical records.

Response: The retention requirement of this regulation only applies to the documentation required by the rule, for example, keeping a record of accounting for disclosures or copies of policies and procedures. It does not apply to medical records.

Comments: Comments on the six year retention period were mixed. Some commenters endorsed the six-year retention period for maintaining documentation. One of the comments stated this retention period would assist physicians legally. Other commenters believed that the retention period would be an undue burden. One commenter noted that most State Board of Pharmacy regulations require ***82750** pharmacies to keep records for two years, so the six year retention period would triple document retention costs.

Response: We established the retention period at six years because this is the statute of limitations for the civil monetary penalties. This rule does not apply to all pharmacy records, but only to the documentation required by this rule.

Section 164.530(k)—Group Health Plans

There were no comments directly about this section because it was not included in the proposed rule.

Section 164.532—Transition Provisions

Comment: Commenters urged the Department to clarify whether the "reach of the transition requirement" is limited to a particular time frame, to the provider's activities in a particular job, or work for a particular employer. For example, one commenter questioned how long a nurse is a covered entity after she moves from a job reviewing files with protected health information to an administrative job that does not handle protected health information; or whether an occupational health nurse who used to transmit first reports of injury to her company's workers' compensation carrier last year but no longer does so this year because of a carrier change still is a covered entity.

Response: Because this comment addresses a question of enforcement, we will address it in the enforcement regulation.

Comment: Several commenters sought clarification as to the application of the privacy rule to research already begun prior to the effective date or compliance date of the final rule. These commenters argued that applying the privacy rule to research already begun prior the rule's effective date would substantially overburden IRBs and that the resulting research interruptions could harm participants and threaten the reliability and validity of conclusions based upon clinical trial data. The commenters recommended that the rule grandfather in any ongoing research that has been approved by and is under the supervision of an IRB.

Response: We generally agree with the concerns raised by commenters. In the final rule, we have provided that covered entities may rely upon consents, authorizations, or other express legal permissions obtained from an individual for a specific research project that includes the treatment of individuals to use or disclose protected health information the covered entity obtained before or after the applicable compliance date of this rule as long as certain requirements are met. These consents, authorizations, or other express legal permissions may specifically permit a use or disclosure of individually identifiable health information for purposes of the project or be a general consent of the individual to participate in the project. A covered entity may use or disclose protected health information it created or received before or after the applicable compliance date of this rule for purposes of the project provided that the covered entity complies with all limitations expressed in the consent, authorization, or permission.

In regard to research projects that include the treatment of individuals, such as clinical trials, covered entities engaged in these projects will have obtained at least an informed consent from the individual to participate in the project. In some cases, the researcher may also have obtained a consent, authorization, or other express legal permission to use or disclose individually identifiable health information in a specific manner. To avoid disrupting ongoing research and because the participants have already agreed to participate in the project (which expressly permits or implies the use or disclosure of their protected health information), we have grandfathered in these consents, authorizations, and other express legal permissions.

It is unlikely that a research project that includes the treatment of individuals could proceed under the Common Rule with a waiver of informed consent. However, to the extent such a waiver has been granted, we believe individuals participating in the project should be able to determine how their protected health information is used or disclosed. Therefore, we require researchers engaged in research projects that include the treatment of individuals who obtained an IRB waiver of informed consent under the Common Rule to obtain an authorization or a waiver of such authorization from an IRB or a privacy board under § 164.512(i) of this rule.

If a covered entity obtained a consent, authorization, or other express legal permission from the individual who is the subject of the research, it would be able to rely upon that consent, authorization, or permission, consistent with any limitations it expressed, to use or disclose the protected health information it created or received prior to or after the compliance date of this regulation. If a covered entity wishes to use or disclose protected health information but no such consent, authorization, or permission exists, it must obtain an authorization pursuant to § 164.508 or obtain a waiver of authorization under § 164.512(i). To the extent such a project is ongoing and the researchers are unable to locate the individuals whose protected health information they are using or disclosing, we believe the IRB or privacy board under the criteria set forth in § 164.512(i) will be able to take that circumstance into account when conducting its review. In most instances, we believe this type of research will be able to obtain a waiver of authorization and be able to continue uninterrupted.

Comment: Several comments raised questions about the application of the rule to individually identifiable information created prior to (1) the effective date of the rule, and (2) the compliance dates of the rule. One commenter suggested that the rule should apply only to information gathered after the effective date of the final rule. A drug manufacturer asked what would be the effect of the rule on research on records compiled before the effective date of the rule.

Response: We disagree with the commenter's suggestion. The requirements of this regulation apply to all protected health information held by a covered entity, regardless of when or how the covered entity obtained the information. Congress required us to adopted privacy standards that apply to individually identifiable health information. While it limited the compliance date for health plans, covered health care providers, and healthcare clearinghouses, it did not provide similar limiting language with regard to individually identifiable health information. Therefore, uses and disclosures of protected health information made by a covered entity after the compliance date of this regulation must meet the requirements of these rules. Uses or disclosures of individually identifiable health information made prior to the compliance date are not affected; covered entities will not be sanctioned under this rule based on past uses or disclosures that are inconsistent with this regulation.

Consistent with the definition of individually identifiable health information in HIPAA, of which protected health information is a subset, we do not distinguish between protected health information in research records and protected health information in other records. Thus, a covered entity's research records are subject to this regulation to the extent they contain protected health information. ***82751**

Section 164.534—Effective Date and Compliance Date

Section 1175(b)(1)(A) of the Act requires all covered entities other than small health plans to comply with a standard or implementation specification "not later than 24 months after the date on which an initial standard or implementation specification is adopted or established"; section 1175(b)(1)(B) provides that small health plans must comply not later than 36 months after that date. The proposed rule provided, at proposed § 164.524 (which was titled "Effective date"), that a covered entity was required to be in compliance with the proposed subpart E not later than 24 months following the effective date of the rule, except that small health plans were required to be in compliance not later than 36 months following the effective date of the rule.

The final rules retain these dates in the text of Subpart E, but denominate them as "compliance dates," to distinguish the statutory dates from the date on which the rules become effective. The effective date of the final rules is 60 days following publication in the Federal Register.

Meaning of Effective Date

Comment: A number of commenters expressed confusion about the difference between the effective date of the rule and the effective date on which compliance was required (the statutory compliance dates set out at section 1175(b)(1), summarized above).

Response: The Department agrees that the title of proposed § 164.524 was confusing. Similar comments were received on the Transactions Rule. Those comments were addressed by treating the "effective date" of the rule as the date on which adoption takes effect (the "Effective Date" heading at the beginning of the preamble), while the dates provided for by section 1175(b)(1) of the statute were denominated as "compliance dates." These changes are reflected in the definition of "compliance date" in § 160.103 below (initially published as part of the Transactions Rule) and are also reflected at § 164.524 below. Section 164.524 below has also been reorganized to follow the organization of the analogous provisions of the Transactions Rule. The underlying policy, however, remains as proposed.

Extend the Compliance Date

Comment: Some commenters recommended that the compliance date be extended. A number of comments objected that the time frame for compliance with the proposed standards is unrealistically short. It was pointed out that providers and others would have

to do the following, among other things, prior to the applicable compliance date: assess their current systems and departments, determine which state laws were preempted and which were not, update and reprogram computer systems, train workers, create and implement the required privacy policies and procedures, and create or update contracts with business partners. One comment also noted that the task of coming into compliance during the same time period with the other regulations being issued under HIPAA would further complicate the task. These comments generally supported an extension of the compliance dates by one or more years. Other comments supported extending the compliance dates on the ground that the complexity of the tasks involved in implementing the regulation would be a heavy financial burden for providers and others, and that they should be given more time to comply, in order to spread the associated capital and workforce costs over a longer period. It was also suggested that there be provision for granting extensions of the compliance date, based on some criteria, such as a good faith effort to comply or that the compliance dates be extended to two years following completion of a "state-by-state preemption analysis" by the Department.

Response: The Secretary acknowledges that covered entities will have to make changes to their policies and procedures during the period between the effective date of the rules below and the applicable compliance dates. The delayed compliance dates which the statute provides for constitute a recognition of the fact changes will be required and are intended to permit covered entities to manage and implement these changes in an orderly fashion. However, because the time frames for compliance with the initial standards are established by statute, the Secretary has no discretion to extend them: Compliance is statutorily required "not later than" the applicable compliance date. Nor do we believe that it would be advisable to accomplish this result by delaying the effective date of the final rules beyond 60 days. Since the Transactions Rule is now in effect, it is imperative to bring the privacy protections afforded by the rules below into effect as soon as possible. Retaining the delayed effective date of 60 days, as originally contemplated, will minimize the gap between transactions covered by those rules and not also afforded protection under the rules below.

Phase-in Requirements

Comment: Several comments suggested that the privacy standards be phased in gradually, to ease the manpower and cost burdens of compliance. A couple of equipment manufacturing groups suggested that updating of various types of equipment would be necessary for compliance purposes, and suggested a phased approach to this—for example, an initial phase consisting of preparation of policies, plans, and risk assessments, a second phase consisting of bringing new equipment into compliance, and a final phase consisting of bringing existing equipment into compliance.

Response: As noted in the preceding response, section 1175(b)(1) does not allow the Secretary discretion to change the time frame within which compliance must be achieved. Congress appears to have intended the phasing in of compliance to occur during the two-year compliance period, not thereafter.

Compliance Gap Vis-a2-Vis State Laws and Small Health Plans

Comment: Several comments stated that, as drafted, the preemption provisions would be effective as of the rule's effective date (i.e., 60 days following publication), even though covered entities would not be required to comply with the rules for at least another two years. According to these comments, the "preempted" state laws would not be in effect in the interim, so that the actual privacy protection would decrease during that period. A couple of comments also expressed concern about how the preemption provisions would work, given the one-year difference in applicable compliance dates for small health plans and other covered entities. A state medical society pointed out that this gap would also be very troublesome for providers who deal with both "small health plans" and other health plans. One comment asked what entities that decided to come into compliance early would have to do with respect to conflicting state laws and suggested that, since all parties "need to know with confidence which laws govern at the moment, * * * [t]here should be uniform effective dates."

Response: We agree that clarification is needed with respect to the applicability of state laws in the interim between the effective date and the compliance dates. What the comments summarized above appeared to assume is that the preemption provisions of section 1178 operate to broadly and generally invalidate any state law that comes within their ambit. We do not agree that

this is the effect of section ***82752** 1178. Rather, what section 1178 does—where it acts to preempt—is to preempt the state law in question with respect to the actions of covered entities to which the state law applies. Thus, if a provision of state law is preempted by section 1178, covered entities within that state to which the state law applies do not have to comply with it, and must instead comply with the contrary federal standard, requirement, or implementation specification. However, as compliance with the contrary federal standard, requirement, or implementation specification is not required until the applicable compliance date, we do not view the state law in question as meeting the test of being "contrary." That is, since compliance with the federal standard, requirement, or implementation standard is not required prior to the applicable compliance date, it is possible for covered entities to comply with the state law in question. See § 160.202 (definition of "contrary"). Thus, since the state law is not "contrary" to an applicable federal standard, requirement, or implementation specification in the period before which compliance is required, it is not preempted.

Several implications of this analysis should be spelled out. First, one conclusion that flows from this analysis is that preemption is specific to covered entities and does not represent a general invalidation of state law, as suggested by many commenters. Second, because preemption is covered entity-specific, preemption will occur at different times for small health plans than it will occur for all other covered entities. That is, the preemption of a given state law for a covered entity, such as a provider, that is covered by the 24-month compliance date of section 1175(b)(1)(A) will occur 12 months earlier than the preemption of the same state law for a small health plan that is covered by the 36-month compliance date of section 1175(b)(1)(B). Third, the preemption occurs only for covered entities; a state law that is preempted under section 1178(a)(1) would not be preempted for persons and entities to which it applies who are not covered entities. Thus, to the extent covered entities or non-covered entities follow the federal standards on a voluntary basis (i.e., the covered entity prior to the applicable compliance date, the non-covered entity at any time), the state law in question will not be preempted for them.

Small Health Plans

Comment: Several comments, pointing to the "Small Business" discussion in the preamble to the proposed rules, applauded the decision to extend the compliance date to three years for small businesses. It was requested that the final rules clarify that the three year compliance date applies to small doctors offices and other small entities, as well as to small health plans.

Response: We recognize that our discussion in the preamble to the proposed rules may have suggested that more covered entities came within the 36 month compliance date than is in fact the case. Again, this is an area in which we are limited by statute. Under section 1175(b) of the Act, only small health plans have three years to come into compliance with the standards below. Thus, other "small businesses" that are covered entities must comply by the two-year compliance date.

Coordination With the Security Standard

Comment: Several comments suggested that the security standard be issued either with or after the privacy standards. It was argued that both sets of standards deal with protecting health information and will require extensive personnel training and revisions to business practices, so that coordinating them would make sense. An equipment manufacturers group also pointed out that it would be logical for covered entities and their business partners to know what privacy policies are required in purchasing security systems, and that "the policies on privacy are implemented through the security standards rather than having already finalized security standards drive policy."

Response: We agree with these comments, and are making every effort to coordinate the final security standards with the privacy standards below. The privacy standards below are being published ahead of the security standards, which is also responsive to the stated concerns.

Prospective Application

Comment: Several comments raised questions about the application of the rule to individually identifiable information created prior to (1) the effective date of the rule, and (2) the compliance dates of the rule. One provider group suggested that the rule

should apply only to information gathered after the effective date of the final rule. A drug manufacturer asked what would be the effect of the rule on research on records compiled before the effective date of the rule.

Response: These comments are addressed in connection with the discussion of § 164.532 above.

Impact Analyses

Cost/Benefit Analysis

Comment: Many commenters made general statements to the effect that the cost estimates for implementing the provisions of the proposed regulation were incomplete or greatly understated.

Response: The proposal, including the cost analysis, is, in effect, a first draft. The purpose of the proposal was to solicit public comment and to use those comments to refine the final regulation. As a result of the public comment, the Department has significantly refined our initial cost estimates for implementing this regulation. The cost analysis below reflects a much more complete analysis of the major components of the regulation than was presented in the proposal.

Comment: Numerous commenters noted that significant areas of potential cost had not been estimated and that if they were estimated, they would greatly increase the total cost of the regulation. Potential cost areas identified by various respondents as omitted from the analyses include the minimum disclosure requirements; the requisite monitoring by covered entities of business partners with whom they share private health information; creation of de-identified information; internal complaint processes; sanctions and enforcement; the designation of a privacy official and creation of a privacy board; new requirements for research/optional disclosures; and future litigation costs.

Response: We noted in the proposed rule that we did not have data from which to estimate the costs of many provisions, and solicited comments providing such data. The final analysis below reflects the best estimate possible for these areas, based on the information available. The data and the underlying assumptions are explained in the cost analysis section below.

Comment: A number of comments suggested that the final regulation be delayed until more thorough analyses could be undertaken and completed. One commenter stated that the Department should refrain from implementing the regulation until a more realistic assessment of costs could be made and include local governments in the process. Similarly, a commenter requested that the Department assemble an outside panel of health industry experts, including systems analysts, legal counsel, and management consultants to develop stronger estimates.

Response: The Department has engaged in extensive research, data collection and fact-finding to improve ***82753** the quality of its economic analysis. This has included comments from and discussions with the kinds of experts one commenter suggested. The estimates represent a reasonable assessment of the policies proposed.

Comment: Several commenters indicated that the proposed regulation would impose significant new costs on providers' practices. Furthermore, they believe that it runs counter to the explicit statutory intent of HIPAA's Administrative Simplification provisions which require that "any standard adopted * * * shall be consistent with the objective of reducing the administrative costs of providing and paying for health care."

Response: As the Department explained in the Transactions Rule, this provision applies to the administrative simplification regulations of HIPAA in the aggregate. The Transactions Rule is estimated to save the health care system $29.9 billion in nominal dollars over ten years. Other regulations published pursuant to the administrative simplification authority in HIPAA, including the privacy regulation, will result in costs, but these costs are within the statutory directive so long as they do not exceed the $29.9 billion in estimated savings. Furthermore, as explained in the Transactions Rule, and the preamble to this rule, assuring privacy is essential to sustaining many of the advances that computers will provide. If people do not have confidence

that their medical privacy will be protected, they will be much less likely to allow their records to be used for any purpose or might even avoid obtaining necessary medical care.

Comment: Several commenters criticized the omission of aggregate, quantifiable benefit estimates in the proposed rule. Some respondents argued that the analysis in the proposed rule used "de minimis" cost estimates to argue only that benefits would certainly exceed such a low barrier. These commenters further characterized the benefits analysis in the Notice of Proposed Rulemaking as "hand waving" used to divert attention from the fact that no real cost-benefit comparison is presented. Another commenter stated that the benefit estimates rely heavily on anecdotal and unsubstantiated inferences. This respondent believes that the benefit estimates are based on postulated, but largely unsubstantiated causal linkages between increased privacy and earlier diagnosis and medical treatment.

Response: The benefits of privacy are diffused and intangible but real. Medical privacy is not a good people buy or sell in a market; therefore, it is very difficult to quantify. The benefits discussion in the proposal reflects this difficulty. The examples presented in the proposal were meant to be illustrative of the benefits based on a few areas of medicine where some relevant data was available. Unfortunately, no commenters provided either a better methodological approach or better data for assessing the overall benefits of privacy. Therefore, we believe the analysis in the proposal represents a valid illustration of the benefits of privacy, and we do not believe it is feasible to provide an overall dollar estimate of the benefits of privacy in the aggregate.

Comment: One commenter criticized the benefit analysis as being incomplete because it did not consider the potential cost of new treatments that might be engendered by increased confidence in medical privacy resulting from the regulation.

Response: There is no data or model to reliably assess such long-term behavioral and scientific changes, nor to determine what portion of the increasingly rapid evolution of new improved treatments might stem from improved privacy protections. Moreover, to be complete, such analysis would have to include the savings that might be realized from earlier detection and treatment. It is not possible at this time to project the magnitude or even the direction of the net effects of the response to privacy that the commenter suggests.

Scope of the Regulation

Comment: Numerous commenters noted the potential cost and burden of keeping track in medical records of information which had been transmitted electronically, which would be subject to the rule, as opposed to information that had only been maintained in paper form.

Response: This argument was found to have considerable merit and was one of the reasons that the Department concluded that the final regulation should apply to all medical records maintained by covered entities, including information that had never been transmitted electronically. The costs analysis below reflects the change in scope.

Notice Requirements

Comment: Several commenters expressed their belief that the administrative and cost burdens associated with the notice requirements were understated in the proposed rule. While some respondents took issue with the policy development cost estimates associated with the notice, more were focused on its projected implementation and production costs. For example, one respondent stated that determining "first service" would be an onerous task for many small practices, and that provider staff will now have to manually review each patient's chart or access a computer system to determine whether the patient has been seen since implementation of the rule.

Response: The policy in the final rule has been changed to make the privacy policy notice to patients less burdensome. Providers will be able to distribute the notice when a patient is seen and will not have to distribute it to a patient more than once, unless substantive changes are made in the notice. This change will significantly reduce the cost of distributing the privacy notices.

Comment: Some commenters also took issue with the methodology used to calculate the cost estimates for notices. These respondents believe that the survey data used in the proposed rule to estimate the costs (i.e., "encounters," "patients," and "episodes" per year) are very different concepts that, when used together, render the purported total meaningless. Commenters further stated that they can verify the estimate of 543 million patients cited as being seen at least once every five years.

Response: In the course of receiving treatment, a patient may go to a number of medical organizations. For example, a person might see a doctor in a physician's office, be admitted to a hospital, and later go to a pharmacy for medication. Each time a person "encounters" a facility, a medical record may be started or additions made to an existing record. The concept in the proposal was to identify the number of record sets that a person might have for purposes of estimating notice and copying costs. For example, whether a person made one or ten visits in the course of a year to a specific doctor would, for our purposes, be one record set because in each visit the doctor would most likely be adding information to an existing medical record. The comments demonstrated that we had not explained the concept well. As explained below we modified the concept to more effectively measure the number of record sets that exist and explain it more clearly.

Comment: Several commenters criticized the lack of supporting evidence for the cost estimates of notice development and dissemination. Another opinion voiced in the comments is that the estimated cost for plans of $0.75 per insured person is so low that it may cover postage, but it ***82754** cannot include labor and capital usage costs.

Response: Based on comments and additional fact finding, the Department was able to gain a better understanding of how covered entities would develop policies and disseminate information. The cost analysis below explains more fully how we derived the final cost estimates for these areas.

Comment: A commenter noted that privacy policy costs assume that national associations will develop privacy policies for members but HHS analysis does not account for the cost to the national associations. A provider cost range of $300-$3,000 is without justification and seems low.

Response: The cost to the national associations was included in the proposal estimates, and it is included in the final analysis (see below).

Comment: A commenter states that the notice costs discussion mixes the terms "patients", "encounters" and "episodes" and 397 million encounter estimate is unclear.

Response: A clearer explanation of the concepts employed in this analysis is provided below.

Systems Compliance Costs

Comment: Numerous commenters questioned the methodology used to estimate the systems compliance cost and stated that the ensuing cost estimates were grossly understated. Some stated that the regulation will impose significant information technology costs to comply with requirement to account for disclosures, additional costs for hiring new personnel to develop privacy policies, and higher costs for training personnel.

Response: Significant comments were received regarding the cost of systems compliance. In response, the Department retained the assistance of consultants with extensive expertise in health care information technology. We have relied on their work to revise our estimates, as described below. The analysis does not include "systems compliance" as a cost item, per se. Rather, in the final analysis we organized estimates around the major policy provisions so the public could more clearly see the costs associated with them. To the extent that the policy might require systems changes (and a number of them do), we have incorporated those costs in the provision's estimate.

Comment: Items explicitly identified by commenters as significantly adding to systems compliance costs include tracking disclosures of protected health information and patient authorizations; restricting access to the data; accommodating minimum

disclosure provisions; installing notices and disclaimers; creating de-identified data; tracking uses of protected health information by business partners; tracking amendments and corrections; increased systems capacity; and annual systems maintenance. The commenters noted that some of the aforementioned items are acknowledged in the proposed rule as future costs to covered entities, but several others are singularly ignored.

Response: The Department recognizes the validity of much of this criticism. Unfortunately, other than general criticism, commenters provided no specific data or methodological information which might be used to improve the estimates. Therefore, the Department retained consultants with extensive expertise in these areas to assess the proposed regulation, which helped the Department refine its policies and cost estimates.

In addition, it is important to note that the other HIPAA administrative simplification regulations will require systems changes. As explained generally in the cost analysis for the electronic Transactions rule, it is assumed that providers and vendors will undertake systems changes for these regulations collectively, thereby minimizing the cost of changes.

Inspection and Copying

Comment: Numerous commenters disagreed with the cost estimates in the NPRM for inspection and copying of patient records, believing that they were too low.

Response: The Department has investigated the potential costs through a careful reading of the comments and subsequent factfinding discussions with a variety of providers. We believe the estimates, explained more fully below, represent a reasonable estimate in the aggregate. It is important to note, however, that this analysis is not measuring the cost of all inspection and copying because a considerable amount of this already occurs. The Department is only measuring the incremental increase likely to occur as a result of this regulation.

Comment: One commenter speculates that, even at a minimum charge of $.50/page, (and not including search and retrieval charges), costs could run as high as $450 million annually.

Response: The $0.50 per page in the proposal represent an average of several data sources. Subsequently, an industry commenter, which provided extensive medical records copying, stated that this was a reasonable average cost. Hence, we retained the number for the final estimate.

Comment: One respondent states that, since the proposed rules give patients the right to inspect and copy their medical records regardless of storage medium, HHS must make a distinction in its cost estimates between records stored electronically and those which must be accessed by manual means, since these costs will differ.

Response: The cost estimates made for regulations are not intended to provide such refined gradations; rather, they are intended to show the overall costs for the regulation as a whole and its major components. For inspections and copying (and virtually all other areas for which estimates are made) estimates are based on averages; particular providers may experience greater or lesser costs than the average cost used in this analysis.

Comment: Several commenters noted that the Department did not appear to include the cost of establishing storage systems, retrieval fees and the cost of searching for records, and that these costs, if included, would significantly increase the Department's estimate.

Response: Currently, providers keep and maintain medical records and often provide copies to other providers and patients. Therefore, much of the cost of maintaining records already exists. Indeed, based on public comments, the Department has concluded that there will be relatively few additional copies requested as the result of this regulation (see below). We have measured and attributed to this regulation the incremental cost, which is the standard for conducting this kind of analysis.

Comment: A federal agency expressed concern over the proposal to allow covered entities to charge a fee for copying personal health information based on reasonable costs. The agency requests personal health information from many covered entities and pays a fee that it establishes. Allowing covered entities to establish the fee, the agency fears, may cost them significantly more than the current amounts they pay and as a result, could adversely affect their program.

Response: The proposal and the final rule establish the right to access and copy records only for individuals, not other entities; the "reasonable fee" is only applicable to the individual's request. The Department's expectation is that other existing practices regarding fees, if any, for the exchange of records not requested by an individual will not be affected by this rule. ***82755**

Appending Records (Amendment and Correction)

Comment: The proposed rule estimated the cost of amending and correcting patients' records at $75 per instance and $260 million per year for small entities. At least one commenter stated that such requests will rise significantly upon implementation of the regulations and increase in direct proportion to the number of patients served. Another commenter described the more subtle costs associated with record amendment and correction, which would include a case-by-case clinical determination by providers on whether to grant such requests, forwarding the ensuing record changes to business partners, and issuing written statements to patients on the reasons for denials, including a recourse for complaints.

Response: The comments were considered in revising the proposal, and the decision was made to clarify in the final regulation that providers must only append the record (the policy is explained further in the preamble and the regulation text). The provider is now only required to note in the medical record any comments from the patient; they may, but are not required to, correct any errors. This change in policy significantly reduces the cost from the initial proposal estimate.

Comment: Several commenters criticized the proposed rule's lack of justification for assumptions regarding the percentage of patients who request inspection and copying, who also request amendment and correction. Another commenter pointed out that the cost estimate for amendment and correction is dependent on a base assumption that only 1.5 percent of patients will request inspection of their records. As such, if this estimate were too low by just one percentage point, then the estimates for inspection and copying plus the costs for amendment and correction could rise by 67 percent.

Response: Based on information and data received in the public comments, the estimate for the number of people requesting inspection and copying has been revised. No commenter provided specific information on the number of amended record requests that might result, but the Department subsequently engaged in fact-finding and made appropriate adjustments in its estimates. The revisions are explained further below.

Consent and Authorizations

Comment: One respondent indicated that the development, collection, and data entry of all the authorizations will create a new transaction type for employers, health plans, and providers, and result in duplicated efforts among them. This commenter estimates that the costs of mailing, re-mailing, answering inquiries, making outbound calls and performing data entry in newly created authorization computer systems could result in expenses of close to $2.0 billion nationally. Another commenter indicated that authorization costs will be at least double the notice dissemination costs due to the cost of both outbound and return postage.

Response: Public commenters and subsequent factfinding clearly indicate that most providers with patient contact already obtain authorizations for release of records, so for them there is virtually no new cost. Further, this comment does not reflect the actual regulatory requirement. For example, there is no need to engage in mailing and re-mailing of forms, and we do not foresee any reason why there should be any significant calls involved.

Comment: A commenter criticized the percentage (1%) that we used to calculate the number of health care encounters expected to result in requests to withhold the release of protected information. This respondent postulates that even if one in six patients

who encounter the U.S. health care system opt to restrict access to their records, the total expected national cost per year could rise to $900 million.

Response: The final regulation requirements regarding the release of protected health information has been substantially changed, thereby greatly reducing the potential cost burden. A fuller explanation of the cost is provided below in the regulatory impact analysis.

Comment: An additional issue raised by commenters was the added cost of seeking authorizations for health promotion and disease management activities, health care operations that traditionally did not require such action.

Response: In the final regulation, a covered entity can use medical information collected for treatment or operations for its own health promotion and disease management efforts without obtaining additional authorization. Therefore, there is no additional cost incurred.

Business Associates

Comment: A number of commenters were concerned about the cost of monitoring business partners. Specifically, one commenter stated that the provisions of the proposed regulation pertaining to business partners would likely force the discontinuation of outsourcing for some functions, thereby driving up the administrative cost of health care.

Response: The final regulation clarifies the obligations of the business associates in assuring privacy. As explained in the preamble, business associates must take reasonable steps to assure confidentiality of health records they may have, and the covered entity must take appropriate action if they become aware of a violation of the agreement they have with the business associate. This does not represent an unreasonable burden; indeed, the provider is required to take the same kind of precautions and provide the same kind of oversight that they would in many other kinds of contractual relationships to assure they obtain the quality and level of performance that they would expect from a business associate.

Comment: HHS failed to consider enforcement costs associated with monitoring partners and litigation costs arising from covered entities seeking restitution from business partners whose behavior puts the covered entity at risk for noncompliance.

Response: The Department acknowledged in the proposal that it was not estimating the cost of compliance with the business associates provision because of inadequate information. It requested information on this issue, but no specific information was provided in the comments. However, based on revisions in the final policy and subsequent factfinding, the Department has provided an estimate for this requirement, as explained below.

Training

Comment: Many of the commenters believe that the Department used unrealistic assumptions in the development of the estimated cost of the training provisions and they provided their own estimates.

Response: The commenters' estimates varied widely, and could not be used by the Department in revising its analysis because there was inadequate explanation of how the estimates were made.

Comment: Several commenters argued that if even an hour of time of each of the entity's employees is spent on training instead of “work” and they are paid the minimum wage, an entity would incur $100 of cost for training no more than 20 employees. The commenters noted that the provision of health care services is a labor-intensive enterprise, and many covered entities have thousands of employees, most of whom make well in excess of minimum ***82756** wage. They questioned whether the estimates include time taken from the employee's actual duties (opportunity cost) and the cost of a trainer and materials.

Response: As explained in more detail below, the Department made extensive revisions in its training estimate, including the number of workers in the health care sector, the cost of workers in training based on average industry wages, and training costs (instructors and materials). The revised estimate is a more complete and accurate estimate of the costs likely to be borne as a result of the final regulation.

Comment: One commenter estimated that simply training an employee could have a burdensome impact on his company. He argued, for example, a 10-hour annual requirement takes 0.5% of an employee's time if they work a 2000-hour year, but factoring in sick and vacation leave, the effects of industry turnover could significantly increase the effect.

Response: In the analysis below, the Department has factored in turnover rates, employment growth and greater utilization based on data obtained from broad-based surveys and a public comment.

Comment: Some commenters felt that the regulatory training provisions are overly burdensome. Specific concerns centered around the requirement to train all individuals who may come in contact with protected health information and the requirement to have such individuals sign a new certifying statement at least every three years. Some commenters felt that the content of the training program should be left to the discretion of the covered entity.

Response: Changes and clarifications in the training requirements are made in the final regulation, explained below. For example, the certification requirement has been eliminated. As in the NPRM, the content of the training program is left to the discretion of the covered entity. These changes are expected to lessen the training burden and are reflected in the final cost estimates.

Compliance and Enforcement

Comment: A Member of Congress and a number of privacy and consumer groups expressed their concern with whether the Office for Civil Rights (OCR) in HHS has adequate funding to carry out the major responsibility of enforcing the complaint process established by this rule. The Member stated that "[d]ue to the limited enforcement ability allowed for in this rule by HIPAA, it is essential that OCR have the capacity to enforce the regulations. Now is the time for The Secretary to begin building the necessary infrastructure to enforce the regulation effectively."

Response: The Secretary agrees with the commenters and is committed to an effective enforcement program. We will work with Congress to ensure that the Department has the necessary funds to secure voluntary compliance through education and technical assistance, to investigate complaints and conduct compliance reviews, to provide states with exception determinations and to use civil and criminal penalties when necessary.

Economic Effect on Small Entities

Comment: Many commenters stated that the cost estimates on the effect of the proposed regulation on small businesses were understated or incomplete.

Response: The Department conducted a thorough review of potential data sources that would improve the quality of the analysis of the effects on small business. The final regulatory flexibility analysis below is based on the best data available (much of it from the Small Business Administration) and represents a reliable estimate for the effects on small entities in various segments of the health care industry. It is important to note that the estimates are for small business segments in the aggregate; the cost to individual firms will vary, perhaps considerably, based on its particular circumstances.

Comment: The cost of implementing privacy regulations, when added to the cost of other required HIPAA regulations, could increase overhead significantly. As shown in the 1993 Workgroup on Electronic Data Interchange (WEDI) Report, providers will bear the larger share of implementation costs and will save less than payors.

Response: The regulatory flexibility analysis below shows generally the marginal effect of the privacy regulation on small entities. Collectively, the HIPAA administrative standards will save money in the health care system. As important, given the rapid expansion of electronic commerce, it is probable that small entities would need to comply with standards for electronic commerce in order to complete effectively, even if the standards were voluntary. The establishment of uniform standards through regulation help small entities because they will not have to invest in multiple systems, which is what they would confront if the system remained voluntary.

Comment: One respondent believed that the initial and ongoing costs for small provider offices could be as much as 11 times higher than the estimates provided in the proposed rule. Other commenters stated that the estimates for small entities are "absurdly low".

Response: Although there were a number of commenters highly critical of the small business analysis, none provided alternative estimates or even provided a rationale for their statements. Many appeared to assume that all costs associated with medical record confidentiality should be estimated. This represents a misunderstanding of the purpose of the analysis: to estimate the incremental effects of this regulation, i.e., the new costs (and savings) that will result from changes required by the regulation. The Department has made substantial changes in the final small entities analysis (below), reflecting policy changes in the final rule and additional information and data collected by the Department since the issuance of the proposal last fall. We believe that these estimates reasonably reflect the costs that various types of small entities will experience in general, though the actual costs of particular providers might vary considerably based on their current practices and technology.

Comment: A respondent expressed the belief that small providers would bear a disproportionate share of the regulation's administrative burden because of the likelihood of larger companies incurring fewer marginal costs due to greater in-house resources to aid in the legal and technical analysis of the proposed rule.

Response: As explained below, the Department does not agree with the assertion that small entities will be disproportionately affected. Based on discussions with a number of groups, the Department expects many professional and trade associations to provide their members with analysis of the regulation, including model policies, statements and basic training materials. This will minimize the cost for most small entities. Providers that use protected health information for voluntary practices, such as marketing or research, are more likely to need specific legal and technical assistance, but these are likely to be larger providers.

Comment: Several commenters took issue with the "top-down" approach that we used to estimate costs for small businesses, believing that this methodology provided only a single point estimate, gave no indication of the variation around the estimate, and was subject to numerous methodological errors since the entities to which the numerator pertained may not have been ***82757** the same as the denominator. These respondents further recommended that we prepare a "bottom-up" analysis using case studies and/or a survey of providers to refine the estimates.

Response: The purpose of the regulatory flexibility analysis is to provide a better insight into the relative burden of small businesses compared to larger firms in complying with a regulation. There may be considerable variance around average costs within particular industry sectors, even among small businesses within them. The estimates are based on the best data available, including information from the Small Business Administration, the Census Bureau, and public comments.

Comment: A commenter stated that the proposal's cost estimate does not account for additional administrative costs imposed on physicians, such as requirements to rewrite contracts with business partners.

Response: Such costs are included in the analysis below.

Comment: Numerous public comments were directed specifically at the systems compliance cost estimates for small businesses. One respondent maintained that the initial upgrade cost alone would range from $50 thousand to more than $1 million per covered entity.

Response: The cost estimates for systems compliance varied enormously; unfortunately, none of the commenters provided documentation of how they made their estimates, preventing us from comparing their data and assumptions to the Department's. Because of concern about the costs in this area, however, the Department retained an outside consultant to provide greater expertise and analysis. The product of this effort has been incorporated in the analysis below.

Comment: One commenter stated that just the development and documentation of new health information policies and procedures (which would require an analysis of the federal regulations and state law privacy provisions), would cost far more than the $396 cited in the Notice of Proposed Rulemaking as the average start-up cost for small businesses.

Response: As explained below in the cost analysis, the Department anticipates that most of the policies and procedures that will be required under the final rule will be largely standardized, particularly for small businesses. Thus, much of the work and cost can be done by trade associations and professional groups, thereby minimizing the costs and allowing it to be spread over a large membership base.

Comment: A number of comments criticized the initial estimates for notices, inspection and copying, amendments and correction, and training as they relate to small businesses.

Response: The Department has made substantial revisions in its estimates for all of these areas which is explained below in the regulatory flexibility analysis.

Comment: One commenter noted that there appeared to be a discrepancy in the number of small entities cited. There is no explanation for the difference and no explanation for difference between “establishments” and “entities.”

Response: There are discrepancies among the data bases on the number of “establishments” and “entities” or “firms”. The problem arises because most surveys count (or survey) establishments, which are physical sites. A single firm or entity may have many establishments. Moreover, although an establishment may have only a few employees, the firm may have a large number of workers (the total of all its various establishments) and therefore not be a small entity.

As discussed below, there is some discrepancy between the aggregate numbers we use for the regulatory impact analysis (RIA) and the regulatory flexibility analysis (RFA). We concluded that for purposes of the RFA, which is intended to measure the effects on small entities, we would use Small Business Administration data, which defines entities based on revenues rather than physical establishments to count the number of small entities in various SIC. This provides a more accurate estimate of small entities affected. For the RIA, which is measuring total effects, we believe the establishment based surveys provide a more reliable count.

Comment: Because small businesses must notify patients of their privacy policies on patients' first visit after the effective date of the regulation, several commenters argued that staff would have to search records either manually or by computer on a daily basis to determine if patients had been seen since the regulation was implemented.

Response: Under the final regulation, all covered entities will have to provide patients copies of their privacy policy at the first visit after the effective date of the regulation. The Department does not view this as burdensome. We expect that providers will simply place a note or marker at the beginning of a file (electronic or paper) when a patient is given the notice. This is neither time-consuming nor expensive, and it will not require constant searches of records.

Comment: A commenter stated that the definitions of small business, small entity, and a small health plan are inconsistent because the NPRM includes firms with annual receipts of $5 million or less and non-profits.

Response: The Small Business Administration, whose definitions we use for this analysis, includes firms with $5 million or less in receipts and all non-profits as "small businesses." We recognize that some health plans, though very large in terms of receipts (and insured lives), nonetheless would be considered "small businesses" under this definition because they are non-profits. In the final regulatory flexibility analysis, we generally have maintained the Small Business Administration definitions because it is the accepted standard for these analyses. However, we have added several categories, such as IRBs and employer sponsored group health plans, which are not small entities, per se, but will be effected by the final rule and we were able to identify costs imposed by the regulation on them.

Comment: The same commenter wanted clarification that all non-profit organizations are small entities and that the extended effective date for compliance applies to them.

Response: For purposes of the regulatory flexibility analysis, the Department is utilizing the Small Business Administration guidelines. However, under HIPAA the Secretary may extend the effective compliance date from 24 months to 36 months for "small health plans". The Secretary is given the explicit discretion of defining the term for purposes of compliance with the regulation. For compliance purposes, the Secretary has decided to define "small health plans" as those with receipts of $5 million or less, regardless of their tax status. As noted above, some non-profit plans are large in terms of revenues (i.e., their revenues exceed $5 million annually). The Department determined that such plans do not need extra time for compliance.

Comment: Several commenters requested that "small providers" [undefined] be permitted to take 36 months to come into compliance with the final regulation, just as small health plans will be permitted to do so.

Response: Congress specified small health plans, but not small providers, as needing extra time to comply. The majority of providers affected by the regulation are "small", based on the SBA definitions; in other words, granting the delay would be tantamount to make the effective date three years rather than two. In making policy decisions for the final regulation, extensive consideration was given to minimizing the cost and administrative burden associated with implementing ***82758** the rule. The Department believes that the requirements of the final rule will not be difficult to fulfill, and therefore, it has maintained the two year effective date.

External Studies

Comment: One commenter submitted a detailed analysis of privacy legislation that was pending and concluded that they might cost over $40 billion.

Response: The study did not analyze the policies in the proposal, and therefore, the estimates do not reflect the costs that would have been imposed by the proposed regulation. In fact, the analysis was prepared before the Administration's proposed privacy regulation was even published. As a result, the analysis is of limited relevance to the regulation actually proposed.

The following are examples of assumptions and costs in the analysis that do not match privacy policies or requirements stated in the proposed rule.

1. Authorizations: The study assumed rules requiring new authorizations from current subscribers to use their data for treatment, payment of claims, or other health plan operations. The proposed rule would have prohibited providers or plans from obtaining patient authorization to use data for treatment, payment or health care operations, and the final rule makes obtaining consent for these purposes voluntary for all health plans and for providers that do not have direct treatment relationships with individuals.

2. Disclosure History: The study assumes that providers, health plans, and clearinghouses would have to track all disclosures of health information. Under the NPRM and the final rule, plans, providers and clearinghouses are only required to account for disclosures that are not for treatment, payment, and health care operations, a small minority of all disclosures.

3. Inspection, Copying, and Amendment: The study assumed requirements to allow patients and their subscribers to inspect, copy, and amend all information that includes their name, social security number or other identifying feature (e.g. customer service calls, internal memorandum, claim runs). However, the study assumed broader access than provided in the rule, which requires access only to information in records used to make decisions about individuals, not all records with identifiable information.

4. Infrastructure development: The study attributed significant costs to infrastructure implementation of (computer systems, training, and other compliance costs). As explained below, the compliance requirements are much less extensive than assumed in this study. For example, many providers and plans will not be required to modify their privacy systems but will only be required to document their practices and notify patients of these practices, and others will be able to purchase low-cost, off-the-shelf software that will facilitate the new requirements. The final regulation will not require massive capital expenditures; we assumed, based on our consultants' work, that providers will rely on low-cost incremental adjustments initially, and as their technology becomes outdated, they will replace it with new systems that incorporate the HIPAA standard requirements.

Although many of the policy assumptions in the study are fundamentally different than those in the proposed or final regulation, the study did provide some assistance to the Department in preparing its final analysis. The Department compared data, methodologies and model assumptions, which helped us think more critically about our own analysis and enhanced the quality of our final work.

Comment: One commenter submitted a detailed analysis of the NPRM Regulatory Impact Analysis and concluded that it might cost over $64 billion over 5 years. This analysis provided an interesting framework for analyzing the provision for the rule. More precisely, the analysis generally attempted to identify the number of entities would be required to comply with each of the significant provision of the proposed rule, then estimated the numbers of hours required to comply per entity, and finally, estimated an hourly wage.

Response: HHS adopted this general structure for the final RIA because it provided a better framework for analysis than what the Department had done in the NPRM. However, HHS did not agree with many of the specific assumptions used by in this analysis, for several reasons. First, in some instances the assumptions were no longer relevant because the requirements of the NPRM were altered in the final rule. For other assumptions, HHS found more appropriate data sources for the number of covered entities, wages rates and trend rates or other factors affecting costs. In addition, HHS believes that in a few instances, this analysis over-estimated what is required of covered entities to comply. Based on public comments and its own factfinding, the Department believes many of its assumptions used in the final analysis more accurately reflect what is likely to be the real cost of the regulation.

IV. Final Regulatory Impact Analysis

5 U.S.C. 804(2) (as added by section 251 of Pub. L. 104-21), specifies that a “major rule” is any rule that the Office of Management and Budget finds is likely to result in:

- An annual effect on the economy of $100 million or more;

- A major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or

- Significant adverse effects in competition, employment, investment productivity, innovation, or on the ability of United States based enterprises to compete with foreign-based enterprises in domestic and export markets. The impact of this final rule will be over $1 billion in the first year of implementation. Therefore, this rule is a major rule as defined in 5 U.S.C. 804(2).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public

health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is "significant" if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or more adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The purpose of the regulatory impact analysis is to assist decision-makers in understanding the potential ramifications of a regulation as it is being developed. The analysis is also intended to assist the public in understanding the general economic ramifications of a regulation, both in the aggregate as well as the major policy areas of a regulation and how they are likely to affect the major industries or sectors of the economy covered by it.

In accordance with the Small Business Regulatory Enforcement and Fairness Act (Pub. L. 104-121), the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB) has determined that this rule is a major rule for the purpose of congressional review.

The proposal for the privacy regulation included a preliminary regulatory impact analysis (RIA) which estimated the cost of the rule at $3.8 billion over five years. The preliminary ***82759** analysis also noted that a number of significant areas were not included in the estimate due to inadequate information. The proposal solicited public comment on these and all other aspects of the analysis. In this preamble, the Department has summarized the public comments pertinent to the cost analysis and its response to them. However, because of the extensive policy changes incorporated in the final regulation, additional data collected from the public comments and the Department's fact-finding, and changes in the methodology underlying the estimates, the Department is setting forth in this section a more complete explanation of its revised estimates and how they were obtained. This will facilitate a better understanding by the public of how the estimates were developed and provide more insight into how the Department believes the regulation will ultimately affect the health care sector.

The impact analysis measures the effect of the regulation on current practices. In the case of privacy, as discussed in the preamble, there already exists considerable, though quite varied, efforts to protect the confidentiality of medical information. The RIA is measuring the change in these current practices and the cost of new and additional responsibilities that are required to conform to the new regulation.

To achieve a reasonable level of privacy protection, the Department defined three objectives for the final rule: (1) To establish national baseline standards, implementation specifications, and requirements for health information privacy protection, (2) to protect the privacy of individually identifiable health information maintained or transmitted by covered entities, and (3) to protect the privacy of all individually identifiable health information within covered entities, regardless of its form.

Establishing minimum standards, implementation specifications, and requirements for health information privacy protection creates a level baseline of privacy protection for patients across states. The Health Privacy Project's report, The State of Health Privacy: An Uneven Terrain[FN33] makes it clear that under the current system of state laws, privacy protection is extremely variable. The Department's statutory authority under HIPAA which allows the privacy regulation to preempt any state law if such law is contrary to and not more stringent than privacy protection pursuant to this regulation. This sets a floor, but permits a state to create laws that are more protective of privacy. We discuss preemption in greater detail in other parts of the preamble.

The second objective is to establish a uniform base of privacy protection for individually identifiable health information maintained or transmitted by covered entities. HIPAA restricts the type of entities covered by the rule to three broad categories: health care providers that transmit health information in HIPAA standard transactions, health plans, and health care clearinghouses. However, there are similar public and private entities that are not within the Department's authority to regulate under HIPAA. For example, life insurance companies are not covered by this rule but may have access to a large amount of individually identifiable health information.

The third objective is to protect the privacy of all individually identifiable health information held by covered entities, including their business associates. Health information is currently stored and transmitted in multiple forms, including electronic, paper, and oral forms. To provide consistent protection to information, and to avoid requiring covered entities from distinguishing

between health information that has been transmitted or maintained electronically and that which has not, this rule covers all individually identifiable health information in any form maintained or transmitted by a covered entity.

For purposes of this cost analysis, the Department has assumed all health care providers will be affected by the rule. This results in an overestimation of costs because there are providers that do not engage in any HIPAA standard transactions, and therefore, are not affected. The Department could not obtain any reliable data on the number of such providers, but the available data suggest that there are very few such entities, and given the expected increase in all forms of electronic health care in the coming decade, the number of paper-only providers is likely to decrease.

A. Relationship of This Analysis to Analyses in Other HIPAA Regulations

Congress has recognized that privacy standards, implementation specifications and requirements must accompany the electronic data interchange standards, implementation specifications and requirements because the increased ease of transmitting and sharing individually identifiable health information will result in an increase in concern regarding privacy and confidentiality of such information. The bulk of the first Administrative Simplification section that was debated on the floor of the Senate in 1994 (as part of the Health Security Act) was made up of privacy provisions. The requirement for the issuance of concomitant privacy measures remained a part of the HIPAA bill passed by the House of Representatives in 1996, but the requirement for privacy measures was removed in conference. Instead, Congress added section 264 to Title II of HIPAA, which directs the Secretary to develop and submit to Congress recommendations addressing at least the following:

(1) The rights that an individual who is a subject of individually identifiable health information should have.

(2) The procedures that should be established for the exercise of such rights.

(3) The uses and disclosures of such information that should be authorized or required. The Secretary's Recommendations were submitted to Congress on September 11, 1997, and are summarized below. Section 264(c)(1) of HIPAA provides that: If legislation governing standards with respect to the privacy of individually identifiable health information transmitted in connection with the transactions described in section 1173(a) of the Social Security Act (as added by section 262) is not enacted by (August 21, 1999), the Secretary of Health and Human Services shall promulgate final regulations containing such standards not later than (February 21, 2000). Such regulations shall address at least the subjects described in subsection (regarding recommendations).

Because the Congress did not enact legislation governing standards with respect to the privacy of individually identifiable health information prior to August 21, 1999, the Department has, in accordance with this statutory mandate, developed final rules setting forth standards to protect the privacy of such information.

Title II of the Health Insurance Portability and Accountability Act (HIPAA) also provides a statutory framework for the promulgation of other administrative simplification regulations. On August 17, 2000, the Transactions Rule was published. Proposals for health care provider identifier (May 1998), employer identifier (June 1998), and security and electronic signature standards (August 1998) have also been published. These ***82760** regulations are expected to be made final in the foreseeable future.

HIPAA states that, “any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.” (Section 1172 (b)). This provision refers to the administrative simplification regulations in their totality, including this rule regarding privacy standards. The savings and costs generated by the various standards should result in a net savings to the health care system. The Transactions Rule shows a net savings of $29.9 billion over ten years (2002-2011), or a net present value savings of $19 billion. This estimate does not include the growth in “e-health” and “e-commerce” that may be spurred by the adoption of uniform codes and standards.

This final Privacy Rule is estimated to produce net costs of $18.0 billion, with net present value costs of $11.8 billion (2003 dollars) over ten years (2003-2012). This estimate is based on some costs already having been incurred due to the requirements of the Transactions Rule, which included an estimate of a net savings to the health care system of $29.9 billion over ten years (2002 dollars) and a net present value of $19.1 billion. The Department expects that the savings and costs generated by all administrative simplification standards should result in a net savings to the health care system.

B. Summary of Costs and Benefits

Measuring both the economic costs and benefits of health information privacy is difficult. Traditionally, privacy has been addressed by state laws, contracts, and professional practices and guidelines. Moreover, these practices have been evolving as computers have dramatically increased the potential use of medical data; the scope and form of health information is likely to be very different ten years from now than it is today. This final regulation is both altering current health information privacy practice and shaping its evolution as electronic uses expand.

To estimate costs, the Department used information from published studies, trade groups and associations, public comments to the proposed regulation, and fact-finding by staff. The analysis focused on the major policy areas in the regulation that would result in significant costs. Given the vast array of institutions affected by this regulation and the considerable variation in practices, the Department sought to identify the "typical" current practice for each of the major policy areas and estimate the cost of change resulting from the regulation. Because of the paucity of data and incomplete information on current practices, the Department has consistently made conservative assumptions (that is, given uncertainty, we have made assumptions that, if incorrect, are more likely to overstate rather than understate the true cost).

Benefits are difficult to measure because people conceive of privacy primarily as a right, not as a commodity. Furthermore, a wide gap appears to exist between what people perceive to be the level of privacy afforded health information about them and what actually occurs with the use of such information today. Arguably, the "cost" of the privacy regulation is the amount necessary to bring health information privacy to these perceived levels.

The benefits of enhanced privacy protections for individually identifiable health information are significant, even though they are hard to quantify. The Department solicited comments on this issue, but no commenters offered a better alternative. Therefore, the Department is essentially reiterating the analysis it offered in the proposed Privacy Rule. The illustrative examples set forth below, using existing data on mental health, cancer screening, and HIV/AIDS patients, suggest the level of economic and health benefits that might accrue to individuals and society. Moreover, the benefits of improved privacy protection are likely to increase in the future as patients gain trust in health care practitioners' ability to maintain the confidentiality of their health information.

The estimated cost of compliance with the final rule is $17.6 billion over the ten year period, 2003-2012.[FN34] This includes the cost of all the major requirements for the rule, including costs to federal, state and local governments. The net present value of the final rule, applying a 11.2 percent discount rate[FN35], is $11.8 billion.[FN36]

The first year estimate is $3.2 billion (this includes expenditures that may be incurred before the effective date in 2003). This represents about 0.23 percent of projected national health expenditures for 2003.[FN37] By 2008, seven years after the rule's effective date, the rule is estimated to cost 0.07 percent of projected national health expenditures.

The largest cost items are the requirement to have a privacy official, $5.9 billion over ten years, and the requirement that disclosures of protected health information only involve the minimum amount necessary, $5.8 billion over ten years (see Table 1). These costs reflect the change that affected organizations will have to undertake to implement and maintain compliance with the requirements of the rule and achieve enhanced privacy of protected health information. ***82761**

Table 1.—The Cost of Complying With the Proposed Privacy Regulation

[In dollars]

Provision	Initial or first year cost (2003, $million)	Average annual cost ($million, years 2-10)	Ten year cost (2003-2012) ($million)
Policy Development	597.7	0	597.7
Minimum Necessary	926.2	536.7	5,756.7
Privacy Officials	723.2	575.8	5,905.8
Disclosure Tracking/History	261.5	95.9	1,125.1
Business Associates	299.7	55.6	800.3
Notice Distribution	50.8	37.8	391.0
Consent	166.1	6.8	227.5
Inspection/Copying	1.3	1.7	16.8
Amendment	5.0	8.2	78.8
Requirements on Research	40.2	60.5	584.8
Training	287.1	50.0	737.2
De-Identification of Information	124.2	117.0	1,177.4
Employers with Insured Group Health Plans	52.4	0	52.4
Internal Complaints	6.6	10.7	103.2
Total *	3,242.0	1,556.9	17,554.7
Net Present Value	3,242.0	917.8	11,801.8

C. Need for the Final Rule

The need for a national health information privacy framework is described in detail in Section I of the preamble above. In short, privacy is a necessary foundation for delivery of high quality health care—the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers. At the same time, there is increasing public concern about loss of privacy generally, and health privacy in particular. The growing use of interconnected electronic media for business and personal activities, our increasing ability to know an individual's genetic make-up, and the increasing complexity of the health care system each bring the potential for tremendous benefits to individuals and society, but each also brings new potential for invasions of our privacy.

Concerns about the lack of attention to information privacy in the health care industry are not merely theoretical. Section I of the preamble, above, lists numerous examples of the kinds of deliberate or accidental privacy violations that call for a national legal framework of health privacy protections. Disclosure of health information about an individual can have significant implications well beyond the physical health of that person, including the loss of a job, alienation of family and friends, the loss of health

insurance, and public humiliation. The answer to these concerns is not for consumers to withdraw from the health care system, but for society to establish a clear national legal framework for privacy.

This section adds to the discussion in Section I, above, a discussion of the market failures inherent in the current system which create additional and compelling reasons to establish national health information privacy standards. Market failures will arise to the extent that privacy is less well protected than the parties would have agreed to, if they were fully informed and had the ability to monitor and enforce contracts. The chief market failures with respect to privacy of health information concern information, negotiation, and enforcement costs between the entity and the individual. The information costs arise because of the information asymmetry between the company and the patient—the company typically knows far more than the patient about how the protected health information will be used by that company. A health care provider or plan, for instance, knows many details about how protected health information may be generated, combined with other databases, or sold to third parties.

Absent this regulation, patients face at least two layers of cost in learning about how their information is used. First, as with many aspects of health care, patients face the challenge of trying to understand technical medical terminology and practices. A patient generally will have difficulty understanding medical records and the implications of transferring health information about them to a third party. Second, in the absence of consistent national rules, patients may face significant costs in trying to learn and understand the nature of a company's privacy policies.

The costs of learning about companies' policies are magnified by the difficulty patients face in detecting whether companies, in fact, are complying with those policies. Patients might try to adopt strategies for monitoring whether companies have complied with their announced policies. These sorts of strategies, however, are both costly (in time and effort) and likely to be ineffective. In addition, modern health care often requires protected health information to flow legitimately among multiple entities for purposes of treatment, payment, health care operations, and other necessary uses. Even if the patient could identify the provider whose data ultimately leaked, the patient could not easily tell which of those multiple entities had impermissibly transferred her information. Therefore, the cost and ineffectiveness of monitoring leads to less than optimal protection of individually identifiable health information.

The incentives facing a company that acquires individually identifiable health information also discourage privacy protection. A company gains the full benefit of using such information, including its own marketing efforts or its ability to sell the information to third parties. The company, however, does not suffer the losses from disclosure of protected health information; the patient does. Because of imperfect monitoring, customers often will not ***82762** learn of, and thus not be able to take efficient action to prevent uses or disclosures of sensitive information. Because the company internalizes the gains from using the information, but does not bear a significant share, if any, of the cost to patients (in terms of lost privacy), it will have a systematic incentive to over-use individually identifiable health information. In market failure terms, companies will have an incentive to use individually identifiable health information where the patient would not have freely agreed to such use.

These difficulties are exacerbated by the third-party nature of many health insurance and payment systems. Even where individuals would wish to bargain for privacy, they may lack the legal standing to do so. For instance, employers often negotiate the terms of health plans with insurers. The employee may have no voice in the privacy or other terms of the plan, facing a take-it-or-leave-it choice of whether to be covered by insurance. The current system leads to significant market failures in bargaining privacy protection. Many privacy-protective agreements that patients would wish to make, absent barriers to bargaining, will not be reached.

The economic arguments become more compelling as the medical system shifts from predominantly paper to predominantly electronic records. Rapid changes in information technology should result in increased market failures in the markets for individually identifiable health information. Improvements in computers and networking mean that the costs of gathering, analyzing, and disseminating electronic data are plunging. Market forces are leading many health care providers and health plans to shift from paper to electronic records, due both to lower cost and the increased functionality provided by having information in electronic form. These market changes will be accelerated by the administrative simplification implemented by the other

regulations promulgated under HIPAA. A chief goal of administrative simplification, in fact, is to create a more efficient flow of medical information, where appropriate. This privacy regulation is an integral part of the overall effort of administrative simplification; it creates a framework for more efficient flows for certain purposes, including treatment and payment, while restricting flows in other circumstances except where appropriate institutional safeguards exist.

If the medical system shifts predominantly to electronic records in the near future, accompanying privacy rules will become more critical to prevent unanticipated, inappropriate, or unnecessary uses or disclosures of individually identifiable health information without patient consent and without effective institutional controls against further dissemination. In terms of the market failure, it will become more difficult for patients to know how their health provider or health plan is using health information about them. It will become more difficult to monitor the subsequent flows of individually identifiable health information, as the number of electronic flows and possible points of leakage both increase. Similarly, the costs and difficulties of bargaining to get the patients' desired level of use will likely rise due to the greater number and types of entities that receive protected health information.

As the benefits section, below, discusses in more detail, the protection of privacy and correcting the market failure also have practical implications. Where patients are concerned about lack of privacy protections, they might fail to get medical treatment that they would otherwise seek. This failure to get treatment may be especially likely for certain conditions, including mental health, and HIV. Similarly, patients who are concerned about lack of privacy protections may report health information inaccurately to their providers when they do seek treatment. For instance, they might decide not to mention that they are taking prescription drugs that indicate that they have an embarrassing condition. These inaccurate reports may lead to mis-diagnosis and less-than-optimal treatment, including inappropriate additional medications. In short, the lack of privacy safeguards can lead to efficiency losses in the form of forgone or inappropriate treatment.

In summarizing the economic arguments supporting the need for this regulation, the discussion here has emphasized the market failures that will be addressed by this regulation. These arguments become considerably stronger with the shift from predominantly paper to predominantly electronic records. As discussed in the benefits section below, the proposed privacy protections may prevent or reduce the risk of unfair treatment or discrimination against vulnerable categories of persons, such as those who are HIV positive, and thereby, foster better health. The proposed regulation may also help educate providers, health plans, and the general public about how protected health information is used. This education, in turn, may lead to better information practices in the future.

D. Baseline Privacy Protections

An analysis of the costs and benefits of the regulation requires a baseline from which to measure the regulation's effects. For some regulations, the baseline is relatively straightforward. For instance, an industry might widely use a particular technology, but a new regulation may require a different technology, which would not otherwise have been adopted by the industry. In this example, the old and widely used technology provides the baseline for measuring the effects of the regulation. The costs and the benefits are the difference between keeping the old technology and implementing the new technology.

Where the underlying technology and industry practices are rapidly changing, however, it can be far more difficult to determine the baseline and thereby measure the costs and benefits of a regulation. There is no simple way to know what technology industry would have chosen to introduce if the regulation had never existed, nor how industry practices would have evolved.

Today, the entities covered by the HIPAA privacy regulation are in the midst of a shift from primarily paper records to electronic records. As covered entities spend significant resources on hardware, software, and other information technology costs, questions arise about which of these costs are fairly attributable to the privacy regulations as opposed to costs that would have been expended even in the absence of the regulations. Industry practices generally are rapidly evolving, as described in more detail in Part I of this preamble. New technological or other measure taken to protect privacy are in part attributable to the expected expense of shifting to electronic medical records, rather than being solely attributable to the new regulations. In addition, the existence of privacy rules in other sectors of the economy help set a norm for what practices will be considered good practices for health information. The level of privacy protection that would exist in the health care sector, in the absence

of regulations, thus would likely be affected by regulatory and related developments in other sectors. In short, it is therefore difficult to project a cost or benefits baseline for this rule.

The common security practice of using "firewalls" illustrates how each of the three baselines might apply. Under the first baseline, the full cost of implementing firewalls should be included in a Regulatory Impact ***82763** Analysis for a rule that expects entities to have firewalls. Because current law has not required firewalls, a new rule expecting this security measure must include the full cost of creating firewalls. This approach, however, would seem to overstate the cost of such a regulation. Firewalls would seem to be an integral part of the decision to move to an on-line, electronic system of records. Firewalls are also being widely deployed by users and industries where no binding security or privacy regulations have been proposed.

Under the second baseline, the touchstone is the level of risk of security breaches for individually identifiable health information under current practices. There is quite possibly a greater risk of breach for an electronic system of records, especially where such records are accessible globally through the Internet, than for patient records dispersed among various doctors' offices in paper form. Using the second baseline, the costs of firewalls for electronic systems should not be counted as a cost of the regulation except where firewalls create greater security than existed under the previous, paper-based system.

Finally, the third baseline would require an estimate of the typical level of firewall protections that covered entities would adopt in the absence of regulation, and include in the Regulatory Impact Analysis only the costs that exceed what would otherwise have been adopted. For this analysis, the Department has generally assumed that the status quo would otherwise exist throughout the ten-year period (in a few areas we explicitly discuss likely changes). We made this decision for two reasons. First, predicting the level of change that would otherwise occur is highly problematic. Second, it is a "conservative" assumption—that is, any error will likely be an overstatement of the true costs of the regulation.

Privacy practices are most often shaped by professional organizations that publish ethical codes of conduct and by state law. On occasion, state laws defer to professional conduct codes. At present, where professional organizations and states have developed only limited guidelines for privacy practices, an entity may implement privacy practices independently. However, it is worth noting that changes in privacy protection continue to increase in various areas. For example, European Union countries may only send individually identifiable information to companies, including U.S. firms, that comply with their privacy standards, and the growing use of health data in other areas of commerce, such as finance and general commercial marketing, have also increased the demand for privacy in ways that were not of concern in the past.

1. Professional Codes of Ethics

The Department examined statements issued by five major professional groups, one national electronic network association and a leading managed care association.[FN38] There are a number of common themes that all the organizations appear to subscribe to:

- The need to maintain and protect an individual's health information;

- The development of policies to ensure the confidentiality of individually identifiable health information;

- A restriction that only the minimum necessary information should be released to accomplish the purpose for which the information is sought.

Beyond these principles, the major associations differ with respect to the methods used to protect individually identifiable health information. There is no common professional standard across the health care field with respect to the protection of individually identifiable health information. One critical area of difference is the extent to which professional organizations should release individually identifiable health information. A major mental health association advocates the release of identifiable patient information "* * * only when de-identified data are inadequate for the purpose at hand." A major association of physicians counsels members who use electronically maintained and transmitted data to require that they and their patients know in advance

who has access to protected patient data, and the purposes for which the data will be used. In another document, the association advises physicians not to “sell” patient information to data collection companies without fully informing their patients of this practice and receiving authorization in advance to release of the information.

Only two of the five professional groups state that patients have the right to review their medical records. One group declares this as a fundamental patient right, while the second association qualifies its position by stating that the physician has the final word on whether a patient has access to his or her health information. This association also recommends that its members respond to requests for access to patient information within ten days, and recommends that entities allow for an appeal process when patients are denied access. The association further recommends that when a patient contests the accuracy of the information in his or her record and the entity refuses to accept the patient's change, the patient's statement should be included as a permanent part of the patient's record.

In addition, three of the five professional groups endorse the maintenance of audit trails that can track the history of disclosures of individually identifiable health information.

The one set of standards that we reviewed from a health network association advocated the protection of individually identifiable health information from disclosure without patient authorization and emphasized that encrypting information should be a principal means of protecting individually identifiable health information. The statements of a leading managed care association, while endorsing the general principles of privacy protection, were vague on the release of information for purposes other than treatment. The association suggested allowing the use of protected health information without the patient's authorization for what they term “health promotion.” It is possible that the use of protected health information for “health promotion” may be construed under the rule as part of marketing activities.

Based on the review of the leading association standards, we believe that the final rule embodies most or all of the major principles expressed in the standards. However, there are some major areas of difference between the rule and the professional standards reviewed. The final rule generally provides stronger, more consistent, and more comprehensive guarantees of privacy for individually identifiable health information than the professional standards. The differences between the rule and the professional codes include the individual's right of access to health information in the covered entity's possession, relationships between contractors and covered entities, and the requirement that covered entities make their privacy policies and practices available to patients through a notice ***82764** and the ability to respond to questions related to the notice. Because the regulation requires that (with a few exceptions) patients have access to their protected health information that a covered entity possesses, large numbers of health care providers may have to modify their current practices in order to allow patient access, and to establish a review process if they deny a patient access. Also, none of the privacy protection standards reviewed require that health care providers or health plans prepare a formal statement of privacy practices for patients (although the major physician association urges members to inform patients about who would have access to their protected health information and how their health information would be used). Only one HMO association explicitly made reference to information released for legitimate research purposes. The regulation allows for the release of protected health information for research purposes without an individual's authorization, but only if the research where such authorization is waived by an institutional research board or an equivalent privacy board. This research requirement may cause some groups to revise their disclosure authorization standards.

2. State Laws

The second body of privacy protections is found in a complex, and often confusing, myriad of state laws and requirements. To determine whether or not the final rule would preempt a state law, first we identified the relevant laws, and second, we addressed whether state or federal law provides individuals with greater privacy protection.

Identifying the Relevant State Statutes: Health information privacy provisions can be found in laws applicable to many issues including insurance, worker's compensation, public health, birth and death records, adoptions, education, and welfare. In many cases, state laws were enacted to address a specific situation, such as the reporting of HIV/AIDS, or medical conditions that would impair a person's ability to drive a car. For example, Florida has over 60 laws that apply to protected health information.

According to the Georgetown Privacy Project,[FN39] Florida is not unique. Every state has laws and regulations covering some aspect of medical information privacy. For the purpose of this analysis, we simply acknowledge the variation in state requirements.

We recognize that covered entities will need to learn the laws of their states in order to comply with such laws that are not contrary to the rule, or that are contrary to and more stringent than the rule. This analysis should be completed in the context of individual markets; therefore, we expect that professional associations or individual businesses will complete this task.

Recognizing the limits of our ability to effectively summarize state privacy laws, we discuss conclusions generated by the Georgetown University Privacy Project's report, The State of Health Privacy: An Uneven Terrain. The Georgetown report is among the most comprehensive examination of state health privacy laws currently published, although it is not exhaustive. The report, which was completed in July 1999, is based on a 50-state survey.

To facilitate discussion, we have organized the analysis into two sections: access to health information and disclosure of health information. Our analysis is intended to suggest areas where the final rule appears to preempt various state laws; it is not designed to be a definitive or wholly comprehensive state-by-state comparison.

Access to Subject's Information: In general, state statutes provide individuals with some access to medical records about them. However, only a few states allow individuals access to health information held by all their health care providers and health plans. In 33 states, individuals may access their hospital and health facility records. Only 13 states guarantee individuals access to their HMO records, and 16 states provide individuals access to their medical information when it is held by insurers. Seven states have no statutory right of patient access; three states and the District of Columbia have laws that only assure individuals' right to access their mental health records. Only one state permits individuals access to records about them held by health care providers, but it excludes pharmacists from the definition of provider. Thirteen states grant individuals statutory right of access to pharmacy records.

The amount that entities are allowed to charge for copying of individuals' records varies widely from state to state. A study conducted by the American Health Information Management Association[FN40] found considerable variation in the amounts, structure, and combination of fees for search and retrieval, and the copying of the record.

In 35 states, there are laws or regulations that set a basis for charging individuals inspecting and copying fees. Charges vary not only by state, but also by the purpose of the request and the facility holding the health information. Also, charges vary by the number of pages and whether the request is for X-rays or for standard medical information.

Of the 35 states with laws regulating inspection and copying charges, seven states either do not allow charges for retrieval of records or require that the entity provide the first copy free of charge. Some states may prohibit hospitals from charging patients a retrieval and copying fee, but allow clinics to do so. Many states allow fee structures, while eleven states specify only that the record holder may charge “reasonable/actual costs.”

According to the report by the Georgetown Privacy Project, among states that do grant access to patient records, the most common basis for denying individuals access is concern for the life and safety of the individual or others.

The amount of time an entity is given to supply the individual with his or her record varies widely. Many states allow individuals to amend or correct inaccurate health information, especially information held by insurers. However, few states provide the right to insert a statement in the record challenging the covered entity's information when the individual and entity disagree.[FN41]

Disclosure of Health Information: State laws vary widely with respect to disclosure of individually identifiable health information. Generally, states have applied restrictions on the disclosure of health information either to specific entities or for specific health conditions. Only three state laws place broad limits on disclosure of individually identifiable health information

without regard for policies and procedures developed by covered entities. Most states require patient authorization before an entity may disclose health information to certain recipients, but the patient often does not have an opportunity to object to any disclosures.[FN42]

It is also important to point out that none of the states appear to offer individuals the right to restrict disclosure of their health information for treatment. ***82765**

State statutes often have exceptions to requiring authorization before disclosure. The most common exceptions are for purposes of treatment, payment, or auditing and quality assurance functions. Restrictions on re-disclosure of individually identifiable health information also vary widely from state to state. Some states restrict the re-disclosure of health information, and others do not. The Georgetown report cites state laws that require providers to adhere to professional codes of conduct and ethics with respect to disclosure and re-disclosure of protected health information.

Most states have adopted specific measures to provide additional protections for health information regarding certain sensitive conditions or illnesses. The conditions and illnesses most commonly afforded added privacy protection are:

- Information derived from genetic testing;

- Communicable and sexually-transmitted diseases;

- Mental health; and

- Abuse, neglect, domestic violence, and sexual assault.

Some states place restrictions on releasing condition-specific health information for research purposes, while others allow release of information for research without the patient's authorization. States frequently require that researchers studying genetic diseases, HIV/AIDS, and other sexually transmitted diseases have different authorization and privacy controls than those used for other types of research. Some states require approval from an IRB or agreements that the data will be destroyed or identifiers removed at the earliest possible time. Another approach has been for states to require researchers to obtain sensitive, identifiable information from a state public health department. One state does not allow automatic release of protected health information for research purposes without notifying the subjects that their health information may be used in research and allowing them an opportunity to object to the use of their information.[FN43]

Comparing state statutes to the final rule: The variability of state law regarding privacy of individually identifiable health information and the limitations of the applicability of many such laws demonstrates the need for uniformity and minimum standards for privacy protection. This regulation is designed to meet these goals while allowing stricter state laws to be enacted and remain effective. A comparison of state privacy laws with the final regulation highlights several of the rule's key implications:

- No state law requires covered entities to make their privacy and access policies available to patients. Thus, all covered entities that have direct contact with patients will be required by this rule to prepare a statement of their privacy protection and access policies. This necessarily assumes that entities have to develop procedures if they do not already have them in place.

- The rule will affect more entities than are covered or encompassed under many state laws.

- Among the three categories of covered entities, it appears that health plans will be the most significantly affected by the access provisions of the rule. Based on the Health Insurance Association of America (HIAA) data[FN44], there are approximately 94.7 million non-elderly persons with private health insurance in the 35 states that do not provide patients a legal right to inspect and copy their records.

- Under the rule, covered entities will have to obtain an individual's authorization before they could use or disclose their information for purposes other than treatment, payment, and health care operations—except in the situations explicitly defined as allowable disclosures without authorization. Although the final rule would establish a generally uniform disclosure and re-disclosure requirement for all covered entities, the entities that currently have the greatest ability and economic incentives to use and disclose protected health information for marketing services to both patients and health care providers without individual authorization.

- While the final rule appears to encompass many of the requirements found in current state laws, it also is clear that within state laws, there are many provisions that cover specific cases and health conditions. Certainly, in states that have no restrictions on disclosure, the rule will establish a baseline standard. But in states that do place conditions on the disclosure of protected health information, the rule may place additional requirements on covered entities.

3. Other Federal Laws

The relationship with other federal statutes is discussed above in the preamble.

E. Costs

Covered entities will be implementing the privacy final rules at the same time many of the administrative simplification standards are being implemented. As described in the overall impact analysis for the Transactions Rule, the data handling change occurring due to the other HIPAA standards will have both costs and benefits. To the extent the changes required for the privacy standards, implementation specifications, and requirements can be made concurrently with the changes required by the other regulations, costs for the combined implementation should be only marginally higher than for the administrative simplification standards alone. The extent of this incremental cost is uncertain, in the same way that the costs associated with each of the individual administrative simplification standards is uncertain.

The costs associated with implementing the requirements under this Privacy Rule will be directly related to the number of affected entities and the number of affected transactions in each entity. There are approximately 12,200 health plans (including self-insured employer and government health plans that are at least partially self-administered)[FN45], 6480 hospitals, and 630,000 non-hospital providers that will bear implementation costs under the final rule.

The relationship between the HIPAA security and privacy standards is particularly relevant. On August 17, 2000, the Secretary published a final rule to implement the HIPAA standards on electronic transactions. That rule adopted standards for eight electronic code sets to be used for those transactions. The proposed rule for security and electronic signature standards was published on August 12, 1998. That proposal specified the security requirements for covered entities that transmit and store information specified in Part C, Title II of the Act. In general, that proposed rule proposed administrative and technical standards for protecting "* * * any health information pertaining to an individual that is electronically ***82766** maintained or transmitted." (63 FR 43243). The final Security Rule will detail the system and administrative requirements that a covered entity must meet in order to assure itself and the Secretary that health information is safe from destruction and tampering from people without authorization for its access.

By contrast, the Privacy Rule describes the requirements that govern the circumstances under which protected health information must be used or disclosed with and without patient involvement and when a patient may have access to his or her protected health information.

While the vast majority of health care entities are privately owned and operated, we note that federal, state, and local government providers are reflected in the total costs as well. Federal, state, and locally funded hospitals represent approximately 26 percent of hospitals in the United States. This is a significant portion of hospitals, but it represents a relatively small proportion of all provider entities. We estimated that the number of government providers who are employed at locations other than government

hospitals is significantly smaller (approximately two percent of all providers). Weighting the relative number of government hospital and non-hospital providers by the revenue these types of providers generate, we estimate that health care services provided directly by government entities represent 3.4 percent of total health care services. Indian Health Service and tribal facilities costs are included in the total, since the adjustments made to the original private provider data to reflect federal providers included them. In developing the rule, the Department consulted with states, representatives of the National Congress of American Indians, representatives of the National Indian Health Board, and a representative of the self-governance tribes. During the consultation we discussed issues regarding the application of Title II of HIPAA to the states and tribes.

The costs associated with this final rule involve, for each provision, consideration of both the degree to which covered entities must modify their existing records management systems and privacy policies under the final rule, and the extent to which there is a change in behavior by both patients and the covered entities as a result of the final rule. The following sections examine these provisions as they apply to the various covered entities under the final rule. The major costs that covered entities will incur are one-time costs associated with implementation of the final rules, and ongoing costs that result in continuous requirements in the final rule.

The Department has quantified the costs imposed by the final regulation to the extent possible. The cost of many provisions were estimated by first using data from the Census Bureau's Statistics of U.S. Business to identify the number of non-hospital health care providers, hospitals and health plans. Then, using the Census Bureau's Current Population Survey (CPS) wage data for the classes of employees affected by the rule, the Department identified the hourly wage of the type of employee assumed to be mostly likely responsible for compliance with a given provision. Where the Department believed a number of different types of employees might be responsible for complying with a certain provision, as is often expected to be the case, the Department established a weighted-average wage based on the types of employees involved. Finally, the Department made assumptions regarding the number of person-hours per institution required to comply with the rule.

The Department cannot determine precisely how many person-hours per institution will be required to comply with a given provision, however, the Department attempted to establish reasonable estimates based on fact-finding discussions with private sector health care providers, the advice of the Department's consultants, and the Department's own best judgement of the level of burden required to comply with a given provision. Moreover, the Department recognizes that the number of hours required to comply with a given requirement of the rule will vary from provider to provider and health plan to health plan, particularly given the flexibility and scalability permitted under the rule. Therefore, the Department considers the estimates to be averages across the entire class of health care providers, hospitals, or health plans in question.

Underlying all annual cost estimates are growth projections. For growth in the number of patients, the Department used data from the National Ambulatory Medical Care Survey, the National Hospital Ambulatory Medical Care Survey, the National Home and Hospice Survey, the National Nursing Home Survey, and information from the American Hospital Association. For growth in the number of health care workers, the Department used data from the Bureau of Health Professions in the Department's Health Resources Services Administration (HRSA). For insurance coverage growth (private and military coverage), we used a five-year average annual growth rate in employer-sponsored, individual, military, and overall coverage growth from the Census Bureau's CPS, 1995-1999. To estimate growth in the number of Medicare and Medicaid enrollees, the Department used the enrollment projections of the Health Care Financing Administration's Office of the Actuary. For growth in the number of hospitals, health care providers and health plans, trend rates were derived from the Census Bureau's Statistics of U.S. Businesses, using SIC code-specific five-year annual average growth rate from 1992-1997 (the most recent data available). For wage growth, the Department used the same assumptions made in the Medicare Trustees' Hospital Insurance Trust Fund report for 2000.

In some areas, the Department was able to obtain very reliable data, such as survey data from the Statistics of U.S. Businesses and the Medical Expenditures Panel Survey (MEPS). In numerous areas, however, there was too little information or data to support quantitative estimates. As a result, the Department relied on data provided in the public comments or subsequent fact-finding to provide a basis for making key assumptions. We were able to provide a reasonable cost estimate for virtually all aspects of the regulation, except law enforcement. In this latter area, the Department was unable to obtain sufficient data

about current practices (e.g., the number of criminal and civil investigations that may involve requests for protected health information, the number of subpoenas for protected health information, etc.) to determine the marginal effects of the regulation. As discussed more fully below, the Department believes the effects of the final rule are marginal because the policies adopted in the final rule appear to largely reflect current practice.

The NPRM included an estimate of $3.8 billion for the privacy proposal. The estimate for the final rule is $18.0 billion. Much of the difference can be explained by two factors. First, the NPRM estimate was for five years; the final rule estimate is for ten years. The Department chose the longer period for the final rule because ten years was also the period of analysis in the Transactions Rule RIA, and we wanted to facilitate comparisons, given that the net benefits and costs of the administrative simplification rules should be considered together. Second, the final impact analysis includes cost estimates for a number of key provisions that were not estimated in the NPRM because the Department did not have adequate information at the time. ***82767** Although we received little useable data in the public comments (see comment and response section), the Department was able to undertake more extensive fact-finding and collect sufficient information to make informed assumptions about the level of effort and time various provisions of the final rule are likely to impose on different types of affected entities.

The estimate of $18.0 billion represents a gross cost, not a net cost. As discussed more fully below in the benefits section, the benefits of enhanced privacy and confidentiality of personal health information are very significant. If people believe their information will be used properly and not disseminated beyond certain bounds without their knowledge and consent, they will be much more likely to seek proper health care, provide all relevant health information, and abide by their providers' recommendations. In addition, more confidence by individuals and covered entities that privacy will be maintained will lead to an increase in electronic transactions and the efficiencies and cost savings that stem from such action. The benefits section quantifies some examples of benefits. The Department was not able to identify data sources or models that would permit us to measure benefits more broadly or accurately. The inability to quantify benefits, however, does not lessen the importance or value that is ultimately realized by having a national standard for health information privacy.

The largest initial costs resulting from the final Privacy Rule stem primarily from the requirement that covered entities use and disclose only the minimum necessary protected health information, that covered entities develop policies and codify their privacy procedures, and that covered entities designate a privacy official and train all personnel with access to individually identifiable health information. The largest ongoing costs will result from the minimum necessary provisions pertaining internal uses of individually identifiable health information, and the cost of a privacy official. In addition, covered entities will have recurring costs for training, disclosure tracking and notice requirements. A smaller number of large entities may have significant costs for de-identification of protected health information and additional requirements for research.

The privacy costs are in addition to the Transactions Rule estimates. The cost of complying with the regulation represents approximately 0.23 percent of projected national health expenditures the first year the regulation is enacted. The costs for the first eight years of the final regulation represents 0.07 percent of the increase in national health care costs experienced over the same period.[FN46]

Minimum Necessary

The “minimum necessary” policy in the final rule has essentially three components: first, it does not pertain to certain uses and disclosures including treatment-related exchange of information among health care providers; second, for disclosures that are made on a routine and recurring basis, such as insurance claims, a covered entity is required to have policies and procedures for governing such exchanges (but the rule does not require a case-by-case determination); and third, providers must have a process for reviewing non-routine requests on a case-by-case basis to assure that only the minimum necessary information is disclosed.

Based on public comments and subsequent fact-finding, the Department has concluded that the requirements of the final rule are generally similar to the current practice of most providers. For standard disclosure requests, for example, providers generally have established procedures for determining how much health information is released. For non-routine disclosures, providers have indicated that they currently ask questions to discern how much health information is necessary for such disclosure. Under

the final rule, we anticipate providers will have to be more thorough in their policies and procedures and more vigilant in their oversight of them; hence, the costs of this provision are significant.

To make the final estimates for this provision, the Department considered the minimum necessary requirement in two parts. First, providers, hospitals, and health plans will need to establish policies and procedures which govern uses and disclosures of protected health information. Next, these entities will need to adjust current practices that do not comply with the rule, such as updating passwords and making revisions to software.

To determine the policies and procedures for the minimum necessary requirement, the Department assumed that each hospital would spend 160 hours, health plans would spend 107 hours, and non-hospital providers would spend 8 hours. As noted above, the time estimates for this and other provisions of the rule are considered an average number of person-hours for the institutions involved. An underlying assumption is that some hospitals, and to a lesser extent health plans, are part of chains or larger entities that will be able to prepare the basic materials at a corporate level for a number of covered entities.

Once the policies and procedures are established, the Department estimates there will be costs resulting from implementing the new policies and procedures to restrict internal uses of protected health information to the minimum necessary. Initially, this will require 560 hours for hospitals, 160 hours for health plans, and 12 hours for non-hospital providers.[FN47] The wage for health care providers and hospitals is estimated at $47.28, a weighted average of various health care professionals based on CPS data; the wage for health plans is estimated to be $33.82, based on average wages in the insurance industry (note that all wage assumptions in this impact analysis assume a 39 percent load for benefits, the standard Bureau of Labor Statistics assumption). In addition, there will be time required on an annual basis to ensure that the implemented practices continue to meet the requirements of the rule. Therefore, the Department estimates that on an annual ongoing basis (after the first year), hospitals will require 320 hours, health plans 100 hours, and non-hospital providers 8 hours to comply with this provision.

The initial cost attributable to the minimum necessary provision is $926 million. The total cost of the provision is $5.757 billion. (These estimates are for the cost of complying with the minimum necessary provisions that restrict internal uses to the minimum necessary. The Department has estimated in the business associates section below the requirement limiting disclosures outside the covered entity to the minimum amount necessary.)

Privacy Official

The final rule requires entities to designate a privacy official who will be responsible for the development and implementation of privacy policies and procedures. In this cost analysis, the Department has estimated each of the primary administrative requirements of the rule (e.g., training, policy and ***82768** procedure development, etc), including the development and implementation costs associated with each specific requirement. These activities will certainly involve the privacy official to some degree; thus, some costs for the privacy official, particularly in the initial years, are subsumed in other cost requirements. Nonetheless, we anticipate that there will be additional ongoing responsibilities that the privacy official will have to address, such as coordinating between departments, evaluating procedures and assuring compliance. To avoid double-counting, the cost calculated in this section is only for the ongoing, operational functions of a privacy official (e.g., clarifying procedures for staff) that are in addition to items discussed in other sections of this impact analysis.

The Department assumes the privacy official role will be an additional responsibility given to an existing employee in the covered entity, such as an office manager in a small entity or a compliance official in a larger institution. Moreover, today any covered entity that handles individually identifiable health information has one or more people with responsibility for handling and protecting the confidentiality of such information. As a result of the specific requirement for a privacy official, the Department assumes covered entities will centralize this function, but the overall effort is not likely to increase significantly. Specifically, the Department has assumed non-hospital providers will need to devote, on average, an additional 30 minutes per week of an official's time (i.e., 26 hours per year) to compliance with the final regulation for the first two years and 15 minutes per week for the remaining eight years (i.e., 13 hours per year). For hospitals and health plans, which are more likely to have a

greater diversity of activities involving privacy issues, we have assumed three hours per week for the first two years (i.e., 156 hours per year), and 1.5 hours per week for the remaining eight years (i.e., 78 hours per year).

For non-hospital providers, the time was calculated at a wage of $34.13 per hour, which is the average wage for managers of medicine and health according to the CPS. For hospitals, we used a wage of $79.44, which is the rate for senior planning officers.[FN48] For health plans, the Department assumed a wage of $88.42 based on the wage for top claims executives.[FN49] Although individual hospitals and health plans may not necessarily select their planning officers or claims executives to be their privacy officials, we believe they will be of comparable responsibility, and therefore comparable pay, in larger institutions.

The initial year cost for privacy officials will be $723 million; the ten-year cost will be $5.9 billion.

Internal Complaints

The final rule requires each covered entity to have an internal process to allow an individual to file a complaint concerning the covered entity's compliance with its privacy policies and procedures. The requirement includes designating a contact person or office responsible for receiving complaints and documenting the disposition of them, if any. This function may be performed by the privacy official, but because it is a distinct right under the final rule and may be performed by someone else, we are costing it separately.

The covered entity only is required to receive and document a complaint (no response is required), which we assume will take, on average, ten minutes (the complaint can be oral or in writing). The Department believes that such complaints will be uncommon. We have assumed that one in every thousand patients will file a complaint, which is approximately 10.6 million complaints over ten years. Based on a weighted-average hourly wage of $47.28 at ten minutes per complaint, the cost of this policy is $6.6 million in the first year. Using wage growth and patient growth assumptions, the cost of this policy is $103 million over ten years.

Disclosure Tracking and History

The final rule requires providers to be able to produce a record of all disclosures of protected health information, except in certain circumstances. The exceptions include disclosures for treatment, payment, health care operations, or disclosures to an individual. This requirement will require a notation in the record (electronic or paper) of when, to whom, and what information was disclosed, as well as the purpose of such disclosure or a copy of an individual's written authorization or request for a disclosure.

Based on information from several hospital sources, the Department assumes that all hospitals already track disclosures of individually identifiable health information and that 15 percent of all patient records held by a hospital will have an annual disclosure that will have to be recorded in an individual's record. It was more difficult to obtain a reliable estimate for non-hospital providers, though it appears that they receive many fewer requests. The Department assumed a ten percent rate for ambulatory care patients and five percent, for nursing homes, home health, dental and pharmacy providers. (It was difficult to obtain any reliable data for these latter groups, but those we talked to said that they had very few, and some indicated that they currently keep track of them in the records.) These estimated percentages represent about 63 million disclosures that will have to be recorded in the first year, with each recording estimated to require two minutes. At the average nurse's salary of $30.39 per hour, the cost in the first year is $25.7 million. For health plans, the Department assumed that disclosures of protected health information are more rare than for health care providers. Therefore, the Department assumed that there will be disclosures of protected health information for five percent of covered lives. At the average wage for the insurance industry of $33.82 per hour, the initial cost for health plans is $6.8 million. Using our standard growth rates for wages, patients, and covered entities, the ten-year cost for providers and health plans is $519 million.

In addition, although hospitals generally track patient disclosures today, the Department assumes that hospitals will seek to update software systems to assure full compliance. Based on software upgrade costs provided by the Department's private sector

consultants with expertise in the area (the Gartner Group), the Department assumed that each upgrade would cost $35,000 initially and $6,300 annually thereafter, for a total cost of $572 million over ten years.

The final rule also requires covered entities to provide individuals with an accounting of disclosures upon request. The Department assumes that few patients will request a history of disclosures of their protected medical information. Therefore, we estimate that one in a thousand patients will request such an accounting each year, which is approximately 850,000 requests. If it takes an average of five minutes to copy any disclosures and the work is done by a nurse, the cost for the first year will be $2.1 million. The total ten-year cost is $33.8 million. ***82769**

De-Identification of Information

The rule allows covered entities to determine that health information is de-identified (i.e., that it is not individually identifiable health information) if certain conditions are met. Currently, some entities release de-identified information for research purposes. De-identified information may originate from automated systems (such as records maintained by pharmacy benefit managers) and non-automated systems (such as individual medical records maintained by providers). As compared with current practice, the rule requires that an expanded list of identifiers be removed for the data (such as driver's license numbers, and detailed geographic and certain age information). For example, as noted in a number of public comments, currently complete birth dates (day, month, and year) and zip codes are often included in de-identified information. The final rule requires that only the year of birth (except in certain circumstances) and the first three digits of the zip code can be included in de-identified information.

These changes will not require extensive change from current practice. Providers generally remove most of the 19 identifiers listed in the final rule. The Department relied on Gartner Group estimates that some additional programmer time will be required by covered entities that produce de-identified information to make revisions in their procedures to eliminate additional identifiers. Entities that de-identify information will have to review existing and future data flows to assure compliance with the final rule. For example, an automated system may need to be re-programmed to remove additional identifiers from otherwise protected health information. (The costs of educating staff about the de-identification requirements are included in the cost estimate for training staff on privacy policies.)

The Department was not able to obtain any reliable information on the volume of medical data that is currently de-identified. To provide some measure of the potential magnitude, we assumed that health plans and hospitals would have an average of two existing agreements that would need to be reviewed and modified. Based on information provided by our consultants, we estimate that these agreements would require an average of 152 hours by hospitals and 116 hours by health plans to review and revise existing agreements to conform to the final rule. Using the weighted average wage of $47.28, the initial costs will be $124 million. Using our standard growth rates for wages, patients, and covered entities, the total cost of the provision is $1.1 billion over ten years.

The Department expects that the final rule and the increasing trend toward computerization of large record sets will result over time in de-identification being performed by relatively few firms or associations. Whether the covered entity is a small provider with relatively few files or a hospital or health plan with large record files, it will be more efficient to contract with specialists in these firms or associations (as “business associates” of the covered entity) to de-identify files. The process will be different but the ultimate cost is likely to be the same or only slightly higher, if at all, than the costs for de-identification today. The estimate is for the costs required to conform existing and future agreements to the provisions of the rule. The Department has not quantified the benefits that might arise from changes in the market for de-identified information because the centralization and efficiency that will come from it will not be fully realized for several years, and we do not have a reliable means of estimating such changes.

Policy and Procedures Development

The final regulation imposes a variety of requirements which collectively will necessitate entities to develop policies and procedures (henceforth in this section to be referred to as policies) to establish and maintain compliance with the regulation. These include policies such as those for inspection and copying, amending records, and receiving complaints.[FN50] In

developing the final regulations, simplifying the administrative burden was a significant consideration. To the extent practical, consistent with maintaining adequate protection of protected health information, the final rule is designed to encourage the development of policies by professional associations and others, that will reduce costs and facilitate greater consistency across providers and other covered entities.

The development of policies will occur at two levels: first, at the association or other large scale levels; and second, at the entity level. Because of the generic nature of many of the final rule's provisions, the Department anticipates that trade, professional associations, and other groups serving large numbers of members or clients will develop materials that can be used broadly. These will likely include the model privacy practice notice that all covered entities will have to provide patients; general descriptions of the regulation's requirements appropriate for various types of health care providers; checklists of steps entities will have to take to comply; training materials; and recommended procedures or guidelines. The Department spoke with a number of professional associations, and they confirmed that they would expect to provide such materials for their members at either the federal or state level.

Using Faulkner and Gray's Health Data Directory 2000, we identified 216 associations that would be likely to provide guidance to members. In addition, we assume three organizations (i.e., one for hospitals, health plans, and other health care providers) in each state would also provide some additional services to help covered entities coordinate the requirements of this rule with state laws and requirements. The Department assumed that these associations would each provide 320 hours of legal analysis at $150 per hour, and 640 hours of senior analysts time at $50 per hour. This equals $17.3 million. Hourly rates for legal council are the average billing rate for a staff attorney.[FN51] The senior analysts rates are based on a salary of $75,000 per year, plus benefits, which was provided by a major professional association.

For larger health care entities such as hospitals and health plans, the Department assumed that the complexity of their operations would require them to seek more customized assistance from outside council or consultants. Therefore, the Department assumes that each hospital and health plan (including self-administered, self-insured health plans) will, on average, require 40 hours of outside assistance. The resulting cost for external policy development is estimated to be $112 million.

All covered entities are expected to require some time for internal policy development beyond what is provided by associations or outside consultants. For most non-hospital providers, the external assistance will provide most of the necessary information. Therefore, we expect these health care providers will need only eight hours to adapt these policies for their specific use (training cost is estimated separately in the impact analysis). Hospitals and ***82770** health plans, which employ more individuals and are involved in a wider array of endeavors, are likely to require more specific policies tailored to their operations to comply with the final rule. For these entities, we assume an average of 320 hours of policy development per institution. The total cost for internal policy development is estimated to be $468 million.

The total cost for policy, plan, and procedures development for the final regulation is estimated to be $598 million. All of these costs are initial costs.

Training

The final regulation's requirements provide covered entities with considerable flexibility in how to best fulfill the necessary training of their workforce. As a result, the actual practices may vary substantially based on such factors as the number of members of the workforce, the types of operations, worker turnover, and experience of the workforce. Training is estimated to cost $737 million over ten years. The Department estimates that at the time of the effective date, approximately 6.7 million health care workers will have to be trained, and in the subsequent ten years, 7 million more will have to be trained because of worker turnover. The estimate of employee numbers are based on 2000 CPS data regarding the number of health care workers who indicated they worked for a health care institution. To estimate a workforce turnover rate, the Department relied on a study submitted in the public comments which used a turnover rate of ten percent or less, depending on the labor category. To be conservative, the Department assumed ten percent for all categories.

Covered entities will need to provide members of the workforce with varying amounts of training depending on their responsibilities, but on average, the Department estimates that each member of the workforce who is likely to have access to protected health information will require one hour of training in the policies and procedures of the covered entity. The initial training cost estimate is based on teacher training with an average class size of ten. After the initial training, the Department expects some training (for example, new employees in larger institutions) will be done by videotape, video conference, or computer, all of which are likely to be less expensive. Training materials were assumed to cost an average of $2 per worker. The opportunity cost for the training time is based on the average wage for each health care labor category listed in the CPS, plus a 39 percent load for benefits. Wages were increased based on the wage inflation factor utilized for the short-term assumptions (which covers ten years) in the Medicare Trustees' Annual Report for 1999.

Notice

This section describes only the cost associated with the production and provision of a notice. The cost of developing the policy stated in the notice is covered under policies and procedures, above.

Covered health care providers with direct treatment relationships are required to provide a notice of privacy practices no later than the date of the first service delivery to individuals after the compliance date for the covered health care provider. The Department assumed that for most types of health care providers (such as physicians, dentists, and pharmacists) one notice would be distributed to each patient during his or her first visit following the compliance date for the covered provider, but not for subsequent visits. For hospitals, however, the Department assumed that a notice would be provided at each admission, regardless of how many visits an individual has in a given year. In subsequent years, the Department assumed that non-hospital providers would only provide notices to their new patients, because it is assumed that providers can distinguish between new and old patients, although hospitals will continue to provide a notice for each admission. The total number of notices provided in the initial year is estimated to be 816 million.

Under the final rule, only providers that have direct treatment relationships with individuals are required to provide notices to them. To estimate the number of visits that trigger a notice in the initial year and in subsequent years, the Department relied on the Medical Expenditure Panel Survey (MEPS, 1996 data) conducted by the Department's Agency for Healthcare Quality and Research. This data set provides estimates for the number of total visits to a variety of health care providers in a given year and estimates of the number of patients with at least one visit to each type of each care provider. To estimate the number of new patients in a given year, the Department used the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey, which indicate that for ambulatory care visits to physician offices and hospital ambulatory care departments, 13 percent of all patients are new. This data was used as a proxy for other types of providers, such as dentists and nursing homes, because the Department did not have estimates for new patients for other types of providers. The number of new patients was increased over time to account for growth in the patient population. Therefore, the number of notices provided in years 2004 through 2012 is estimated to be 5.3 billion.

For health plans, the Department estimated the number of notices by trending forward the average annual rate of growth from 1995 through 1998 (the most recent data available) of private policy holders using the Census Bureau's Current Population Survey, and also by using Health Care Financing Administration Office of the Actuary's estimates for growth in Medicare and Medicaid enrollment. It should be noted that the regulation does not require that the notice be mailed to individuals. Therefore, the Department assumed that health plans would include their privacy policy in the annual mailings they make to members, such as by adding a page to an existing information booklet.

Since clinical laboratories generally do not have direct contact with patients, they would not normally be required to provide notices. However, there are some laboratory services that involve direct patient contact, such as patients who have tests performed in a laboratory or at a health fair. We found no data from which we could estimate the number of such visits. Therefore, we have assumed that labs would incur no costs as a result of this requirement.

The printing cost of the policy is estimated to be $0.05, based on data obtained from the Social Security Administration, which does a significant number of printings for distribution. Some large bulk users, such as health plans, can probably reproduce the document for less, and small providers simply may copy the notice, which would also be less than $0.05. Nonetheless, at $0.05, the total cost of the initial notice is $50.8 million.

Using our standard growth rate for patients, the total cost for notices is estimated to be $391 million for the ten-year period.

Requirements on Use and Disclosure for Research

The final regulation places certain requirements on covered entities that supply individually identifiable health information to researchers. As a result of these requirements, researchers who seek such health information and the Institutional Review Boards (IRBs) that review research projects will have additional responsibilities. Moreover, a covered entity doing research, or another entity requesting disclosure of ***82771** protected health information for research that is not currently subject to IRB review (research that is 100 percent privately funded and which takes place in institutions which do not have "multiple project assurances") may need to seek IRB or privacy board approval if they want to avoid the requirement to obtain authorization for use or disclosure of protected health information for research, thereby creating the need for additional IRBs and privacy boards that do not currently exist.

To estimate the additional requirements placed on existing IRBs, the Department relied on a survey of IRBs conducted by James Bell Associates on behalf of NIH and on estimates of the total number of existing IRBs provided by NIH staff. Based on this information, the Department concluded that of the estimated 4,000 IRBs in existence, the median number of initial current research project reviews is 133 per IRB, of which only ten percent do not receive direct consent for the use of protected health information. (Obtaining consent nullifies the need for IRB privacy scrutiny.) Therefore, in the first year of implementation, there will be 76,609 initial reviews affected by the regulation, and the Department assumes that the requirement to consider the privacy protections in the research protocols under review will add an average of 1 hour to each review. The cost to researchers for having to develop protocols which protect protected health information is difficult to estimate, but the Department assumes that each of the affected 76,609 studies will require an average of an additional 8 hours of time for protocol development and implementation. At the average medical scientist hourly wage of $46.61, the initial cost is $32.1 million; the total ten-year cost of these requirements is $468 million over ten years.

As stated above, some privately funded research not subject to any IRB review currently may need to obtain IRB or privacy board approval under the final rule. Estimating how much research exists which does not currently go through any IRB review is highly speculative, because the experts consulted by the Department all agree that there is no data on the volume of privately funded research. Likewise, public comments on this subject provided no useful data. However, the Department assumed that most research that takes place today is subject to IRB review, given that so much research has some government funding and many large research institutions have multiple project assurances. As a result, the Department assumed that the total volume of non-IRB reviewed research is equal to 25 percent of all IRB-reviewed research, leading to 19,152 new IRB or privacy board reviews in the first year of the regulation. Using the same assumptions as used above for wages, time spent developing privacy protection protocols for researchers, and time spent by IRB and privacy board members, the total one-year cost for new IRB and privacy board reviews is $8 million.

For estimating total ten-year costs, the Department used the Bell study, which showed an average annual growth rate of 3.7 percent in the number of studies reviewed by IRBs. Using this growth rate, the total ten-year cost for the new research requirements is $117 million.

Consent

Under the final rule, a covered health care provider with direct treatment relationships must obtain an individual's consent for use or disclosure of protected health information for treatment, payment, or health care operations. Covered providers with indirect treatment relationships and health plans may obtain such consent if they so choose. Providers and health plans that

seek consent under this rule can condition treatment or enrollment upon provision of such consent. Based on public comments and discussions with a wide array of health care providers, it is apparent that most currently obtain written consent for use and disclosure of individually identifiable health information for payment. Under the final rule, they will have to obtain consent for treatment and health care operations, as well, but this may entail only minor changes in the language of the consent to incorporate these other categories and to conform to the rule.

Although the Department was unable to obtain any systematic data, the anecdotal evidence suggests that most non-hospital providers and virtually all hospitals follow this practice. For the cost analysis, the Department assumes that 90 percent of the non-hospital providers and all hospitals currently obtain some consent for use and disclosure of individually identifiable health information. For providers that currently obtain written consent, there is only a nominal cost for changing the language on the document to conform to the rule. For this activity, we assumed $0.05 cost per document for revising existing consent documents.

For the ten percent of treating providers who currently do not obtain consent, there is the cost of creating consent documents (which will be standardized), which is also assumed to be $0.05 per document. It is assumed that all providers required to obtain consent under the rule will do so upon the first visit, so there will be no mailing cost. For non-hospital providers, we assume the consent will be maintained in paper form, which is what most providers currently do (electronic form, if available, is cheaper to maintain). There is no new cost for records maintenance because the consent will be kept in active files (paper or electronic).

The initial cost of the consent requirement is estimated to be $166 million. Using our standard assumptions for patient growth, the total costs for the ten years is estimated to be $227 million.

Authorizations

Patient authorizations are required for uses or disclosures of protected health information that are not otherwise explicitly permitted under the final rule with or without consent. In addition to uses and disclosures of protected health information for treatment, payment, and health care operations with or without consent, the rule also permits certain uses of protected health information, such as fund-raising for the covered entity and certain types of marketing activity, without prior consent or authorization. Authorizations are generally required if a covered entity wants to provide protected health information to third party for use by the third party for marketing or for research that is not approved by an IRB or privacy board.

The requirement for obtaining authorizations for use or disclosure of protected health information for most marketing activity will make direct third-party marketing more difficult because covered entities may not want to obtain and track such authorizations, or they may obtain too few to make the effort economically worthwhile. However, the final rule permits an alternative arrangement: the covered entity can engage in health-related marketing on behalf of a third party, presumably for a fee. Moreover, the covered entity could retain another party, through a business associate relationship, to conduct the actual health-related marketing, such as mailings or telemarketing, under the covered entity's name. The Department is unable to estimate the cost of these changes because there is no credible data on the extent of current third party marketing practices or the price that third party marketers currently pay for information from covered entities. The effect of the final rule is to change the ***82772** arrangement of practices to enhance accountability of protected health information by the covered entity and its business associates; however, there is nothing inherently costly in these changes.

Examples of other circumstances in which authorizations are required under the final rule include disclosure of protected health information to an employer for an employment physical, pre-enrollment underwriting for insurance, or the sharing of protected health insurance information by an insurer with an employer. The Department assumes there is no new cost associated with these requirements because providers have said that obtaining authorization under such circumstances is current practice.

To use or disclose psychotherapy notes for most purposes (including for treatment, payment, or health care operations), a covered entity must obtain specific authorization by the individual that is distinct from any authorization for use and disclosure of other protected health information. This is current practice, so there is no new cost associated with this provision.

Confidential Communications

The final rule permits individuals to receive communications of protected health information from a covered health care provider or a health plan by an alternative means or at an alternative address. A covered provider and a health plan must accommodate reasonable requests; however, a health plan may require the individual to state that disclosure of such information may endanger the individual. A number of providers and health plans indicated that they currently provide this service for patients who request it. For providers and health plans with electronic records system, maintaining separate addresses for certain information is simple and inexpensive, requiring little or no change in the system. For providers with paper records, the cost may be higher because they will have to manually check records to determine which information must be treated in accordance with such requests. Although some providers currently provide this service, the Department was unable to obtain any reliable estimate of the number of such requests today or the number of providers who perform this service. The cost attributable to this requirement to send materials to alternate addresses does not appear to be significant.

Employers With Insured Group Health Plans

Some group health plans will use or maintain protected health information, particularly group health plans that are self-insured. Also, some plan sponsors that perform administrative functions on behalf of their group health plans, may need protected health information. The final rule permits a group health plan, or a health insurance issuer or HMO that provides benefits on behalf of the group health plan, to disclose protected health information to a plan sponsor who performs administrative functions on its behalf for certain purposes and if certain requirements are met. The plan documents must be amended to: describe the permitted uses and disclosures of protected health information by the plan sponsor; specify that disclosure is permitted only upon receipt of a certification by the plan sponsor that the plan documents have been amended and the plan sponsor agrees to certain restrictions on the use of protected health information; and provide for adequate firewalls to assure unauthorized personnel do not have access to individually identifiable health information.

Some plan sponsors may need information, not to administer the group health plan, but to amend, modify, or terminate the plan. ERISA case law describes such activities as settlor functions. For example, a plan sponsor may want to change its contract from a preferred provider organization to a health maintenance organization (HMO). In order to obtain premium information, the plan sponsor may need to provide the HMO with aggregate claims information. Under the rule, the plan sponsor can obtain summary information with certain identifiers removed, in order to provide it to the HMO and receive a premium rate.

The Department assumes that most plan sponsors who are small employers (those with 50 or fewer employees) will elect not to receive protected health information because they will have little, if any, need for such data. Any needs that plan sponsors of small group health plans may have for information can be accomplished by receiving the information in summary form. The Department has assumed that only 5 percent of plan sponsors of small group health plans that provide coverage through a contract with an issuer will actually take the steps necessary to receive protected health information. This is approximately 96,900 firms. For these firms, the Department assumes it will take one hour to determine procedural and organization issues and an additional ⅓ hour of an attorney's time to make plan document changes, which will be simple and essentially standardized. This will cost $7.1 million.

Plan sponsors who are employers of medium (51-199 employees) and large (over 200 employees) firms that provide health benefits through contracts with issuers are more likely to want access to protected health information for plan administration, for example to use it to audit claims or perform quality assurance functions on behalf of the group health plan. The Department assumes that 25 percent of plan sponsors of medium sized firms and 75 percent of larger firms will want to receive protected health information. This is approximately 38,000 medium size firms and 27,000 larger firms. To provide access to protected health information by the group health plan, a plan sponsor will have to assess the current flow of protected health information from their issuer and determine what information is necessary and appropriate. The plan sponsors may then have to make internal organizational changes to assure adequate protection of protected health information so that the relevant requirements are met for the group health plan. We assume that medium size firms will take 16 work hours to complete organizational changes, plus one hour of legal time to make changes to plan documents and certify to the insurance carrier that the firm is eligible to receive

protected health information. We assume that larger firms will require 32 hours of internal organizational work and one hour of legal time. This will cost $52.4 million and is a one-time expense.

Business Associates

The final rule requires a covered entity to have a written contract or other arrangement that documents satisfactory assurance that business associate will appropriately safeguard protected health information in order to disclose it to a business associate based on such an arrangement. The Department expects business associate contracts to be fairly standardized, except for language that will have to be tailored to the specific arrangement between the parties, such as the allowable uses and disclosures of information. The Department assumes the standard language initially will be developed by trade and professional associations for their members. Small providers are likely to simply adopt the language or make minor modifications, while health plans and hospitals may start with the prototype language but may make more specific changes to ***82773** meet their institutional needs. The regulation includes a requirement that the covered entity take steps to correct, and in some cases terminate, a contract, if necessary, if they know of violations by a business associate. This oversight requirement is consistent with standard oversight of a contract.

The Department could not derive a per entity cost for this work directly. In lieu of this, we have assumed that the trade and professional associations' work plus any minor tailoring of it by a covered entity would amount to one hour per non-hospital provider and two hours for hospitals and health plans. The larger figure for hospitals and health plans reflects the fact that they are likely to have a more extensive array of relationships with business associates.

The cost for the changes in business associate contracts is estimated to be $103 million. This will be an initial year cost only because the Department assumes that this contract language will become standard in future contracts.

In addition, the Department has estimated the cost for business associates to comply with the minimum necessary provisions. As part of the minimum necessary provisions, covered entities will have to establish policies to ensure that only the minimum necessary protected health information is shared with business associates. To the extent that data are exchanged, covered entities will have to review the data and systems programs to assure compliance.

For non-hospital providers, we estimate that the first year will require an average of three hours to review existing agreements, and thereafter, they will require an additional hour to assure business associate compliance. We estimate that hospitals will require an additional 200 hours the first year and 16 hours in subsequent years; health plans will require an additional 112 hours the first year and 8 hours in subsequent years. As in other areas, we have assumed a weighted average wage for the respective sectors.

The cost of the covered entities assuring business associates' complying with the minimum necessary is $197 million in the first year, and a total of $697 million over ten years. (These estimates include the both the cost for the covered entity and the business associates.)

Inspection and Copying

In the NPRM estimate, inspection and copying were a major cost. Based on data and information from the public comments and further fact-finding, however, the Department has re-estimated these policies and found them to be much less expensive.

The public comments demonstrate that copying of records is wide-spread today. Records are routinely copied, in whole or in part, as part of treatment or when patients change providers. In addition, copying occurs as part of legal proceedings. The amount of inspection and copying of medical records that occurs for these purposes is not expected to change measurably as a result of the final regulation.

The final regulation establishes the right of individuals to access, that is to inspect and obtain a copy of, protected health information about them in designated record sets. Although this is an important right, the Department does not expect it to result in dramatic increases in requests from individuals. The Georgetown report on state privacy laws indicates that 33 states currently give patients some right to access medical information. The most common right of access granted by state law is the right to inspect personal information held by physicians and hospitals. In the process of developing estimates for the cost of providing access, we assumed that most providers currently have procedures for allowing patients to inspect and obtain a copy of individually identifiable health information about themselves. The economic impact of requiring entities to allow individuals to access their records should be relatively small. One public commenter addressed this issue and provided specific data which supports this conclusion.

Few studies address the cost of providing medical records to patients. The most recent was a study in 1998 by the Tennessee Comptroller of the Treasury. It found an average cost of $9.96 per request, with an average of 31 pages per request. The cost per page of providing copies was $0.32 per page. This study was performed on hospitals only. The cost per request may be lower for other types of providers, since those seeking hospital records are more likely to have more complicated records than those in a primary care or other types of offices. An earlier report showed much higher costs than the Tennessee study. In 1992, Rose Dunn published a report based on her experience as a manager of medical records. She estimated a 10-page request would cost $5.32 in labor costs only, equaling labor cost per page of $0.53. However, this estimate appears to reflect costs before computerization. The expected time spent per search was 30.6 minutes; 85 percent of this time could be significantly reduced with computerization (this includes time taken for file retrieval, photocopying, and re-filing; file retrieval is the only time cost that would remain under computerization).

In estimating the cost of copying records, the Department relied on the public comment from a medical records outsourcing industry representative, which submitted specific volume and cost data from a major firm that provides extensive medical record copying services. According to these data, 900 million pages of medical records are copied each year in the U.S., the average medical record is 31 pages, and copying costs are $0.50 per page. In addition, the commenter noted that only 10 percent of all requests are made directly from patients, and of those, the majority are for purposes of continuing care (transfer to another provider), not for purposes of individual inspection. The Department assumed that 25 percent of direct patient requests to copy medical records are for purposes of inspecting their accuracy (i.e., 2.5 percent of all copy requests) or 850,000 in 2003 if the current practice remained unchanged.

To estimate the marginal increase in copying that might result from the regulation, the Department assumed that as patients gained more awareness of their right to inspect and copy their records, more requests will occur. As a result, the Department assumed a ten percent increase in the number of requests to inspect and copy medical records over the current baseline, which would amount to a little over 85,000 additional requests in 2003 at a cost of $1.3 million. Allowing for a 5.3 percent increase in records based on the increase in ambulatory care visits, the highest growth rate among health service sectors (the National Ambulatory Medical Care Survey, 1998), the total cost for the ten-year period would be $16.8 million.

The final rule allows a provider to deny an individual the right to inspect or obtain a copy of protected health information in a designated record set under certain circumstances, and it provides, in certain circumstances, that the patient can request the denial to be reviewed by another licensed health care professional. The initial provider can choose a licensed health care professional to render the second review.

The Department assumes denials and subsequent requests for reviews will be extremely rare. The Department estimates there are about 932,000 annual requests for inspections (i.e., base plus new requests resulting from the regulation), or approximately 11 million over the ten-year period. If one- ***82774** tenth of one percent of these requests were to result in a denial in accordance with the rule, the result would be 11,890 cases. Not all these cases would be appealed. If 25 percent were appealed, the result would be 2,972 cases. If a second provider were to spend 15 minutes reviewing the case, the cost would be $6,000 in the first year and $86,360 over ten years.

Amendments to Protected Health Information

Many providers and health plans currently allow patients to amend the information in their medical record, where appropriate. If an error exists, both the patient and the provider or health plan benefit from the correction. However, as with inspection and copying, many states do not provide individuals with the right to request amendment to protected health information about themselves. Based on these assumptions, the Department concludes that the principal economic effect of the final rule would be to expand the right to request amendments to protected health information held by a health plan or provider to those who are not currently covered by amendment requirements under state laws or codes of conduct. In addition, the rule may draw additional attention to the issue of inaccuracies in information and may stimulate patient demand for amendment of medical records, including in those states that currently provide a right to amend medical records.

Under the final regulation, if a patient requests an amendment to his or her medical record, the provider must either accept the amendment or provide the individual with the opportunity to submit a statement disagreeing with the denial. The provider must acknowledge the request and inform the patient of his action.

The cost calculations assume that individuals who request an opportunity to amend their medical record have already obtained a copy of it. Therefore, the administrative cost of amending the patient's record is completely separate from inspection and copying costs.

Based on fact-finding discussions with a variety of providers, the Department assumes that 25 percent of the projected 850,000 people who request to inspect their records will seek to amend them. This number is the existing demand plus the additional requests resulting from the rule. Over ten years, the number of expected amendment requests will be 2.7 million. Unlike inspections, which currently occur in a small percentage of cases, our fact-finding suggests that patients very rarely seek to amend their records, but that the establishment of this right in the rule will spur more requests. The 25 percent appears to be high based on our discussions with providers but it is being used to avoid an underestimation of the cost.

As noted, the provider or health plan is not required to evaluate any amendment requests, only to append or otherwise link to the request in the record. We expect the responses will vary: sometimes an assistant will only make the appropriate notation in the record, requiring only a few minutes; other times a provider or manager will review the request and make changes if appropriate, which may require as much as an hour. To be conservative in its estimate, the Department has assumed, on average, 30 minutes for each amendment request at a cost of $47.28 per hour (2000 CPS).

The first-year cost for the amendment policy is estimated to be $5 million. The ten-year cost of this provision is $78.8 million.

Law Enforcement and Judicial and Administrative Proceedings

The law enforcement provisions of the final rule allow disclosure of protected health information without patient authorization under four circumstances: (1) Pursuant to legal process or as otherwise required by law; (2) to locate or identify a suspect, fugitive, material witness, or missing person; (3) under specified conditions regarding a victim of crime; and (4) and when a covered entity believes the protected health information constitutes evidence of a crime committed on its premises. As under current law and practice, a covered entity may disclose protected health information to a law enforcement official if such official.

Based on our fact finding, we are not able to estimate any additional costs from the final rule regarding disclosures to law enforcement officials. The final rule makes clear that current court orders and grand jury subpoenas will continue to provide a basis for covered entities to disclose protected health information to law enforcement officials. The three-part test, which covered entities must use to decide whether to disclose information in response to an administrative request such as an administrative subpoena, represents a change from current practice. There will be only minimal costs to draft the standard language for such subpoenas. We are unable to estimate other costs attributable to the use of administrative subpoenas. We have not been able to discover any specific information about the costs to law enforcement of establishing the predicates for issuing the administrative

subpoena, nor have we been able to estimate the number of such subpoenas that will likely be issued once the final rule is implemented.

A covered entity may disclose protected health information in response to an order in the course of a judicial or administrative proceeding if reasonable efforts have been made to give the individual, who is the subject of the protected health information, notice of and an opportunity to object to the disclosure or to secure a qualified protective order.

The Department was unable to estimate any additional costs due to compliance with the final rule's provisions regarding judicial and administrative proceedings. The provision requiring a covered entity to make efforts to notify an individual that his or her records will be used in proceedings is similar to current practice; attorneys for plaintiffs and defendants agreed that medical records are ordinarily produced after the relevant party has been notified. With regard to protective orders, we believe that standard language for such orders can be created at minimal cost. The cost of complying with such protective orders will also likely be minimal, because attorney's client files are ordinarily already treated under safeguards comparable to those contemplated under the qualified protective orders. The Department was unable to make an estimate of how many such protective orders might be created annually.

We thus do not make any estimate of the initial or ongoing costs for judicial, administrative, or law enforcement proceedings.

Costs to the Federal Government

The rule will have a cost impact on various federal agencies that administer programs that require the use of individual health information. The federal costs of complying with the regulation and the costs when federal government entities are serving as providers are included in the regulation's total cost estimate outlined in the impact analysis. Federal agencies or programs clearly affected by the rule are those that meet the definition of a covered entity. However, non-covered agencies or programs that handle medical information, either under permissible exceptions to the disclosure rules or through an individual's expressed authorization, will likely incur some costs complying with provisions of this rule. A sample of federal agencies encompassed by the ***82775** broad scope of this rule include the: Department of Health and Human Services, Department of Defense, Department of Veterans Affairs, Department of State, and the Social Security Administration.

The greatest cost and administrative burden on the federal government will fall to agencies and programs that act as covered entities, by virtue of being either a health plan or provider. Examples include the Medicare, Medicaid, Children's Health Insurance and Indian Health Service programs at the Department of Health and Human Services; the CHAMPVA health program at the Department of Veterans Affairs; and the TRICARE health program at the Department of Defense. These and other health insurance or provider programs operated by the federal government are subject to requirements placed on covered entities under this rule, including, but not limited to, those outlined in Section D of the impact analysis. While many of these federal programs already afford privacy protections for individual health information through the Privacy Act and standards set by the Departments and implemented through their contracts with providers, this rule is nonetheless expected to create additional requirements. Further, we anticipate that most federal health programs will, to some extent, need to modify their existing practices to comply fully with this rule. The cost to federal programs that function as health plans will be generally the same as those for the private sector.

A unique cost to the federal government will be in the area of enforcement. The Office for Civil Rights (OCR), located at the Department of Health and Human Services, has the primary responsibility to monitor and audit covered entities. OCR will monitor and audit covered entities in both the private and government sectors, will ensure compliance with requirements of this rule, and will investigate complaints from individuals alleging violations of their privacy rights. In addition, OCR will be required to recommend penalties and other remedies as part of their enforcement activities. These responsibilities represent an expanded role for OCR. Beyond OCR, the enforcement provisions of this rule may have additional costs to the federal government through increased litigation, appeals, and inspector general oversight.

Examples of other unique costs to the federal government may include such activities as public health surveillance at the Centers for Disease Control and Prevention, health research projects at the Agency for Healthcare Research and Quality, clinical trials at the National Institutes of Health, and law enforcement investigations and prosecutions by the Federal Bureau of Investigations. For these and other activities, federal agencies will incur some costs to ensure that protected health information is handled and tracked in ways that comply with the requirements of this title.

We estimate that federal costs under this rule will be approximately $196 million in 2003 and $1.8 billion over ten years. The ten-year federal cost estimate represents about 10.2 percent of the privacy regulation's total cost. This estimate was derived in two steps.

First, we assumed that the proportion of the privacy regulation's total cost accruing to the federal government in a given year will be equivalent to the proportion of projected federal costs as a percentage of national health expenditures for that year. To estimate these proportions, we used the Health Care Financing Administration's November 1998 National Health Expenditure projections (the most recent data available) of federal health expenditures as a percent of national health expenditures from 2003 through 2008, trended forward to 2012. We then adjusted these proportions to exclude Medicare and Medicaid spending, reflecting the fact that the vast majority of participating Medicare and Medicaid providers will not be able to pass through the costs of complying with this rule to the federal government because they are not reimbursed under cost-based payment systems. This calculation yields a partial federal cost of $166 million in 2003 and $770 million over ten years.

Second, we add the Medicare and federal Medicaid costs resulting from the privacy regulation that HCFA's Office of the Actuary project can be passed through to the federal government. These costs reflect the actuaries' assumption regarding how much of the total privacy regulation cost burden will fall on participating Medicare and Medicaid providers, based on the November 1998 National Health Expenditure data. Then the actuaries estimate what percentage of the total Medicare and federal Medicaid burden could be billed to the programs, assuming that (1) only 3 percent of Medicare providers and 5 percent of Medicaid providers are still reimbursed under cost-based payment systems, and (2) over time, some Medicaid costs will be incorporated into the state's Medicaid expenditure projections that are used to develop the federal cost share of Medicaid spending. The results of this actuarial analysis add another $30 million in 2003 and $1.0 billion over ten years to the federal cost estimate. Together, these three steps constitute the total federal cost estimate of $236 million in 2003 and $2.2 billion over ten years.

Costs to State and Local Governments

The rule will also have a cost effect on various state and local agencies that administer programs requiring the use of individually identifiable health information. State and local agencies or programs clearly affected by the rule are those that meet the definition of a covered entity. The costs when government entities are serving as providers are included in the total cost estimates. However, non-covered agencies or programs that handle individually identifiable health information, either under permissible exceptions to the disclosure rules or through an individual's expressed authorization, will likely incur some costs complying with provisions of this rule. Samples of state and local agencies or programs encompassed by the broad scope of this rule include: Medicaid, State Children's Health Insurance Programs, county hospitals, state mental health facilities, state or local nursing facilities, local health clinics, and public health surveillance activities, among others. We have included state and local costs in the estimation of total costs in this section.

The greatest cost and administrative burden on the state and local government will fall to agencies and programs that act as covered entities, by virtue of being either a health plan or provider, such as Medicaid, State Children's Health Insurance Programs, and county hospitals. These and other health insurance or provider programs operated by state and local government are subject to requirements placed on covered entities under this rule, including, but not limited to, those outlined in this section (Section E) of the impact analysis. Many of these state and local programs already afford privacy protections for individually identifiable health information through the Privacy Act. For example, state governments often become subject to Privacy Act requirements when they contract with the federal government. This rule is expected to create additional requirements beyond those covered by the Privacy Act. Furthermore, we anticipate that most state and local health programs will, to some extent,

need to modify their existing Privacy Act practices to fully comply with this rule. The cost to state ***82776** and local programs that function as health plans will be different than the private sector, much as the federal costs vary from private health plans.

A preliminary analysis suggests that state and local government costs will be on the order of $460 million in 2003 and $2.4 billion over ten years. We assume that the proportion of the privacy regulation's total cost accruing to state and local governments in a given year will be equivalent to the proportion of projected state and local costs as a percentage of national health expenditures for that year. To estimate these proportions, we used the Health Care Financing Administration's November 1998 National Health Expenditure projections of state and local health expenditures as a percent of national health expenditures from 2003 through 2008, trended forward to 2012. Based on this approach, we assume that over the entire 2003 to 2012 period, 13.6 percent, or $2.4 billion, of the privacy regulation's total cost will accrue to state and local governments. Of the $2.4 billion state and local government cost, 19 percent will be incurred in the regulation's first year (2003). In each of the out-years (2004-2012), the average percent of the total cost incurred will be about nine percent per year. These state and local government costs are included in the total cost estimates discussed in the regulatory impact analysis.

F. Benefits

There are important societal benefits associated with improving health information privacy. Confidentiality is a key component of trust between patients and providers, and some studies indicate that a lack of privacy may deter patients from obtaining preventive care and treatment.[FN52] For these reasons, traditional approaches to estimating the value of a commodity cannot fully capture the value of personal privacy. It may be difficult for individuals to assign value to privacy protection because most individuals view personal privacy as a right. Therefore, the benefits of the proposed regulation are impossible to estimate based on the market value of health information alone. However, it is possible to evaluate some of the benefits that may accrue to individuals as a result of proposed regulation, and these benefits, alone, suggest that the regulation is warranted. Added to these benefits is the intangible value of privacy, the security that individuals feel when personal information is kept confidential. This benefit is very real and very significant but there are no reliable means of measuring dollar value of such benefit.

As noted in the comment and response section, a number of commenters raised legitimate criticisms of the Department's approach to estimating benefits. The Department considered other approaches, including attempts to measure benefits in the aggregate rather than the specific examples set forth in the NPRM. However, we were unable to identify data or models that would provide credible measures. Privacy has not been studied empirically from an economic perspective, and therefore, we concluded that the approach taken in the NPRM is still the most useful means of illustrating that the benefits of the regulation are significant in relation to the economic costs.

Before beginning the discussion of the benefits, it is important to create a framework for how the costs and benefits may be viewed in terms of individuals rather than societal aggregates. We have estimated the value an insured individual would need to place on increased privacy to make the privacy regulation a net benefit to those who receive health insurance. Our estimates are derived from data produced by the 1998 Current Population Survey from the Census Bureau (the most recent available at the time of the analysis), which show that 220 million persons are covered by either private or public health insurance. Joining the Census Bureau data with the costs calculated in Section E, we have estimated the cost of the regulation to be approximately $6.25 per year (or approximately $0.52 per month) for each insured individual (including people in government programs). If we assume that individuals who use the health care system will be willing to pay more than this per year to improve health information privacy, the benefits of the proposed regulation will outweigh the cost.

This is a conservative estimate of the number of people who will benefit from the regulation because it assumes that only those individuals who have health insurance or are in government programs will use medical services or benefit from the provisions of the proposed regulation. Currently, there are 42 million Americans who do not have any form of health care coverage. The estimates do not include those who pay for medical care directly, without any insurance or government support. By lowering the number of users in the system, we have inflated our estimate of the per-person cost of the regulation; therefore, we assume that our estimate represents the highest possible cost for an individual.

An alternative approach to determining how people would have to value increased privacy for this regulation to be beneficial is to look at the costs divided by the number of encounters with health care professionals annually. Data from the Medical Expenditure Panel Survey (MEPS) produced by the Agency for Healthcare Policy Research (AHCPR) show approximately 776.3 million health care visits (e.g., office visits, hospital and nursing home stays, etc.) in the first year (2003). As with the calculation of average annual cost per insured patient, we divided the total cost of complying with the regulation by the total annual number of health care visits. The cost of instituting requirements of the proposed regulation is $0.19 per health care visit. If we assume that individuals would be willing to pay more than $0.19 per health care visit to improve health information privacy, the benefits of the proposed regulation outweigh the cost.

Qualitative Discussion

A well designed privacy standard can be expected to build confidence among the public about the confidentiality of their medical records. The seriousness of public concerns about privacy in general are shown in the 1994 Equifax-Harris Consumer Privacy Survey, where "84 percent of Americans are either very or somewhat concerned about threats to their personal privacy."[FN53] A 1999 report, "Promoting Health and Protecting Privacy" notes "* * * many people fear their personal health information will be used against them: to deny insurance, employment, and housing, or to expose them to unwanted judgements and scrutiny."[FN54] These concerns would be partly allayed by the privacy standard.

Fear of disclosure of treatment is an impediment to health care for many Americans. In the 1993 Harris-Equifax Health Information Privacy Survey, seven percent of respondents said they or a member of their immediate family had chosen not to seek medical services due to fear of harm to job prospects or other life opportunities. About two percent reported having chosen not to file an insurance claim because of concerns of lack of privacy or confidentiality.[FN55] Increased confidence ***82777** on the part of patients that their privacy would be protected would lead to increased treatment among people who delay or never begin care, as well as among people who receive treatment but pay directly (to the extent that the ability to use their insurance benefits will reduce cost barriers to more complete treatment). It will also change the dynamic of current payments. Insured patients currently paying out-of-pocket to protect confidentiality will be more likely to file with their insurer and to seek all necessary care. The increased utilization that would result from increased confidence in privacy could be beneficial under many circumstances. For many medical conditions, early and comprehensive treatment can lead to lower costs.

The following are four examples of areas where increased confidence in privacy would have significant benefits. They were chosen both because they are representative of widespread and serious health problems, and because they are areas where reliable and relatively complete data are available for this kind of analysis. The logic of the analysis, however, applies to any health condition, including relatively minor conditions. We expect that some individuals might be concerned with maintaining privacy even if they have no significant health problems because it is likely that they will develop a medical condition in the future that they will want to keep private.

Cancer

The societal burden of disease imposed by cancer is indisputable. Cancer is the second leading cause of death in the US,[FN56] exceeded only by heart disease. In 2000, it is estimated that 1.22 million new cancer cases will be diagnosed.[FN57] The estimated prevalence of cancer cases (both new and existing cases) in 1999 was 8.37 million.[FN58] In addition to mortality, incidence, and prevalence rates, the other primary methods of assessing the burden of disease are cost-of-illness and quality of life measures.[FN59] Cost of illness measures the economic costs associated with treating the disease (direct costs) and lost income associated with morbidity and mortality (indirect costs). The National Institutes of Health estimates that the overall annual cost of cancer in 1990 was $96.1 billion; $27.5 billion in direct medical costs and $68.7 billion for lost income due to morbidity and mortality.[FN60] Health-related quality of life measures integrate the mortality and morbidity effects of disease to produce health status scores for an individual or population. For example, the Quality Adjusted Life Year (QALY) combines the pain, suffering, and productivity loss caused by illness into a single measure. The Disability Adjusted Life Year (DALY) is based on the sum of life years lost to premature mortality and years that are lived, adjusted for disability.[FN61] The analysis below is based on the cost-of-illness measure for cancer, which is more developed than the quality of life measure.

Among the most important elements in the fight against cancer are screening, early detection and treatment of the disease. However, many patients are concerned that cancer detection and treatment will make them vulnerable to discrimination by insurers or employers. These privacy concerns have been cited as a reason patients do not seek early treatment for diseases such as cancer. As a result of forgoing early treatment, cancer patients may ultimately face a more severe illness and/or premature death.

Increasing people's confidence in the privacy of their medical information would encourage more people with cancer to seek cancer treatment earlier, which would increase cancer survival rates and thus reduce the lost wages associated with cancer. For example, only 24 percent of ovarian cancers are diagnosed in the early stages. Of these, approximately 90 percent of patients survive treatment. The survival rate of women who detect breast cancer early is similarly high; more than 90 percent of women who detect and treat breast cancer in its early stages will survive.[FN62]

We have attempted to estimate the annual savings in foregone wages that would result from earlier treatment due to enhanced protection of the privacy of medical records. We do not assume there would be increased medical costs from earlier treatment because the costs of earlier and longer cancer treatment are probably offset by the costs of treating late-stage cancer among people who would otherwise not be treated until their cases had progressed.

Although figures on the number of individuals who avoid cancer treatment due to privacy concerns do not exist, some indirect evidence is available. A 1993 Harris-Equifax Health Information Privacy Survey (noted earlier) found that seven percent of respondents reported that they or a member of their immediate family had chosen not to seek services for a physical or mental health condition due to fear of harm to job prospects or other life opportunities. It should be noted that this survey is somewhat dated and represents only one estimate. Moreover, given the wording of the question, there are other reasons aside from privacy concerns that led these individuals to respond affirmatively. However, for the purposes of this estimate, we assume that privacy concerns were responsible for the majority of positive responses.

Based on the Harris-Equifax survey estimate that seven percent of people did not seek services for physical or mental health conditions due to fears about job prospects or other opportunities, we assume that the proportion of people diagnosed with cancer who did not seek earlier treatment due to these fears is also seven percent. Applying this seven percent figure to the estimated number of total cancer cases (8.37 million) gives us an estimate of 586,000 people who did not seek earlier cancer treatment due to privacy concerns. We estimate annual lost wages due to cancer morbidity and mortality per cancer patient by dividing total lost wages ($68.7 billion) by the number of cancer patients (8.37 million), which rounds to $8,200. We then assume that cancer patients who seek earlier treatment would achieve a one-third reduction in cancer mortality and morbidity due to earlier treatment. The assumption of a one-third reduction in mortality and morbidity is derived from a study showing a one-third reduction in colorectal cancer mortality due to colorectal cancer screening.[FN63] We could have chosen a lower or higher treatment success rate. By multiplying 586,000 by $8,200 by one-third, we calculate that $1.6 billion in lost wages could be saved each year by encouraging more people to seek early cancer treatment through enhanced privacy protections. This estimate illustrates the potential savings ***82778** in lost wages due to cancer that could be achieved with greater privacy protections.

HIV/AIDS

Early detection is essential for the survival of a person with HIV (Human Immunodeficiency Virus). Concerns about the confidentiality of HIV status would likely deter some people from getting tested. For this reason, each state has passed some sort of legislation regarding confidentiality of an individual's HIV status. However, HIV status can be revealed indirectly through disclosure of HAART (Highly Active Anti-Retroviral Therapy) or similar HIV treatment drug use. In addition, since HIV/AIDS (Acquired Immune Deficiency Syndrome) is often the only specially protected condition, “blacked out” information on medical charts could indicate HIV positive status.[FN64] Strengthening privacy protections beyond this disease could increase confidence in privacy regarding HIV as well. Drug therapy for HIV positive persons has proven to be a life-extending, cost-effective tool.[FN65] A 1998 study showed that beginning treatment with HAART in the early asymptomatic stage is more cost-effective than beginning it late. After five years, only 15 percent of patients with early treatment are estimated to develop

an ADE (AIDS-defining event), whereas 29 percent would if treatment began later. Early treatment with HAART prolongs survival (adjusted for quality of life) by 6.2 percent. The overall cost of early HAART treatment is estimated at $23,700 per quality-adjusted year of life saved.[FN66]

Other Sexually Transmitted Diseases

It is difficult to know how many people are avoiding testing for STDs despite having a sexually transmitted disease. A 1998 study by the Kaiser Family Foundation found that the incidence of disease was 15.3 million in 1996, though there is great uncertainty due to under-reporting.[FN67] For a potentially embarrassing disease such as an STD, seeking treatment requires trust in both the provider and the health care system for confidentiality of such information. Greater trust should lead to more testing and greater levels of treatment. Earlier treatment for curable STDs can mean a decrease in morbidity and the costs associated with complications. These include expensive fertility problems, fetal blindness, ectopic pregnancies, and other reproductive complications.[FN68] In addition, there could be greater overall savings if earlier treatment translates into reduced spread of infections.

Mental Health Treatment

When individuals have a better understanding of the privacy practices that we are requiring in this proposed rule, some will be less reluctant to seek mental health treatment. One way that individuals will receive this information is through the notice requirement. Increased use of mental health and services would be expected to be beneficial to the persons receiving the care, to their families, and to society at large. The direct benefit to the individual from treatment would include improved quality of life, reduced disability associated with mental conditions, reduced mortality rate, and increased productivity associated with reduced disability and mortality. The benefit to families would include quality of life improvements and reduced medical costs for other family members associated with abusive behavior by the treated individual.

The potential economic benefits associated with improving privacy of individually identifiable health information and thus encouraging some portion of individuals to seek initial mental health treatment or increase service use are difficult to quantify well. Nevertheless, using a methodology similar to the one used above to estimate potential savings in cancer costs, one can lay out a range of possible benefit levels to illustrate the possibility of cost savings associated with an expansion of mental health and treatment to individuals who, due to protections offered by the privacy regulation, might seek treatment that they otherwise would not have. This can be illustrated by drawing upon existing data on the economic costs of mental illness and the treatment effectiveness of interventions.

The 1998 Substance Abuse and Mental Health Statistics Source Book from the Substance Abuse and Mental Health Services Administration (SAMHSA) estimates that the economic cost to society of mental illness in 1994 was about $204.4 billion. About $91.7 billion was due to the cost of treatment and medical care and $112.6 billion (1994 dollars) was due to loss of productivity associated with morbidity and mortality and other related costs, such as crime.[FN69] Evidence suggests that appropriate treatment of mental health disorders can result in 50-80 percent of individuals experiencing improvements in these types of conditions. Improvements in patient functioning and reduced hospital stays could result in hundreds of millions of dollars in cost savings annually.

Although figures on the number of individuals who avoid mental health treatment due to privacy concerns do not exist, some indirect evidence is available. As noted in the cancer discussion, the 1993 Harris-Equifax Health Information Privacy Survey found that 7 percent of respondents reported that they or a member of their immediate family had chosen not to seek services for a physical or mental health condition due to fear of harm to job prospects or other life opportunities. (See above for limitations to this data).

We assume that the proportion of people with a mental health disorder who did not seek treatment due to fears about job prospects or other opportunities is the same as the proportion in the Harris-Equifax survey sample who did not seek services for physical or mental health conditions due to the same fears (7 percent). The 1999 Surgeon General's Report on Mental Health

estimates that 28 percent of the U.S. adult population has a diagnosable mental and/or substance abuse disorder and 20 percent of the population has a mental and/or substance abuse disorder for which they do not receive treatment.[FN70] Based on the Surgeon General's Report, we estimate that 15 percent of the adult population has a mental disorder for which they do not seek treatment.[FN71] Assuming that 7 ***82779** percent of those with mental disorders did not seek treatment due to privacy concerns, we estimate that 1.05 percent of the adult population[FN72] (15 percent multiplied by 7 percent), or 2.07 million people, did not seek treatment for mental illness due to privacy fears.

The indirect (non-treatment) economic cost of mental illness per person with mental illness is $2,590 ($112.6 billion divided by 43.4 million people with mental illness).[FN73] The treatment cost of mental illness per person with mental illness is $2,110 ($91.7 billion divided by 43.4 million individuals). If we assume that indirect economic costs saved by encouraging more individuals with mental illness to enter treatment are offset by the additional treatment costs, the net savings is about $480 per person.

As stated above, appropriate treatment of mental health disorders can result in 50-80 percent of individuals experiencing improvements in these types of conditions. Therefore, we multiply the number of individuals with mental disorders who would seek treatment with greater privacy protections (2.07 million) by the treatment effectiveness rate by the net savings per effective treatment ($480). Assuming a 50 percent success rate, this equation yields annual savings of $497 million. Assuming an 80 percent success rate, this yields annual savings of $795 million.

Given the existing data on the annual economic costs of mental illness and the rates of treatment effectiveness for these disorders, coupled with assumptions regarding the percentage of individuals who would seek mental health treatment with greater privacy protections, the potential net economic benefits could range from approximately $497 million to $795 million annually.

V. Final Regulatory Flexibility Analysis

A. Introduction

Pursuant to the Regulatory Flexibility Act 5 U.S.C. 601 et seq., the Department must prepare a regulatory flexibility analysis if the Secretary certifies that a final rule would have a significant economic impact on a substantial number of small entities.[FN74]

This analysis addresses four issues: (1) The need for, and objective of, the rule; (2) a summary of the public comments to the NPRM and the Department's response; (3) a description and estimate of the number of small entities affected by the rule; and (4) a description of the steps the agency has taken to minimize the economic impact on small entities, consistent with the law and the intent of the rule. The following sections provide details on each of these issues. A description of the projected reporting and record keeping requirements of the rule are included in Section IX, below.

B. Reasons for Promulgating the Rule

This proposed rule is being promulgated in response to a statutory mandate to do so under section 264 of Public Law 104-191. Additional information on the reasons for promulgating the rule can be found in earlier preamble discussions (see Section I. B. above).

1. Objectives and Legal Basis

This information can be found in earlier preamble discussions (See I. C. and IV., above).

2. Relevant Federal Provisions

This information can be found in earlier preamble discussions (See I. C., above).

C. Summary of Public Comments

The Department received only a few comments regarding the Initial Regulatory Flexibility Analysis (IRFA) contained in the NPRM. A number of commenters argued that the estimates IRFA were too low or incomplete. The estimates were incomplete to the extent that a number of significant policy provisions in the proposal were not estimated because of too little information at the time. In the final IRFA we have estimates for these provisions. As for the estimates being too low, the Department has sought as much information as possible. The methodology employed for allocating costs to the small business sectors is explained in the following section.

Most of the other comments pertaining to the IRFA criticized specific estimates in the NPRM. Generally, the commenters argued that certain cost elements were not included in the cost estimates presented in the NPRM. The Department has expanded our description of our data and methodology in both the final RIA and this final RFA to try to clarify the data and assumptions made and the rationale for using them.

Finally, a number of commenters suggested that small entities be exempted from coverage from the final rule, or that they be given more time to comply. As the Department has explained in the Response to Comment section above, such changes were considered but rejected. Small entities constitute the vast majority of all entities that are covered; to exempt them would essentially nullify the purpose of the rule. Extensions were also considered but rejected. The rule does not take effect for two years, which is ample time for small entities to learn about the rule and make the necessary changes to come into compliance.

D. Economic Effects on Small Entities

1. Number and Types of Small Entities Affected

The Small Business Administration defines small businesses in the health care sector as those organizations with less than $5 million in annual revenues. Nonprofit organizations are also considered small entities;[FN75] however, individuals and states are not included in the definition of a small entity. Similarly, small government jurisdictions with a population of less than 50,000 are considered small entities.[FN76]

Small business in the health care sector affected by this rule may include such businesses as: Nonprofit health plans, hospitals, and skilled nursing facilities (SNFs); small businesses providing health coverage; small physician practices; pharmacies; laboratories; durable medical equipment (DME) suppliers; health care clearinghouses; billing companies; and vendors that supply software applications to health care entities.

The U.S. Small Business Administration reports that as of 1997, there were 562,916 small health care entities[FN77] classified within the SIC ***82780** codes we have identified as being covered establishments (Table A).

Table A.—Number of Health Care Establishments That Meet SBA Size Standards, 1997[1]

Standard Industrial Code (SIC)	Industry	Total Number of Health Care Establishments	Number of Establishments that Meet SBA Size Standards[2] or RFA non-profit standard	% of Establishments that Meet SBA Size Standards[2] or RFA non-profit standard
5910	Drug Stores & Proprietary Stores	48,147	23,925	49.7%
6320	Accident & Health Insurance & Medical Service Plans	8,083	665	8.2%
7352	Medical Equipment Rental and Leasing	3,346	1,836	54.9%
8010	Offices & Clinics Of Doctors Of Medicine	190,233	170,962	89.9%
8020	Offices & Clinics Of Dentists	115,020	113,864	99.0%
8030	Offices & Clinics Of Doctors Of Osteopathy	9,143	8,850	96.8%
8040	Offices & Clinics Of Other Health Practitioners	89,462	86,596	96.8%
8050	Nursing & Personal Care Facilities	33,178	17,727	53.4%
8060	Hospitals	6,991	3,485	49.8%
8070	Medical & Dental Laboratories	17,586	13,015	74.0%
8080	Home Health Care Services	19,562	12,841	65.6%
8090	Miscellaneous Health & Allied Services	22,145	11,219	50.7%
n/a	Fully Insured ERISA[3]	2,125,000	0	NA
n/a	Institutional Review Boards (IRB)[3]	450,000	0	NA
n/a	Total[3]	562,916	464,983	82.6%

[1] Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997. Establishments that have less than $5,000,000 in annual revenue are considered small businesses here, as are non-profit establishments (regardless of revenue). We have non-profit data for the following SICs: 8050, 8060, and 8080 and have included the number of non-profits in each category into the table.

[2] We have not included the number of fully insured ERISA plans or institutional review boards (IRB) in the total number of health care establishments or the number of establishments that meet SBA standards for small entities, since these are not separate businesses with SIC codes and we do not have sufficient data to impute revenues to them.

[3] We have included self-insured, self-administered plans and third party administrators in the total number of health plans, even though neither has individual SIC codes because we have the ability to impute revenues to them. Therefore, the number of health plans in SIC 6320 is greater than the figure usually reported in the Statistics of U.S. Businesses.

These small businesses represent 82.6% of all health care establishments examined.[FN78] Small businesses represent a significant portion of the total number of health care establishments but a small portion of the revenue stream for all health care establishments. In 1997, the small health care businesses represented generated approximately $430 billion in annual receipts, or 30.2% of the total revenue generated by health care establishments (Table B).[FN79] The following sections provide estimates of the number of small health care establishments that will be required to comply with the rule. Note, however, that the SBA's published annual receipts of health care industries differ from the National Health Expenditure data that the Health Care Financing Administration (HCFA) maintains. ***82781** These data do not provide the specific revenue data required for a RFA; only the SBA data has the requisite establishment and revenue data for this analysis.

Table B.—Annual Receipts of Health Care Entities, 1997[1]

Standard Industrial Code (SIC)	Industry	Total Revenue	Revenue Generated by Small Entities	% of Total Revenue Generated by Small Entities
5910	Drug Stores & Proprietary Stores	$100,302,441,000	$25,620,978,000	25.5%
6320	Accident & Health Insurance & Medical Service Plans (SIC 6320), Self-Insured/ Self Administered (no SIC), Third Party Administrators (no SIC)2	$312,111,493,027	$657,074,000	0.1%
7352	Medical Equipment Rental & Leasing	$4,040,646,000	$1,193,345,000	29.5%
8010	Offices & Clinics Of Doctors Of Medicine	$182,148,148,000	$105,334,031,000	57.8%
8020	Offices & Clinics Of Dentists	$48,766,434,000	$47,218,844,000	96.8%
8030	Offices & Clinics Of Doctors Of Osteopathy	$4,613,192,000	$4,039,868,000	87.6%
8040	Offices & Clinics Of Other Health Practitioners	$28,110,189,000	$23,170,899,000	82.4%
8050	Nursing & Personal Care Facilities	$77,166,537,000	$24,484,098,431	31.7%
8060	Hospitals	$382,540,791,000	$172,552,388,454	45.1%
8070	Medical & Dental Laboratories	$19,872,150,000	$6,862,678,000	34.5%
8080	Home Health Care Services	$31,061,036,000	$12,085,755,906	38.9%
8090	Miscellaneous Health & Allied Services	$35,034,774,000	$6,812,006,000	19.4%
N/A	Total Receipts	$1,425,767,831,027	$430,031,915,791	30.2%

1 Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997. Entities that have less than $5,000,000 in annual revenue are considered small businesses here, as are non-profit entities (regardless of revenue). We have non-profit data for the following SICs: 8050, 8080, and 8060 and have included the number of non-profits in each category into the table.

2 We have included self-insured/self-administered plans and third party administrators in the total number of health plans, even though neither has individual SIC codes because we have the ability to impute revenues to them.

***82782** The Small Business Administration reports that approximately 74 percent of the 18,000 medical laboratories and dental laboratories in the U.S. are small entities.[FN80] Furthermore, based on SBA data, 55 percent of the 3,300 durable medical equipment suppliers that are not part of drug and proprietary stores in the U.S. are small entities. Over 90 percent of health practitioner offices are small businesses.[FN81] Doctor offices (90%), dentist offices (99%), osteopathy (97%) and other health practitioner offices (97%) are primarily considered small businesses.

There are also a number of hospitals, home health agencies, non-profit nursing facilities, and skilled nursing facilities that will be affected by the proposed rule. According to the American Hospital Association, there are approximately 3,131 nonprofit hospitals nationwide. Additionally, there are 2,788 nonprofit home health agencies in the U.S. and the Health Care Financing Administration reports that there are 591 nonprofit nursing facilities and 4,280 nonprofit skilled nursing facilities.[FN82]

Some contractors that are not covered entities but that work with covered health care entities will be required to adopt policies and procedures to protect information. We do not expect that the additional burden placed on contractors will be significant. We have not estimated the effect of the proposed rule on these entities because we cannot reasonably anticipate the number or type of contracts affected by the proposed rule. We also do not know the extent to which contractors would be required to modify their policy practices as a result of the rule.

2. Activities and Costs Associated With Compliance

This section summarizes specific activities that covered entities must undertake to comply with the rule's provisions and options considered by the Department that would reduce the burden to small entities. In developing this rule, the Department considered a variety of alternatives for minimizing the economic burden that it will create for small entities. We did not exempt small

businesses from the rule because they represent such a large and critical proportion of the health care industry (82.6 percent); a significant portion of individually identifiable health information is generated or held by these small businesses.

The guiding principle in our considerations of how to address the burden on small entities has been to make provisions performance rather than specification oriented—that is, the rule states the standard to be achieved but allows institutions flexibility to determine how to achieve the standard within certain parameters. Moreover, to the extent possible, we have allowed entities to determine the extent to which they will address certain issues. This ability to adapt provisions to minimize burden has been addressed in the regulatory impact analysis above, but it will be briefly discussed again in the following section.

Before discussing specific provisions, it is important to note some of the broader questions that were addressed in formulating this rule. The Department considered extending the compliance period for small entities but concluded that it did not have the legal authority to do so (see discussion above). The rule, pursuant to HIPAA, creates an extended compliance time of 36 months (rather than 24 months) only for small health plans and not for other small entities. The Department also considered giving small entities longer response times for time limits set forth in the rule, but decided to establish standard time limits that we believe are reasonable for covered entities of all sizes, with the understanding that larger entities may not need as much time as they have been allocated in certain situations. This permits each covered entity the flexibility to establish policies regarding time limits that are consistent with the entity's current practices.

Although we considered the needs of small entities during our discussions of all provisions for this final rule, we are highlighting the most significant discussions in the following sections:

Scalability

Wherever possible, the final rule provides a covered entity with flexibility to create policies and procedures that are best suited to the entity's current practices in order to comply with the standards, implementation specifications, and requirements of the rule. This allows the covered entity to assess its own needs in devising, implementing, and maintaining appropriate privacy policies, procedures, and documentation to address these regulatory requirements. It also will allow a covered entity to take advantage of developments and methods for protecting privacy that will evolve over time in a manner that is best suited to that institution. This approach allows covered entities to strike a balance between protecting privacy of individually identifiable health information and the economic cost of doing so within prescribed boundaries set forth in the rule. Health care entities must consider both factors when devising their privacy solutions. The Department assumes that professional and trade associations will provide guidance to their members in understanding the rule and providing guidance on how they can best achieve compliance. This philosophy is similar to the approach in the Transactions Rule.

The privacy standard must be implemented by all covered entities, regardless of size. However, we believe that the flexible approach under this rule is more efficient and appropriate then a single approach to safeguarding health information privacy. For example, in a small physician practice, the office manager might be designated to serve as the privacy official as one of many of her duties. In a large health plan, the privacy official position may require more time and greater privacy experience, or the privacy official may have the regular support and advice of a privacy staff or board. The entity can decide how to implement this privacy official requirement based on the entity's structure and needs.

The Department decided to use this scaled approach to minimize the burden on all entities, with an emphasis on small entities. The varying needs and capacities of entities should be reflected in the policies and procedures adopted by the organization and the overall approach it takes to achieve compliance.

Minimum Necessary

The “minimum necessary” policy in the final rule has essentially three components: first, it does not pertain to certain uses and disclosures including treatment-related exchange of information among health care providers; second, for disclosures that are made on a routine basis, such as insurance claims, a covered entity is required to have policies and procedures governing such

exchanges (but the rule does not require a case-by-case determination in such cases); and third, providers must have a process for reviewing non-routine requests on a case-by-case basis to assure that only the minimum necessary information is disclosed. The final rule makes changes to the NPRM that reduce the burden of compliance on small businesses.

Based on public comments and subsequent fact-finding, the Department sought to lessen the burden of this ***82783** provision. The NPRM proposed applying the minimum necessary standard to disclosures to providers for treatment purposes and would have required individual review of all uses of protected health information. The final rule exempts disclosures of protected health information from a covered entity to a health care provider for treatment from the minimum necessary provision and eliminates the case-by-case determinations that would have been necessary under the NPRM. The Department has concluded that the requirements of the final rule are similar to the current practice of most health care providers. For standard disclosure requests, for example, providers generally have established procedures. Under the final rule providers will have to have policies and procedures to determine the minimum amount of protected health information to disclose for standard disclosure requests as well, but may need to review and revise existing procedures to make sure they are consistent with the final rule. For non-routine disclosures, providers have indicated that they currently ask questions to discern how much information should be disclosed. In short, the minimum necessary requirements of this rule are similar to current practice, particularly among small providers.

Policy and Procedures

The rule requires that covered entities develop and document policies and procedures with respect to protected health information to establish and maintain compliance with the regulation. Through the standards, requirements, and implementation specifications, we are proposing a framework for developing and documenting privacy policies and procedures rather than adopting a rigid, prescriptive approach to accommodate entities of different sizes, type of activities, and business practices. Small providers will be able to develop more limited policies and procedures under the rule, than will large providers and health plans, based on the volume of protected health information. We also expect that provider and health plan associations will develop model policies and procedures for their members, which will reduce the burden on small businesses.

Privacy Official

The rule requires covered entities to designate a privacy official who will be responsible for the development and implementation of privacy policies and procedures. The implementation of this requirement may vary based on the size of the entity. For example, a small physician's practice might designate the office manager as the privacy official in addition to her broader administrative responsibilities. Once the privacy official has been trained, the time required to accomplish the duties imposed on such person is not likely to be much more than under current practice. Therefore, the requirement imposes a minimal burden on small businesses.

Internal Complaints

The final rule requires covered entities to have an internal process for individuals to make complaints regarding the covered entities' privacy policies and procedures required by the rule and its compliance with such policies. The requirement includes identifying a contact person or office responsible for receiving complaints and documenting all complaints received and the disposition of such complaints, if any. The covered entity only is required to receive and document a complaint (the complaint can be oral or in writing), which should take a short amount of time. The Department believes that complaints about a covered entity's privacy policies and procedures will be uncommon. Thus, the burden on small businesses should be minimal.

Training

In developing the NPRM, the Department considered a number of alternatives for training, including requiring specific training materials, training certification, and periodic retraining. In the NPRM, the Department recommended flexibility in the materials and training method used, but proposed recertification every three years and retraining in the event of material changes in policy.

Based on public comment, particularly from small businesses, the Department has lessened the burden in the final rule. As in the proposal, the final rule requires all employees who are likely to have contact with protected health information to be trained. Covered entities will have to train employees by the compliance date specific to the type of covered entity and train new employees within a reasonable time of initial employment. In addition, a covered entity will have to train each member of its workforce whose functions are affected by a material change in the policies or procedures of such entity. However, the final rule leaves to the employer the decisions regarding the nature and method of training to achieve this requirement. The Department expects a wide variety of options to be made available by associations, professional groups, and vendors. Methods might include classroom instruction, videos, booklets, or brochures tailored to particular levels of need of workers and employers. Moreover, the recertification requirement of the NPRM has been dropped to ease the burden on small entities.

Consent

The NPRM proposed prohibiting covered entities from requiring individuals to provide written consent for the use and disclosure of protected health information for treatment, payment, and health care operations purposes. The final rule requires certain health care providers to obtain written consent before using or disclosing protected health information for treatment, payment, and health care operations, with a few exceptions. This requirement was included in the final rule in response to comments that this reflects current practice of health care providers health care providers with direct treatment relationships. Because providers are already obtaining such consent, this requirement represents a minimal burden.

Notice of Privacy Rights

The rule requires covered entities to prepare and make available a notice that informs individuals about uses and disclosures of protected health information that may be made by the covered entity and that informs of the individual's rights and covered entity's legal duties with respect to protected health information. The final rule makes changes to the NPRM that reduce the burden of this provision on covered entities and allows flexibility. The NPRM proposed that the notice describe the uses and disclosures of information that the entity expected to make without individual authorization. The final rule only requires that the notice describe uses and disclosures that the entity is permitted or required to make under the rule without an individual's written consent or authorization. This change will allow entities to use standardized notice language within a given state, which will minimize the burden of each covered entity preparing a notice. Professional associations may develop model language to assist entities in developing notices required by the rule. While the final rule specifies minimum notice requirements, it allows entities flexibility to add more detail about a covered entity's privacy policies.

The NPRM also proposed that health plans distribute the notice every three years. The final rule reduced this ***82784** burden by requiring health plans (in addition to providing notice to individuals at enrollment and prior to the compliance date of this rule) to inform individuals at least once every three years about the availability of the notice and how to obtain a copy rather than to distribute a copy of the notice.

In discussing the requirement for covered entities to prepare and make available a notice, we considered exempting small businesses (83 percent of entities) or extremely small entities (fewer than 10 employees). The Department decided that informing consumers of their privacy rights and of the activities of covered entities with which they conduct business was too important a goal of this rule to exempt any entities.

In addition to requiring a basic notice, we considered requiring a longer more detailed notice that would be available to individuals on request. However, we decided that it would be overly burdensome to all entities, especially small entities, to require two notice.

We believe that the proposed rule appropriately balances the benefits of providing individuals with information about uses and disclosures of protected health information with covered entities' need for flexibility in describing such information.

Access to Protected Health Information

The public comments demonstrate that inspection and copying of individually identifiable health information is wide-spread today. Individuals routinely request copies of such information, in whole or in part, for purposes that include providing health information to another health care provider or as part of legal proceedings. The amount of inspection and copying of individually identifiable health information that occurs for these purposes is not expected to change as a result of the final regulation.

The final regulation establishes the right of individuals to inspect and copy protected health information about them. Although this is an important right, the Department does not expect it to result in dramatic increases in requests from individuals. We assume that most health care providers currently have procedures for allowing patients to inspect and copy this information. The economic impact on small businesses of requiring covered entities to provide individuals with access to protected health information should be relatively small. Moreover, entities can recoup the costs of copying such information by charging reasonable cost-based fees.

Amendments to Protected Health Information

Many health care providers and health plans currently make provisions to help patients expedite amendments and corrections of their medical record where appropriate. If an error exists, both the patient and the health care provider on health plan benefit from the correction. However, as with inspection and copying, a person's right to request amendment and correction of individually identifiable health information about them is not guaranteed by all states. Based on these assumptions, the Department concludes that the principal economic effect of the final rule will be to expand the right to request amendments to protected health information held by health plans and covered health care providers to those who are currently granted such right by state law. In addition, the rule may draw additional attention to the issue of record inaccuracies and stimulate patient demand for amendment of medical records.

Under the final regulation, if an individual requests an amendment to protected health information about him or her, the health care provider must either accept the amendment or provide the individual with the opportunity to submit a statement disagreeing with the denial. We expect the responses to requests will vary; sometimes an assistant will only make the appropriate notation in the record, requiring only a few minutes; other times a health care provider or manager will review the request and make changes if appropriate, which may require as much as an hour.

Unlike inspections, which currently occur in a small percentage of cases, fact-finding suggests that individuals rarely seek to amend their records today, but the establishment of this right in the rule may spur more requests, including among those who in the past would have only sought to inspect their records. Nevertheless, we expect that the absolute number of additional amendment requests caused by the rule to be small (about 200,000 per per spread over more than 600,000 entities), which will impose only a minor burden on small businesses.

Accounting for Disclosures

The rule grants individuals the right to receive an accounting of disclosures made by a health care provider or plan for purposes other than treatment, payment, or health care operations, with certain exceptions such as disclosures to the individual. The individual may request an accounting of disclosures made up to six years prior to the request. In order to fulfill such requests, covered health care providers and health plans may track disclosures by making a notation in the individual's medical record regarding the (manual or electronic) when a disclosure is made. We have learned through fact-finding that some health care providers currently track various types of disclosures. Moreover, the Department does not expect many individuals will request an accounting of disclosures. Thus, this requirement will impose a minor burden on small businesses.

De-Identification of Information

In this rule, the Department allows covered entities to determine that health information is de-identified (i.e. that it is not individually identifiable health information), if certain conditions are met. Moreover, information that has been de-identified in accordance with the rule is not considered individually identifiable information and may be used or disclosed without regard to the requirements of the regulation. The covered entity may assign a code or other means of record identification to allow de-identified information to be re-identified if requirements regarding derivation and security are met.

As with other components of this rule, the approach used to remove identifiers from data can be scaled to the size of the entity. Individually identifiable health information can be de-identified in one of two ways; by either removing each of the identifiers listed in the rule or by engaging in a statistical and scientific analysis to determine that information is very unlikely to identify an individual. Small entities without the resources to conduct such an analysis can create de-identified information by removing the full list of possible identifiers set forth in this regulation. Unless the covered entity knows that the information could still identify an individual, the requirement of this rule would be fulfilled. However, larger, more sophisticated covered entities may close to determine independently what information needs to be removed based on sophisticated statistical and scientific analysis.

Efforts to remove identifiers from information are optional. If a covered entity can not use or disclose protected health information for a particular purpose but believes that removing identifiers is excessively burdensome, it can choose not to release the protected health information, or it can seek an authorization from individuals for the use or disclosure of protected health ***82785** information including some or all of the identifiers.

Finally, as discussed in the Regulatory Impact Analysis, the Department believes that very few small entities engage in de-identification currently. Fewer small entities are expected to engage in such activity in the future because the increasing trend toward computerization of large record sets will result in de-identification being performed by relatively few firms or associations over time. We expect that a small covered entity will find it more efficient to contract with specialists in large firms to de-identify protected health information. Larger entities are more likely to have both the electronic systems and the volume of records that will make them attractive for this business.

Monitoring Business Associates

The final rule requires a covered entity with a business associate to have a written contract or other arrangement that documents satisfactory assurance that the business associate will appropriately safeguard protected health information. The Department expects business associate contracts to be fairly standardized, except for language that will have to be tailored to the specific arrangement between the parties, such as the allowable uses and disclosures of information. The Department assumes the standard language initially will be developed by trade and professional associations for their members. Small health care providers are likely to simply adopt the language or make minor modifications. The regulation includes a requirement that the covered entity take steps to correct, and in some cases terminate, a contract, if necessary, if they know of violations by a business associate. This oversight requirement is consistent with standard oversight of a contract. The Department expects that most entities, particularly smaller ones, will utilize standard language that restricts uses and disclosures of individually identifiable health information their contracts with business associates. This will limit the burden on small businesses.

The NPRM proposed that covered entities be held accountable for the uses and disclosures of individually identifiable health information by their business associates. An entity would have been in violation of the rule if it knew of a breach in the contract by a business associate and failed to cure the breach or terminate the contract. The final rule reduces the extent to which an entity must monitor the actions of its business associates. The entity no longer has to “ensure” that each business associate complies with the rule's requirements. Entities will be required to cure a breach or terminate a contract for business associate actions only if they knew about a contract violation. The final rule is consistent with the oversight a business would provide for any contract, and therefore, the changes in the final rule will impose no new significant cost for small businesses in monitoring their business associates' behavior.

Employers With Insured Group Health Plans

Some group health plans will use or maintain individually identifiable health information, particularly group health plans that are self-insured. Also, some plan sponsors that perform administrative functions on behalf of their group health plans may need protected health information. The final rule permits a group health plan, or a health insurance issuer or HMO that provides benefits on behalf of the group health plan, to disclose protected health information to a plan sponsor who performs administrative functions on its behalf for certain purposes and if certain requirements are met. The plan documents must be amended to: describe the permitted uses and disclosures of protected health information by the plan sponsor; specify that disclosure is permitted only upon receipt of a certification by the plan sponsor that the plan documents have been amended and the plan sponsor agrees to certain restrictions on the use of protected health information; and provide for adequate firewalls to assure unauthorized personnel do not have access to individually identifiable health information.

Some plan sponsors may need information, not to administer the group health plan, but to amend, modify, or terminate the health plan. ERISA case law describes such activities as settlor functions. For example a plan sponsor may want to change its contract from a preferred provider organization to a health maintenance organization (HMO). In order to obtain premium information, the health plan sponsor may need to provide the HMO with aggregate claims information. Under the rule, the health plan sponsor can obtain summary information with certain identifiers removed, in order to provide it to the HMO and receive a premium rate.

The Department assumes that most health plan sponsors who are small employers (those with 50 or fewer employees) will elect not to receive individually identifiable health information because they will have little, if any, need for such data. Any needs that sponsors of small group health plans may have for information can be accomplished by receiving the information in summary form from their health insurance issuers.

3. The Burden on a Typical Small Business

The Department expects small entities to face a cost burden as a result of complying with the proposed regulation. We estimate that the burden of developing privacy policies and procedures is lower in dollar terms for small businesses than for large businesses, but we recognize that the cost of implementing privacy provisions could be a larger burden to small entities as a proportion of total revenue. Due to these concerns, we have relied on the principle of scalability throughout the rule, and have based our cost estimates on the expectation that small entities will develop less expensive and less complex privacy measures that comply with the rule than large entities.

In many cases, we have specifically considered the impact that rule may have on solo practitioners or rural health care providers. If a health care provider only maintains paper records and does not engage in any electronic transactions, the regulation would not apply to such provider. We assume that those providers will be small health care providers. For small health care providers that are covered health care providers, we expect that they will not be required to change their business practices dramatically, because we based many of the standards, implementation specifications, and requirements on current practice and we have taken a flexible approach to allow scalability based on a covered entity's activities and size. In developing policies and procedures to comply with the proposed regulation, scalability allows entities to consider their basic functions and the ways in which protected health information is used or disclosed. All covered entities must take appropriate steps to address privacy concerns, and in determining the scope and extent of their compliance activities, businesses should weigh the costs and benefits of alternative approaches and should scale their compliance activities to their structure, functions, and capabilities within the requirements of the rule.

Cost Assumptions

To determine the cost burden to small businesses of complying with the final rule, we used as a starting point the overall cost of the regulation determined ***82786** in the regulatory impact analysis (RIA). Then we adopted a methodology that apportions the costs found in the RIA to small business by using Census Bureau's Statistics of U.S. Businesses. This Census Bureau survey contains data on the number and proportion of establishments, by Standard Industrial Classification Code (SIC code), that have revenues of less than $5 million, which meets the Small Business Administration's definition of a small business in the health care sector. This data permitted us to calculate the proportion of the cost of each requirement in the rule that is

attributable to small businesses. This methodology used for the regulatory flexibility analysis (RFA) section is therefore based on the methodology used in the (RIA), which was discussed earlier.

The businesses accounted for in the SIC codes contain three groups of covered entities: non-hospital health care providers, hospitals, and health plans. Non-hospital health care providers include: drug stores, offices and clinics of doctors, dentists, osteopaths, and other health practitioners, nursing and personal care facilities, medical and dental laboratories, home health care services, miscellaneous health and allied services, and medical equipment rental and leasing establishments. Health plans include accident and health insurance and medical service plans.

Data Adjustments

Several adjustments were made to the SIC code data to more accurately determine the cost to small and non-profit businesses. For health plans (SIC code 6320), we adjusted the SIC data to include self-insured, self-administered health plans because these health plans are not included in any SIC code, though they are covered entities under the rule. Similarly, we have added third-party administrators (TPAs) into this SIC. Although they are not covered entities, TPAs are likely to be business associates of covered entities. For purposes of the regulatory analyses, we have assumed that TPAs would bear many of the same costs of the health plans to assure compliance for the covered entity. To make this adjustment, we assumed the self-insured/self administered health plans and TPAs have the average revenue of the health plans contained in the SIC code, and then added those assumed revenues to the SIC code and to the total of all health care expenditures. Moreover, we needed to account for the cost to non-profit institutions that might receive more than $5 million in revenue, because all non-profit institutions are small businesses regardless of revenue. To make this adjustment for hospitals, nursing homes, and home health agencies, we used data on the number of non-profit institutions from industry sources and from data reported to HCFA. With this data, we assumed the current count of establishments in the SIC codes includes these non-profit entities and that non-profits have the same distribution of revenues as all establishments reported in the applicable SIC codes. The proportions discussed below, which determine the cost for small business, therefore include these non-profit establishments in SIC codes 8030, 8060, and 8080.

The SIC code tables provided in this RFA do not include several categories of businesses that are included in the total cost to small businesses. Claims clearinghouses are not included in the table because claims clearinghouses report their revenues under the SIC 7374 “Computer Processing and Data Preparation,” and the vast majority of businesses in this SIC code are involved in non-medical claims data processing. In addition, claims processing is often just one business-line of companies that may be involved in multiple forms of data processing, and therefore, even if the claims processing line of the business generates less than $5 million in revenue, the company in total may exceed the SBA definition for a small business (the total firm revenue, not each line of business, is the standard for inclusion). Similarly, fully-insured ERISA health plans sponsored by employers are not identified as a separate category in the SIC code tables because employers in virtually all SIC codes may sponsor fully-insured health plans. We have identified the cost for small fully-insured ERISA health plans by using the Department of Labor definition of a small ERISA plan, which is a plan with fewer than 100 insured participants. Using this definition, the initial cost for small fully-insured ERISA health plans is $7.1 million. Finally, Institutional Review Boards (IRBs) will not appear in a separate SIC code because IRBs are not “businesses”; rather, they are committees of researchers who work for institutions where medical research is conducted, such as universities or teaching hospitals. IRB members usually serve as a professional courtesy or as part of their employment duties and are not paid separately for their IRB duties. Although IRBs are not “businesses” that generate revenues, we have treated them as small business for illustrative purposes in this RFA to demonstrate the additional opportunity costs that will be faced by those researchers who sit on IRBs. Therefore, assuming IRBs are small businesses, the initial costs are $.089 million and ongoing costs are approximately $84.2 million over 9 years.

The Cost Model Methodology

The RIA model employs two basic methodologies to determine the costs to small businesses that are covered entities. As stated above, the RFA determines the cost to small businesses by apportioning the total costs in the RIA using SIC code data. In places where the cost of a given provision of the final rule is a function of the number of covered entities, we determined the proportion of entities in each SIC code that have less than $5 million in revenues (see Table A). We then multiplied this proportion by the

per-entity cost estimate of a given provision as determined in the RIA. For example, the cost of the privacy official provision is based on the fact that each covered entity will need to have a privacy official. Therefore, we multiplied the total cost of the privacy official, as determined in the RIA, by the proportion of small businesses in each SIC code to determine the small business cost. Using hospitals for illustrative purposes, because small and non-profit hospitals account for 50 percent of all hospitals, our methodology assigned 50 percent of the cost to small hospitals.

We used a second, though similar, method when the cost of a given provision in the RIA did not depend on the number of covered entities. For example, the requirement to provide notice of the privacy policy is a direct function of the number of patients in the health care system because the actual number of notices distributed depends on how many patients are seen. Therefore, for provisions like the notice requirement, we used SIC code revenue data in a two-step process. First, we apportioned the cost of each provision among sectors of the health care industry by SIC code. For example, because hospital revenue accounts for 27 percent of all health care revenue, we multiplied the total cost of each such provision by 27 percent to determine the cost for the hospital sector in total. Then to determine the cost for small hospitals specifically, we calculated the proportion by the overall cost. For example, 45.1 percent of all hospital revenue is generated by small hospital, therefore, the cost to small hospitals was assumed to account for 45.1 percent of all hospital costs. Estimates, by nature ***82787** are inexact. However, we feel this is a reasonable way to determine the small business costs attributable to this regulation given the limited data from which to work.

Total Costs and Costs Per Establishment for Small Business

Based on the methodology described above, the total cost of complying with the final rule in the initial year of 2003 is $1.9 billion. The ongoing costs to small business from 2004 to 2012 is $9.3 billion. Table C presents the initial and ongoing costs to small business by each SIC code. According to this table, small doctors offices, small dentists offices and small hospitals will face the highest cost of complying with the final rule. However, much of the reason for the higher costs faced by these three groups of small health care providers is explained by the fact that there are a significant number of health care providers in these categories.

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Table C.--Annual Cost to Small Business of Implementing Provisions of the Proposed Privacy Regulation[1]

SIC	Industry	Initial Cost (Year 1)[2]	Ongoing Cost (Year 2-10)	Total Costs
5910	Drug Stores & Proprietary Stores	$153,976,159	$780,573,862	$934,550,021
6320	Accident & Health Insurance & Medical Service Plans[3]	$41,348,527	$169,540,638	$210,889,164
7353	Medical Equipment Rental & Leasing	$7,171,728	$36,356,688	$43,528,416
8010	Offices & Clinics of Doctors of Medicine	$633,033,192	$3,209,127,747	$3,842,160,938
8120	Offices & Clinics of Dentists	$283,774,344	$1,438,578,786	$1,722,353,130
8030	Offices & Clinics of Doctors of Osteopathy	$24,278,673	$123,079,430	$147,358,103
8040	Offices & Clinics of Other Health Practitioners	$139,251,750	$705,929,263	$845,181,013
8050	Nursing & Personal Care Facilities	$147,143,775	$745,937,461	$893,081,236
8060	Hospitals	$355,459,094	$1,199,498,063	$1,554,957,157
8070	Medical & Dental Laboratories	$41,242,809	$209,078,203	$250,321,012
8080	Home Health Care Services	$72,632,601	$368,207,067	$440,839,668
8090	Misc Health & And Allied Services	$40,938,582	$207,535,943	$248,474,525
n/a	Fully Insured/ ERISA	$7,137,028	$0	$7,137,028
n/a	IRBs	$88,813	$84,162,446	$84,251,259
n/a	Total Cost For Small Business	$1,947,477,073	$9,277,605,598	$11,225,082,671

[1] Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997. Entities that have less than $5,000,000 in annual revenue are considered small businesses here, as are non-profit entities (regardless of revenue). We have non-profit data for the following SICs: 8050, 8080, and 8060 and have included the number of non-profits in each category into the table.

[2] The initial costs include all costs in the first year, including costs that recur in subsequent years.

[3] We have included self-insured/self-administered health plans and third party administrators in the total number of health plans, even though neither has individual SIC codes because we have the ability to impute revenues to them.

***82789** On a per-establishment basis, Table D demonstrates that the average cost for small business of complying with the proposed rule in the first year is $4,188 per-establishment. The ongoing costs of privacy compliance are approximately $2,217 each year thereafter. We estimate that the average cost of compliance in the first year for each small non-hospital health care provider is approximately 0.6 percent of per-establishment revenues. In subsequent years, per-establishment costs about 0.3 percent of per-establishment revenues. For small hospitals and health plans, the per-establishment cost of compliance in the first year is 0.2 percent and 6.3 percent of per-establishment revenues respectively. For subsequent years, the cost is only 0.1 percent and 2.9 percent of pre-establishment revenues respectively. These costs may be offset in many firms by the savings realized through requirements of the Transactions Rule.

Table D.--Average Annual per Establishment Privacy Costs[1]

SIC	Industry	Year 1 Privacy Costs Per Establishment	Average Year 2-10 Privacy Costs per Establishment
5910	Drug Stores & Proprietary Stores	$6,436	$1,623
6320	Accident & Health Insurance & Medical Service Plans[2]	$62,162	$28,320
7353	Medical Equipment Rental & Leasing	$3,906	$2,200
8010	Offices & Clinics of Doctors of Medicine	$3,703	$2,086
8120	Offices & Clinics of Dentists	$2,492	$1,404
8030	Offices & Clinics of Doctors of Osteopathy	$2,743	$1,545
8040	Offices & Clinics of Other Health Practitioners	$1,608	$906
8050	Nursing & Personal Care Facilities	$8,301	$4,676
8060	Hospitals	$101,999	$58,244
8070	Medical & Dental Laboratories	$3,169	$1,785
8080	Home Health Care Services	$5,656	$3,186
8090	Misc Health & And Allied Services	$3,649	$2,055
n/a	Fully Insured/ ERISA[3]	N/A	N/A
n/a	IRB[3]	N/A	N/A
n/a	Average for All Small Business	$4,188	$2,217

[1] Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997. Entities that have less than $5,000,000 in annual revenue are considered small businesses here, as are non-profit entities (regardless of revenue). We have non-profit data for the following SICs: 8050, 8080, and 8060 and have included the number of non-profits in each category into the table.

[2] We have included self-insured/self-administered health plans and third party administrators in the total number of health plans, even though neither has individual SIC codes because we have the ability to impute revenues to them.

[3] We have not included the number of fully insured ERISA health plans or institutional review boards (IRB) in the total number of health care entities or the number of entities that meet SBA standards for small entities, since these are not separate businesses with SIC codes and we do not have sufficient data to impute revenues to them.

***82791** Table E shows the cost to each SIC code of the major cost items of the final rule. Listed are the top-five most costly provisions of the rule (to small business) and then the cost of all other remaining provisions. The costs of the most expensive five provisions represent 90 percent of the cost of the ongoing costs to small business, while the remaining provisions only represent 7 percent.

***82792 Table E.—Average Annual Ongoing Cost to Small Business of Implementing Provisions of the Privacy Regulation, After the First Year [1]**

Industry	Average Annual Ongoing Cost for Privacy Official, per Industry Sector	Average Annual Ongoing Cost for Minimum Necessary, per Industry Sector	Average Annual Ongoing Cost for Disclosure Tracking, per Industry Sector	Average Annual Ongoing Cost for De-Identification, per Industry Sector	Average Annual Ongoing Cost for Training, per Industry Sector	Average Annual Ongoing Cost for All Other Provisions, per Industry Sector
Drug Stores & Proprietary Stores	$37,997,168	$30,008,085	$3,597,262	$3,751,031	$4,083,677	$7,293,227
Accident & Health Insurance & Medical Service plans (including Self Insured/ Self Administered Health plans, & TPAs)[7]	$5,920,267	$5,395,070	$985,072	$3,614,697	$59,086	$2,863,657
Medical Equipment Rental & Leasing	$1,769,789	$1,397,683	$167,549	$174,710	$190,205	$339,696
Offices & clinics of Doctors of Medicine	$156,215,538	$123,370,486	$14,789,213	$15,421,311	$16,788,984	$29,984,217

Offices & clinics of Doctors of Dentist	$70,027,863	$55,304,176	$6,629,667	$6,913,022	$7,526,119	$13,441,241
Offices & clinics of Doctors of Osteopathy	$5,991,323	$4,731,619	$567,210	$591,452	$643,907	$1,149,982
Offices & clinics of Other Health Practitioners	$34,363,581	$27,138,476	$3,253,264	$3,392,310	$3,693,164	$6,595,791
Nursing & Personal care Facilities	$36,311,120	$28,676,536	$3,437,641	$3,584,567	$3,902,472	$6,969,604
Hospitals	$25,475,393	$56,613,285	$19,558,912	$14,153,321	$309,555	$17,167,095
Medical & Dental Laboratories	$10,177,614	$8,037,723	$963,534	$1,004,715	$1,093,821	$1,953,505
Home Health care Services	$17,923,769	$14,155,212	$1,696,876	$1,769,402	$1,926,325	$3,440,312
Misc Health & Allied Health Services	$10,102,539	$7,978,433	$956,426	$997,304	$1,085,752	$1,939,695
Fully Insured/ERISA	N/A	N/A	N/A	N/A	N/A	$9,351,383
IRB	N/A	N/A	N/A	N/A	N/A	$0
Total	$412,275,964	$362,806,784	$56,602,625	$55,367,822	$41,303,067	$102,488,804

[1] Source: Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997. Entities that have less than $5,000,000 in annual revenue are considered small businesses here, as are

[2] We have included self-insured, self-administered health plans and third party administrators in the total number of health plans, even though neither has individual SIC codes because we have the ability to impute revenues to them.

***82794 VI. Unfunded Mandates**

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4) requires cost-benefit and other analyses for rules that would cost more than $100 million in a single year. The rule qualifies as a significant rule under the statute. The Department has carried out the cost-benefit analysis in sections D and E of this document, which includes a discussion of unfunded costs to state and

local governments resulting from this regulation. In developing this regulation, the Department adopted the least burdensome alternatives, consistent with achieving the rule's goals.

A. Future Costs

The Department estimates some of the future costs of the rule in Section E of the Preliminary Regulatory Impact Analysis of this document. The estimates made include costs for the ten years after the effective date. As discussed in section E, state and local government costs will be in the order of $460 million in 2003 and $2.4 billion over ten years. Estimates for later years are not practical. The changes in technology are likely to alter the nature of medical record-keeping, and the uses of medical data are likely to vary dramatically over this period. Therefore, any estimates for years beyond 2012 are not feasible.

B. Particular Regions, Communities, or Industrial Sectors

The rule applies to the health care industry and would, therefore, affect that industry disproportionately. Any long-run increase in the costs of health care services would largely be passed on to the entire population of consumers. However, as discussed in the administrative implication regulation, the Transactions Rule is estimated to save the health care industry nearly $30 billion over essentially the same time period. This more than offsets the costs of the Privacy Rule; indeed, as discussed above, the establishment of consistent, national standards for the protection of medical information is essential to fully realize the savings from electronic transactions standards and other advances that may be realized through “e-health” over the next decade. Without strong privacy rules, patients and providers may be very reluctant to fully participate in electronic and e-health opportunities.

C. National Productivity and Economic Growth

The rule is not expected to substantially affect productivity or economic growth. It is possible that productivity and growth in certain sectors of the health care industry could be slightly lower than otherwise because of the need to divert research and development resources to compliance activities. The diversion of resources to compliance activities would be temporary. Moreover, the Department anticipates that, because the benefits of privacy are large, both productivity and economic growth would be higher than in the absence of the final rule. In section I.A. of this document, the Department discusses its expectation that this rule will increase communication among consumers, health plans, and providers and that implementation of privacy protections will lead more people to seek health care. The increased health of the population will lead to increased productivity and economic growth.

D. Full Employment and Job Creation

Some of the human resources devoted to the delivery of health care services will be redirected by rule. The rule could lead to some short-run changes in employment patterns as a result of the structural changes within the health care industry. The growth of employment (job creation) for the roles typically associated with health care profession could also temporarily change but be balanced by an increased need for those who can assist entities with complying with this rule. Therefore, while there could be a temporary slowing of growth in traditional health care professions, that will be offset by a temporary increase in growth in fields that may assist with compliance with this rule (e.g. worker training, and management consultants).

E. Exports

Because the rule does not mandate any changes in products, current export products will not be required to change in any way.

The Department consulted with state and local governments, and Tribal governments. See sections X and XI, below.

VII. Environmental Impact

The Department has determined under 21 CFR 25.30(k) that this action is of a type of does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 PRA), agencies are required to provide a 30-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;

- The accuracy of the agency's estimate of the information collection burden;

- The quality, utility, and clarity of the information to be collected; and

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Under the PRA, the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section are to be considered. Due to the complexity of this regulation, and to avoid redundancy of effort, we are referring readers to Section V (Final Regulatory Impact Analysis) above, to review the detailed cost assumptions associated with these PRA requirements. We explicitly seek, and will consider, public comment on our assumptions as they relate to the PRA requirements summarized in this section.

Section 160.204—Process for Requesting Exception Determinations

Section 160.204 would require persons requesting to except a provision of state law from preemption under § 160.203(a) to submit a written request, that meets the requirements of this section, to the Secretary to except a provision of state law from preemption under § 160.203. The burden associated with these requirements is the time and effort necessary for a state to prepare and submit the written request for an exception determination to the Secretary for approval. On an annual basis it is estimated that it will take 40 states 16 hours each to prepare and submit a request. The total annual burden associated with this requirement is 640 hours. The Department solicits public comment on the number of requests and hours for others likely to submit requests.

Section 160.306—Complaints to the Secretary

A person who believes that a covered entity is not complying with the applicable requirements of part 160 or the applicable standards, requirements, ***82795** and implementation specifications of Subpart E of part 164 of this subchapter may file a complaint with the Secretary. This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2), an audit/ administrative action exemption.

Section 160.310—Responsibilities of Covered Entities

A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable requirements of part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164. Refer to § 164.530 for discussion.

Section 164.502—Uses and Disclosures of Protected Health Information: General Rules

A covered entity is permitted to disclose protected health information to an individual, and is required to provide and individual with access to protected health information, in accordance with the requirements set forth under § 164.524. Refer to § 164.524 for discussion.

Section 164.504—Uses and Disclosures—Organizational Requirements

Except for disclosures of protected health information by a covered entity that is a health care provider to another health care provider for treatment purposes, § 164.504 requires a covered entity to maintain documentation demonstrating that it meets the requirements set forth in this section and to demonstrate that it has obtained satisfactory assurance from business associates that meet the requirements of this part with each of its business associates. The burden is 5 minutes per entity times an annual average of 764,799 entities for a total burden of 63,733 burden hours.

Section 164.506—Consent for Treatment, Payment, and Health Care Operations

Except in certain circumstances, a covered health care provider that has a direct treatment relationship must obtain an individual's consent for use or disclosure of protected health information for treatment, payment, or health care operations. While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 164.508—Uses and Disclosures for Which Individual Authorization Is Required

Under this section, a covered entity will need to obtain a written authorization from an individual, before it uses or discloses protected health information of the individual if the use or disclosure is not otherwise permitted or required under the rule without authorization. The burden associated with these requirements is the time and effort necessary for a covered entity to obtain written authorization prior to the disclosure of individually identifiable health information. On an annual basis, we estimate that it will take 764,799 entities, an annual average burden per entity of one hour for a total annual burden of 764,799 burden hours.

Section 164.510—Uses and Disclosures Requiring an Opportunity for the Individual To Agree or To Object

Section 164.510 allows, but does not require, covered entities to use or disclose protected health information: (1) for health care institutions, directories; and (2) to family members, close friends, or other persons assisting in an individual's care, as well as government agencies and disaster relief organizations conducting disaster relief activities. This section of the rule addresses situations in which the interaction between the covered entity and the individual is relatively informal, and agreements may be made orally, without written authorizations for use or disclosure. In general, to disclose protected health information for these purposes, covered entities must inform individuals in advance and must provide a meaningful opportunity for the individual to prevent or restrict the disclosure. In certain circumstances, such as in an emergency, when this informal discussion cannot practicably occur, covered entities can make decisions about disclosure or use, in accordance with the requirements of this section based on their professional judgment of what is in the patient's best interest. While these provisions are subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 164.512—Uses and Disclosures for Which Consent, Individual Authorization, or Opportunity To Agree or Object Is Not Required

Section 164.1512 includes provisions that allow, but that do not require, covered entities to disclose protected health information without individual authorization for a variety of purposes which represent important national priorities. Pursuant to § 164.512, covered entities may disclose protected health information for specified purposes as follows: as required by law; for public health activities; to public officials regarding victims of abuse, neglect, or domestic violence; for health oversight; for judicial and administrative proceedings; for law enforcement; for specified purposes regarding decedents; for organ donation and transplantation; for research; to avert an imminent threat to health or safety; for specialized government functions (such as for intelligence and national security activities); and to comply with workers' compensation laws. While these provisions are

subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

For research, if a covered entity wants to use or disclose protected health information without individual authorization, it must obtain documentation that a waiver, in whole or in part, of the individual authorization required by § 164.508 for use or disclosure of protected health information has been approved by either an Institutional Review Board (IRB), established in accordance with 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or a privacy board. The burden associated with these requirements is the time and effort necessary for a covered entity to maintain documentation demonstrating that they have obtained IRB or privacy board approval, which meet the requirements of this section. On an annual basis it is estimated that these requirements will affect 113,524 IRB reviews. We further estimate that it will take an average of 5 minutes per review to meet these requirements on an annual basis. Therefore, the total estimated annual burden associated with this requirement is 9,460 hours.

Section 164.514—Other Procedural Requirements Relating to Uses and Disclosures of Protected Health Information

Prior to any disclosure permitted by this subpart, a covered entity must verify the identity and authority of persons requesting protected health information, if the identity or authority of such person is not known to the ***82796** covered entity, and obtain any documentation, statements, or representations from the person requesting the protected health information that is required as a condition of the disclosure. In addition, a covered entity must retain any signed consent pursuant to § 164.506 and any signed authorization pursuant to § 164.508 for documentation purposes as required by § 164.530(j). This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4(a)(1) and (1)(2).

Section 164.520—Notice of Privacy Practices for Protected Health Information

Except in certain circumstances set forth in this section, individuals have a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information. To comply with this requirement a covered entity must provide a notice, written in plain language, that includes the elements set forth in this section. For health plans, there will be an average of 160.2 million notices each year. We assume that the most efficient means of distribution for health plans will be to send them out annually as part of the materials they send to current and potential enrollees, even though it is not required by the regulation. The number of notices per health plan per year would be about 10,570. We further estimate that it will require each health plan, on average, only 10 seconds to disseminate each notice. The total annual burden associated with this requirement is calculated to be 267,000 hours. Health care providers with direct treatment relationships would provide a copy of the notice to an individual at the time of first service delivery to the individual, make the notice available at the service delivery site for individuals to request and take with them, whenever the content of the notice is revised, make the notice available upon request and post the notice, if required by this section, and post a copy of the notice in a location where it is reasonable to expect individuals seeking services from the provider to be able to read the notice. The annual number of notices disseminated by all providers is 613 million. We further estimate that it will require each health provider, on average, 10 seconds to disseminate each notice. This estimate is based upon the assumption that the required notice will be incorporated into and disseminated with other patient materials. The total annual burden associated with this requirement is calculated to be 1 million hours.

In addition, a covered entity must document compliance with the notice requirements by retaining copies of the notices issued by the covered entity. Refer to § 164.530 for discussion.

Section 164.522—Rights To Request Privacy Proteciton for Protected Health Information

Given that the burden associated with the following information collection requirements will differ significantly, by the type and size of health plan or health care provider, we are explicitly soliciting comment on the burden associated with the following requirements; as outlined and required by this section, covered entities must provide individuals with the opportunity to request

restrictions related to the uses or disclosures of protected health information for treatment, payment, or health care operations. In addition, covered entities must accommodate requests for confidential communications in certain situations.

Section 164.524—Access of Individuals to Protected Health Information

As set forth in this section, covered entities must provide individuals with access to inspect and obtain a copy of protected health information about them in designated record sets, for so long as the protected health information is maintained in the designated record sets. This includes such information in a business associate's designated record set that is not a duplicate of the information held by the health care provider or health plan for so long as the information is maintained. Where the request is denied in whole or in part, the covered entity must provide the individual with a written statement of the basis for the denial and a description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.530 or to the Secretary pursuant to the procedures established in § 160.306 of this subpart. In certain cases, the covered entity must provide the individual the opportunity to have another health care professional review the denial. Pursuant to public comment, we estimate that each disclosure will contain 31 pages and that 150,000 disclosures will be made on an annual basis at three minutes per disclosure for a total burden of 7,500 hours. Refer to section V.E. for detailed discussion related to the costs associated with meeting these requirements.

Section 164.526—Amendment of Protected Health Information

Given that burden associated with the following information collection requirements will differ significantly, by the type and size of health plan or health care provider, we are explicitly soliciting comment on the burden associated with the following requirements: Individuals have the right to request amendment of protected health information about them in designated record sets created by a covered entity. Where the request is denied, a covered entity must provide the individual with a written statement of the basis for the denial and an explanation of how the individual may pursue the matter, including how to file a complaint with the Secretary pursuant to § 160.306 of this subpart. As appropriate, a covered entity must identify the protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.

Section 164.528—Accounting for Disclosures of Protected Health Information

Based upon public comment it is assumed that it will take 5 minutes per request times 1,081,000 requests for an annual burden of 90,083 hours. An individual may request that a covered entity provide an accounting for disclosure for a period of time less than six years from the date of the individual's request, as outlined in this section.

Section 164.530—Administrative Requirements

A covered entity must maintain such policies and procedures in written or electronic form where policies or procedures with respect to protected health information are required by this subpart. Where a communication is required by this subpart to be in writing, a covered entity must maintain such writing, or an electronic copy, as documentation; and where an action or activity is required by this subpart to be documented, it must maintain a written or electronic record of such action or activity. While these requirements are subject to the PRA, we believe the burden associated with these requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2). ***82797**

We have submitted a copy of this rule to OMB for its review of the information collection requirements in §§ 160.204, 160.306, 160.310, 164.502, 164.504, 164.506, 164.508, 164.510, 164.512, 164.514, 164.520, 164.522, 164.524, 164.526, 164.528, and Sec. 164.530. These requirements are not effective until they have been approved by OMB. If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following: Health Care Financing Administration, Office of Information Services, Division of HCFA Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850. ATTN: John Burke and to the Office of Information and Regulatory Affairs, Office

of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. ATTN: Allison Herron Eydt, HCFA Desk Officer.

IX. Executive Order 13132: Federalism

The Department has examined the effects of provisions in the final privacy regulation on the relationship between the federal government and the states, as required by Executive Order 13132 on "Federalism." Our conclusion is that the final rule does have federalism implications because the rule has substantial direct effects on states, on the relationship between the national government and states, and on the distribution of power and responsibilities among the various levels of government. The federalism implications of the rule, however, flow from, and are consistent with the underlying statute. The statute allows us to preempt state or local rules that provide less stringent privacy protection requirements than federal law is consistent with this Executive Order. Overall, the final rule attempts to balance both the autonomy of the states with the necessity to create a federal benchmark to preserve the privacy of personally identifiable health information.

It is recognized that the states generally have laws that relate to the privacy of individually identifiable health information. The HIPAA statue dictates the relationship between state law and this final rule. Except for laws that are specifically exempted by the HIPAA statute, state laws continue to be enforceable, unless they are contrary to Part C of Title XI of the standards, requirements, or implementation specifications adopted or pursuant to subpart x. However, under section 264(c)(2), not all contrary provisions of state privacy laws are preempted; rather, the law provides that contrary provisions of state law relating to the privacy of individually identifiable health information that are also "more stringent" than the federal regulatory requirements or implementation specifications will continue to be enforceable.

Section 3(b) of Executive Order 13132 recognizes that national action limiting the policymaking discretion of states will be imposed "* * * only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance." Personal privacy issues are widely identified as a national concern by virtue of the scope of interstate health commerce. HIPAA's provisions reflect this position. HIPAA attempts to facilitate the electronic exchange of financial and administrative health plan transactions while recognizing challenges that local, national, and international information sharing raise to confidentiality and privacy of health information.

Section 3(d)(2) of the Executive Order 13132 requires the federal government defer to the states to establish standards where possible. HIPAA requires the Department to establish standards, and we have done so accordingly. This approach is a key component of the final Privacy Rule, and it adheres to section 4(a) of Executive Order 13132, which expressly contemplates preemption when there is a conflict between exercising state and federal authority under federal statute. Section 262 of HIPAA enacted Section 1178 of the Social Security Act, developing a "general rule" that state laws or provisions that are contrary to the provisions or requirements of Part C of Title XI, or the standards or implementation specifications adopted, or established thereunder are preempted. Several exceptions to this rule exist, each of which is designed to maintain a high degree of state autonomy.

Moreover, section 4(b) of the Executive Order authorizes preemption of state law in the federal rule making context when there is "the exercise of state authority is directly conflicts with the exercise of federal authority under federal statute * * *." Section 1178 (a)(2)(B) of HIPAA specifically preempts state laws related to the privacy of individually identifiable health information unless the state law is more stringent. Thus, we have interpreted state and local laws and regulations that would impose less stringent requirements for protection of individually identifiable health information as undermining the agency's goal of ensuring that all patients who receive medical services are assured a minimum level of personal privacy. Particularly where the absence of privacy protection undermines an individual's access to health care services, both the personal and public interest is served by establishing federal rules.

The final rule would establish national minimum standards with respect to the collection, maintenance, access, use, and disclosure of individually identifiable health information. The federal law will preempt state law only where state and federal laws are "contradictory" and the federal regulation is judged to establish "more stringent" privacy protections than state laws.

As required by the previous Executive Order (E.O. 13132), states and local governments were given, through the notice of proposed rule making, an opportunity to participate in the proceedings to preempt state and local laws (section 4(e)). The Secretary also provided a review of preemption issues upon requests from states. In addition, anticipating the promulgation of the Executive Order, appropriate officials and organizations were consulted before this proposed action is implemented (Section 3(a) of Executive Order 13132).

The same section also includes some qualitative discussion of costs that would occur beyond that time period. Most of the costs of proposed rule, however, would occur in the years immediately after the publication of a final rule. Future costs beyond the ten year period will continue but will not be as great as the initial compliance costs.

Finally, we have considered the cost burden that this proposed rule would impose on state and local health care programs, such as Medicaid, county hospitals, and other state health benefits programs. As discussed in Section E of the Regulatory Impact Analysis of this document, we estimate state and local government costs will be in the order of $460 million in 2003 and $2.4 billion over ten years.

The agency concludes that the policy in this final document has been assessed in light of the principles, criteria, and requirements in Executive Order 13132; that this policy is not inconsistent with that Order; that this policy will not impose significant additional costs and burdens on the states; and that this policy will not affect the ability of the states to discharge traditional state governmental functions.

During our consultation with the states, representatives from various state agencies and offices expressed concern that the final regulation would preempt ***82798** all state privacy laws. As explained in this section, the regulation would only preempt state laws where there is a direct conflict between state laws and the regulation, and where the regulation provides more stringent privacy protection than state law. We discussed this issue during our consultation with state representatives, who generally accepted our approach to the preemption issue. During the consultation, we requested further information from the states about whether they currently have laws requiring that providers have a “duty to warn” family members or third parties about a patient's condition other than in emergency circumstances. Since the consultation, we have not received additional comments or questions from the states.

X. Executive Order 13086; Consultation and Coordination With Indian Tribal Governments

In drafting the proposed rule, the Department consulted with representatives of the National Congress of American Indians and the National Indian Health Board, as well as with a representative of the self-governance Tribes. During the consultation, we discussed issues regarding the application of Title II of HIPAA to the Tribes, and potential variations based on the relationship of each Tribe with the IHS for the purpose of providing health services. Participants raised questions about the status of Tribal laws regarding the privacy of health information.

List of Subjects

45 CFR Part 160

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

45 CFR Part 164

Electronic transactions, Employer benefit plan, Health, Health care, Health facilities, Health insurance, Health records, Medicaid, Medical research, Medicare, Privacy, Reporting and record keeping requirements.

Note: to reader: This final rule is one of several proposed and final rules that are being published to implement the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996.45 CFR subchapter C consisting of Parts 160 and 162 was added at 65 FR 50365, Aug. 17, 2000. Part 160 consists of general provisions, Part 162 consists of the various administrative simplification regulations relating to transactions and identifiers, and new Part 164 consists of the regulations implementing the security and privacy requirements of the legislation.

Dated: December 19, 2000.

Donna Shalala,

Secretary,

For the reasons set forth in the preamble, 45 CFR Subtitle A, Subchapter C, is amended as follows:

1. Part 160 is revised to read as follows:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart A—General Provisions

160.101 Statutory basis and purpose.

160.102 Applicability.

160.103 Definitions.

160.104 Modifications.

Subpart B—Preemption of State Law

160.201 Applicability.

160.202 Definitions.

160.203 General rule and exceptions.

160.204 Process for requesting exception determinations.

160.205 Duration of effectiveness of exception determinations.

Subpart C—Compliance and Enforcement

160.300 Applicability.

160.302 Definitions.

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160.306 Complaints to the Secretary.

160.308 Compliance reviews.

160.310 Responsibilities of covered entities.

160.312 Secretarial action regarding complaints and compliance reviews.
Authority: Sec. 1171 through 1179 of the Social Security Act, (42 U.S.C. 1320d-1329d-8) as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031 and sec. 264 of Pub. L. 104-191 (42 U.S.C. 1320d-2(note)).

Subpart A—General Provisions
45 CFR § 160.101

§ 160.101 Statutory basis and purpose.
The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104-191, and section 264 of Public Law 104-191.
45 CFR § 160.102

§ 160.102 Applicability.
(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) To the extent required under section 201(a)(5) of the Health Insurance Portability Act of 1996, (Pub. L. 104-191), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).
45 CFR § 160.103

§ 160.103 Definitions.
Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

ANSI stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (2) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, ***82799** become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Group health plan (also see definition of health plan in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg-91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HCFA stands for Health Care Financing Administration within the Department of Health and Human Services.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg-91(b)(2) and used in the definition of health plan in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg-91(b)(3) and used in the definition of health plan in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(1) Health plan includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

(2) Health plan excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or ***82800**

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Modify or modification refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services or practices:

(i) Classification of components.

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of individually identifiable health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, State means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Other transactions that the Secretary may prescribe by regulation.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

45 CFR § 160.104

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

Subpart B—Preemption of State Law

45 CFR § 160.201

§ 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104-191.

45 CFR § 160.202

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act or section 264 of Pub. L. 104-191, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual who is the subject of the individually identifiable health information of access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable; provided that, nothing in this subchapter may be construed to preempt any State law to the extent that it authorizes or prohibits disclosure of protected health information about a minor to a parent, guardian, or person acting in loco parentis of such minor.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form or substance of an authorization or consent for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the authorization or consent, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration. ***82801**

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.
45 CFR § 160.203

§ 160.203 General rule and exceptions.
A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.
45 CFR § 160.204

§ 160.204 Process for requesting exception determinations.
(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

(1) The State law for which the exception is requested;

(2) The particular standard, requirement, or implementation specification for which the exception is requested;

(3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;

(4) How health care providers, health plans, and other entities would be affected by the exception;

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and

(6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the Federal Register. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met.
45 CFR § 160.205

§ 160.205 Duration of effectiveness of exception determinations.
An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C—Compliance and Enforcement
45 CFR § 160.300

§ 160.300 Applicability.
This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with and the enforcement of the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.
45 CFR § 160.302

§ 160.302 Definitions.
As used in this subpart, terms defined in § 164.501 of this subchapter have the same meanings given to them in that section.
45 CFR § 160.304

§ 160.304 Principles for achieving compliance.
(a) Cooperation. The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) Assistance. The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.
45 CFR § 160.306

§ 160.306 Complaints to the Secretary.
(a) Right to file a complaint. A person who believes a covered entity is not complying with the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter may file a complaint with the Secretary.

(b) Requirements for filing complaints. Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the entity that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable requirements of this part 160 or the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown. ***82802**

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the Federal Register.

(c) Investigation. The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the covered entity and of the circumstances regarding any alleged acts or omissions concerning compliance.
45 CFR § 160.308

§ 160.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

45 CFR § 160.310

§ 160.310 Responsibilities of covered entities.

(a) Provide records and compliance reports. A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(b) Cooperate with complaint investigations and compliance reviews. A covered entity must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of a covered entity to determine whether it is complying with the applicable requirements of this part 160 and the standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter.

(c) Permit access to information. (1) A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records, accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable requirements of this part 160 and the applicable standards, requirements, and implementation specifications of subpart E of part 164 of this subchapter, or if otherwise required by law.

45 CFR § 160.312

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) Resolution where noncompliance is indicated. (1) If an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates a failure to comply, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing and attempt to resolve the matter by informal means whenever possible.

(2) If the Secretary finds the covered entity is not in compliance and determines that the matter cannot be resolved by informal means, the Secretary may issue to the covered entity and, if the matter arose from a complaint, to the complainant written findings documenting the non-compliance.

(b) Resolution when no violation is found. If, after an investigation or compliance review, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant in writing.

2. A new Part 164 is added to read as follows:

PART 164—SECURITY AND PRIVACY

Subpart A—General Provisions

Sec.

Subparts B-D—[Reserved]

Subpart E—Privacy of Individually Identifiable Health Information

Authority: 42 U.S.C. 1320d-2 and 1320d-4, sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320(d-2(note)).

Subpart A—General Provisions
45 CFR § 164.102

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation standards under part C of title XI of the Act and section 264 of Public Law 104-191.
45 CFR § 164.104

§ 164.104 Applicability.
Except as otherwise provided, the provisions of this part apply to covered entities: health plans, health care clearinghouses, and health care providers who transmit health information in electronic form in connection with any transaction referred to in section 1173(a)(1) of the Act.
45 CFR § 164.106

§ 164.106 Relationship to other parts.
In complying with the requirements of this part, covered entities are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

Subpart B-D—[Reserved]

Subpart E—Privacy of Individually Identifiable Health Information
45 CFR § 164.500

§ 164.500 Applicability.
(a) Except as otherwise provided herein, the standards, requirements, and ***82803** implementation specifications of this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities, including the designation of health care components of a covered entity;

(v) Section 164.512 relating to uses and disclosures for which consent, individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

45 CFR § 164.501

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. Other persons held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Disclosure means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions, and any of the following activities of an organized health care arrangement in which the covered entity participates:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from

such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances; ***82804**

(iv) Due diligence in connection with the sale or transfer of assets to a potential successor in interest, if the potential successor in interest is a covered entity or, following completion of the sale or transfer, will become a covered entity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information, fundraising for the benefit of the covered entity, and marketing for which an individual authorization is not required as described in § 164.514(e)(2).

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Marketing means to make a communication about a product or service a purpose of which is to encourage recipients of the communication to purchase or use the product or service.

(1) Marketing does not include communications that meet the requirements of paragraph (2) of this definition and that are made by a covered entity:

(i) For the purpose of describing the entities participating in a health care provider network or health plan network, or for the purpose of describing if and the extent to which a product or service (or payment for such product or service) is provided by a covered entity or included in a plan of benefits; or

(ii) That are tailored to the circumstances of a particular individual and the communications are:

(A) Made by a health care provider to an individual as part of the treatment of the individual, and for the purpose of furthering the treatment of that individual; or

(B) Made by a health care provider or health plan to an individual in the course of managing the treatment of that individual, or for the purpose of directing or recommending to that individual alternative treatments, therapies, health care providers, or settings of care.

(2) A communication described in paragraph (1) of this definition is not included in marketing if:

(i) The communication is made orally; or

(ii) The communication is in writing and the covered entity does not receive direct or indirect remuneration from a third party for making the communication.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates, and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Payment means:

(1) The activities undertaken by:

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A covered health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to: ***82805**

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in any medium described in the definition of electronic media at § 162.103 of this subchapter; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; and

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv).

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. Psychotherapy notes excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Required by law means a mandate contained in law that compels a covered entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.
45 CFR § 164.502

§ 164.502 Uses and disclosures of protected health information: general rules.
(a) Standard. A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) Permitted uses and disclosures. A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) Pursuant to and in compliance with a consent that complies with § 164.506, to carry out treatment, payment, or health care operations;

(iii) Without consent, if consent is not required under § 164.506(a) and has not been sought under § 164.506(a)(4), to carry out treatment, payment, or health care operations, except with respect to psychotherapy notes;

(iv) Pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), and (g).

(2) Required disclosures. A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) Standard: Minimum necessary. (1) Minimum necessary applies. When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) Minimum necessary does not apply. This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section, as required by paragraph (a)(2)(i) of this section, or pursuant to an authorization under § 164.508, except for authorizations requested by the covered entity under § 164.508(d), (e), or (f);

(iii) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter; ***82806**

(iv) Uses or disclosures that are required by law, as described by § 164.512(a); and

(v) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) Standard: Uses and disclosures of protected health information subject to an agreed upon restriction. A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) Standard: Uses and disclosures of de-identified protected health information.

(1) Uses and disclosures to create de-identified information. A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) Uses and disclosures of de-identified information. Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered not to be individually identifiable health information, i.e., de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) Standard: Disclosures to business associates. (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of § 164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e).

(2) Implementation specification: documentation. A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) Standard: Deceased individuals. A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) Standard: Personal representatives. As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) Implementation specification: adults and emancipated minors. If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3) Implementation specification: unemancipated minors. If under applicable law a parent, guardian, or other person acting in loco parentis has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(i) The minor consents to such health care service; no other consent to such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(ii) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting in loco parentis, and the minor, a court, or another person authorized by law consents to such health care service; or

(iii) A parent, guardian, or other person acting in loco parentis assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(4) Implementation specification: Deceased individuals. If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person

as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) Implementation specification: Abuse, neglect, endangerment situations. Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) Standard: Confidential communications. A covered health care provider or health plan must comply with the applicable requirements of § 164.522(b) in communicating protected health information. ***82807**

(i) Standard: Uses and disclosures consistent with notice. A covered entity that is required by § 164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by § 164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in § 164.520(b)(1)(iii)(A)-(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) Standard: Disclosures by whistleblowers and workforce member crime victims.

(1) Disclosures by whistleblowers. A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards, or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) Disclosures by workforce members who are victims of a crime. A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in § 164.512(f)(2)(i).

45 CFR § 164.504

§ 164.504 Uses and disclosures: Organizational requirements.

(a) Definitions. As used in this section:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Health care component has the following meaning:

(1) Components of a covered entity that perform covered functions are part of the health care component.

(2) Another component of the covered entity is part of the entity's health care component to the extent that:

(i) It performs, with respect to a component that performs covered functions, activities that would make such other component a business associate of the component that performs covered functions if the two components were separate legal entities; and

(ii) The activities involve the use or disclosure of protected health information that such other component creates or receives from or on behalf of the component that performs covered functions.

Hybrid entity means a single legal entity that is a covered entity and whose covered functions are not its primary functions.

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at § 164.514(b)(2)(i) has been deleted, except that the geographic information described in § 164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b) Standard: Health care component. If a covered entity is a hybrid entity, the requirements of this subpart, other than the requirements of this section, apply only to the health care component(s) of the entity, as specified in this section.

(c)(1) Implementation specification: Application of other provisions. In applying a provision of this subpart, other than this section, to a hybrid entity:

(i) A reference in such provision to a “covered entity” refers to a health care component of the covered entity;

(ii) A reference in such provision to a “health plan,” “covered health care provider,” or “health care clearinghouse” refers to a health care component of the covered entity if such health care component performs the functions of a health plan, covered health care provider, or health care clearinghouse, as applicable; and

(iii) A reference in such provision to “protected health information” refers to protected health information that is created or received by or on behalf of the health care component of the covered entity.

(2) Implementation specifications: Safeguard requirements. The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this subpart. In particular, and without limiting this requirement, such covered entity must ensure that:

(i) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which this subpart would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(ii) A component that is described by paragraph (2)(i) of the definition of health care component in this section does not use or disclose protected health information that is within paragraph (2)(ii) of such definition for purposes of its activities other than those described by paragraph (2)(i) of such definition in a way prohibited by this subpart; and

(iii) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by this subpart.

(3) Implementation specifications: Responsibilities of the covered entity. A covered entity that is a hybrid entity has the following responsibilities:

(i) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility to comply with this subpart.

(ii) The covered entity has the responsibility for complying with ***82808** § 164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with this subpart, including the safeguard requirements in paragraph (c)(2) of this section.

(iii) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation as required by § 164.530(j).

(d)(1) Standard: Affiliated covered entities. Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of this subpart.

(2) Implementation specifications: Requirements for designation of an affiliated covered entity. (i) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of this subpart, if all of the covered entities designated are under common ownership or control.

(ii) The designation of an affiliated covered entity must be documented and the documentation maintained as required by § 164.530(j).

(3) Implementation specifications: Safeguard requirements. An affiliated covered entity must ensure that:

(i) The affiliated covered entity's use and disclosure of protected health information comply with the applicable requirements of this subpart; and

(ii) If the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, the affiliated covered entity complies with paragraph (g) of this section.

(e)(1) Standard: Business associate contracts. (i) The contract or other arrangement between the covered entity and the business associate required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) Implementation specifications: Business associate contracts. A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(D) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from, or created or received by the business associate on behalf of, the covered entity agrees to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(I) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) Implementation specifications: Other arrangements. (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with paragraph (e) of this section by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section.

(B) The covered entity may comply with paragraph (e) of this section, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph (e), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(3)(i) of this section, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) Implementation specifications: Other requirements for contracts and other arrangements. (i) The contract or other arrangement between the covered entity and the business associate may ***82809** permit the business associate to use the information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(1) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and

(2) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(f)(1) Standard: Requirements for group health plans. (i) Except as provided under paragraph (f)(1)(ii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and discloses of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of :

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(2) Implementation specifications: Requirements for plan documents. The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was

made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) Implementation specifications: Uses and disclosures. A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by § 164.520(b)(1)(iii)(C) is included in the appropriate notice; and (iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) Standard: Requirements for a covered entity with multiple covered functions.

(1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed. ***82810**

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

45 CFR § 164.506

§ 164.506 Consent for uses or disclosures to carry out treatment, payment, or health care operations.

(a) Standard: Consent requirement. (1) Except as provided in paragraph (a)(2) or (a)(3) of this section, a covered health care provider must obtain the individual's consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations.

(2) A covered health care provider may, without consent, use or disclose protected health information to carry out treatment, payment, or health care operations, if:

(i) The covered health care provider has an indirect treatment relationship with the individual; or

(ii) The covered health care provider created or received the protected health information in the course of providing health care to an individual who is an inmate.

(3)(i) A covered health care provider may, without prior consent, use or disclose protected health information created or received under paragraph (a)(3)(i)(A)-(C) of this section to carry out treatment, payment, or health care operations:

(A) In emergency treatment situations, if the covered health care provider attempts to obtain such consent as soon as reasonably practicable after the delivery of such treatment;

(B) If the covered health care provider is required by law to treat the individual, and the covered health care provider attempts to obtain such consent but is unable to obtain such consent; or

(C) If a covered health care provider attempts to obtain such consent from the individual but is unable to obtain such consent due to substantial barriers to communicating with the individual, and the covered health care provider determines, in the exercise of professional judgment, that the individual's consent to receive treatment is clearly inferred from the circumstances.

(ii) A covered health care provider that fails to obtain such consent in accordance with paragraph (a)(3)(i) of this section must document its attempt to obtain consent and the reason why consent was not obtained.

(4) If a covered entity is not required to obtain consent by paragraph (a)(1) of this section, it may obtain an individual's consent for the covered entity's own use or disclosure of protected health information to carry out treatment, payment, or health care operations, provided that such consent meets the requirements of this section.

(5) Except as provided in paragraph (f)(1) of this section, a consent obtained by a covered entity under this section is not effective to permit another covered entity to use or disclose protected health information.

(b) Implementation specifications: General requirements. (1) A covered health care provider may condition treatment on the provision by the individual of a consent under this section.

(2) A health plan may condition enrollment in the health plan on the provision by the individual of a consent under this section sought in conjunction with such enrollment.

(3) A consent under this section may not be combined in a single document with the notice required by § 164.520.

(4)(i) A consent for use or disclosure may be combined with other types of written legal permission from the individual (e.g., an informed consent for treatment or a consent to assignment of benefits), if the consent under this section:

(A) Is visually and organizationally separate from such other written legal permission; and

(B) Is separately signed by the individual and dated.

(ii) A consent for use or disclosure may be combined with a research authorization under § 164.508(f).

(5) An individual may revoke a consent under this section at any time, except to the extent that the covered entity has taken action in reliance thereon. Such revocation must be in writing.

(6) A covered entity must document and retain any signed consent under this section as required by § 164.530(j).

(c) Implementation specifications: Content requirements. A consent under this section must be in plain language and:

(1) Inform the individual that protected health information may be used and disclosed to carry out treatment, payment, or health care operations;

(2) Refer the individual to the notice required by § 164.520 for a more complete description of such uses and disclosures and state that the individual has the right to review the notice prior to signing the consent;

(3) If the covered entity has reserved the right to change its privacy practices that are described in the notice in accordance with § 164.520(b)(1)(v)(C), state that the terms of its notice may change and describe how the individual may obtain a revised notice;

(4) State that:

(i) The individual has the right to request that the covered entity restrict how protected health information is used or disclosed to carry out treatment, payment, or health care operations;

(ii) The covered entity is not required to agree to requested restrictions; and

(iii) If the covered entity agrees to a requested restriction, the restriction is binding on the covered entity;

(5) State that the individual has the right to revoke the consent in writing, except to the extent that the covered entity has taken action in reliance thereon; and

(6) Be signed by the individual and dated.

(d) Implementation specifications: Defective consents. There is no consent under this section, if the document submitted has any of the following defects:

(1) The consent lacks an element required by paragraph (c) of this section, as applicable; or

(2) The consent has been revoked in accordance with paragraph (b)(5) of this section.

(e) Standard: Resolving conflicting consents and authorizations. (1) If a covered entity has obtained a consent under this section and receives any other authorization or written legal permission from the individual for a disclosure of protected health information to carry out treatment, payment, or health care operations, the covered entity may disclose such protected health information only in accordance with the more restrictive consent, authorization, or other written legal permission from the individual.

(2) A covered entity may attempt to resolve a conflict between a consent and an authorization or other written legal permission from the individual described in paragraph (e)(1) of this section by:

(i) Obtaining a new consent from the individual under this section for the disclosure to carry out treatment, payment, or health care operations; or

(ii) Communicating orally or in writing with the individual in order to determine the individual's preference in resolving the conflict. The covered entity must document the individual's preference and may only disclose protected health information in accordance with the individual's preference. ***82811**

(f)(1) Standard: Joint consents. Covered entities that participate in an organized health care arrangement and that have a joint notice under § 164.520(d) may comply with this section by a joint consent.

(2) Implementation specifications: Requirements for joint consents. (i) A joint consent must:

(A) Include the name or other specific identification of the covered entities, or classes of covered entities, to which the joint consent applies; and

(B) Meet the requirements of this section, except that the statements required by this section may be altered to reflect the fact that the consent covers more than one covered entity.

(ii) If an individual revokes a joint consent, the covered entity that receives the revocation must inform the other entities covered by the joint consent of the revocation as soon as practicable.
45 CFR § 164.508

§ 164.508 Uses and disclosures for which an authorization is required.
(a) Standard: Authorizations for uses and disclosures. (1) Authorization required: General rule. Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) Authorization required: psychotherapy notes. Notwithstanding any other provision of this subpart, other than transition provisions provided for in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations, consistent with consent requirements in § 164.506:

(A) Use by originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity in training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).

(b) Implementation specifications: General requirements.—(1) Valid authorizations.

(i) A valid authorization is a document that contains the elements listed in paragraph (c) and, as applicable, paragraph (d), (e), or (f) of this section.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not be inconsistent with the elements required by this section.

(2) Defective authorizations. An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c), (d), (e), or (f) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization lacks an element required by paragraph (c), (d), (e), or (f) of this section, if applicable;

(v) The authorization violates paragraph (b)(3) of this section, if applicable;

(vi) Any material information in the authorization is known by the covered entity to be false.

(3) Compound authorizations. An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information created for research that includes treatment of the individual may be combined as permitted by § 164.506(b)(4)(ii) or paragraph (f) of this section;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) Prohibition on conditioning of authorizations. A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization under paragraph (f) of this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section;

(iii) A health plan may condition payment of a claim for specified benefits on provision of an authorization under paragraph (e) of this section, if:

(A) The disclosure is necessary to determine payment of such claim; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iv) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) Revocation of authorizations. An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy.

(6) Documentation. A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).

(c) Implementation specifications: Core elements and requirements. (1) Core elements. A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion;
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(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure;

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure;

(iv) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure;

(v) A statement of the individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization;

(vi) A statement that information used or disclosed pursuant to the authorization may be subject to redisclosure by the recipient and no longer be protected by this rule;

(vii) Signature of the individual and date; and

(viii) If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual.

(2) Plain language requirement. The authorization must be written in plain language.

(d) Implementation specifications: Authorizations requested by a covered entity for its own uses and disclosures. If an authorization is requested by a covered entity for its own use or disclosure of protected health information that it maintains, the covered entity must comply with the following requirements.

(1) Required elements. The authorization for the uses or disclosures described in this paragraph must, in addition to meeting the requirements of paragraph (c) of this section, contain the following elements:

(i) For any authorization to which the prohibition on conditioning in paragraph (b)(4) of this section applies, a statement that the covered entity will not condition treatment, payment, enrollment in the health plan, or eligibility for benefits on the individual's providing authorization for the requested use or disclosure;

(ii) A description of each purpose of the requested use or disclosure;

(iii) A statement that the individual may:

(A) Inspect or copy the protected health information to be used or disclosed as provided in § 164.524; and

(B) Refuse to sign the authorization; and

(iv) If use or disclosure of the requested information will result in direct or indirect remuneration to the covered entity from a third party, a statement that such remuneration will result.

(2) Copy to the individual. A covered entity must provide the individual with a copy of the signed authorization.

(e) Implementation specifications: Authorizations requested by a covered entity for disclosures by others. If an authorization is requested by a covered entity for another covered entity to disclose protected health information to the covered entity requesting the authorization to carry out treatment, payment, or health care operations, the covered entity requesting the authorization must comply with the following requirements.

(1) Required elements. The authorization for the disclosures described in this paragraph must, in addition to meeting the requirements of paragraph (c) of this section, contain the following elements:

(i) A description of each purpose of the requested disclosure;

(ii) Except for an authorization on which payment may be conditioned under paragraph (b)(4)(iii) of this section, a statement that the covered entity will not condition treatment, payment, enrollment in the health plan, or eligibility for benefits on the individual's providing authorization for the requested use or disclosure; and

(iii) A statement that the individual may refuse to sign the authorization.

(2) Copy to the individual. A covered entity must provide the individual with a copy of the signed authorization.

(f) Implementation specifications: Authorizations for uses and disclosures of protected health information created for research that includes treatment of the individual.

(1) Required elements. Except as otherwise permitted by § 164.512(i), a covered entity that creates protected health information for the purpose, in whole or in part, of research that includes treatment of individuals must obtain an authorization for the use or disclosure of such information. Such authorization must:

(i) For uses and disclosures not otherwise permitted or required under this subpart, meet the requirements of paragraphs (c) and (d) of this section; and

(ii) Contain:

(A) A description of the extent to which such protected health information will be used or disclosed to carry out treatment, payment, or health care operations;

(B) A description of any protected health information that will not be used or disclosed for purposes permitted in accordance with §§ 164.510 and 164.512, provided that the covered entity may not include a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i); and

(C) If the covered entity has obtained or intends to obtain the individual's consent under § 164.506, or has provided or intends to provide the individual with a notice under § 164.520, the authorization must refer to that consent or notice, as applicable, and state that the statements made pursuant to this section are binding.

(2) Optional procedure. An authorization under this paragraph may be in the same document as:

(i) A consent to participate in the research;

(ii) A consent to use or disclose protected health information to carry out treatment, payment, or health care operations under § 164.506; or

(iii) A notice of privacy practices under § 164.520.

45 CFR § 164.510

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

A covered entity may use or disclose protected health information without the written consent or authorization of the individual as described by §§ 164.506 and 164.508, respectively, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the disclosure in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.

(a) Standard: use and disclosure for facility directories. (1) Permitted uses and disclosure. Except when an objection is expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:

(i) Use the following protected health information to maintain a directory of individuals in its facility:

(A) The individual's name;

(B) The individual's location in the covered health care provider's facility;

(C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and

(D) The individual's religious affiliation; and

(ii) Disclose for directory purposes such information:

(A) To members of the clergy; or ***82813**

(B) Except for religious affiliation, to other persons who ask for the individual by name.

(2) Opportunity to object. A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.

(3) Emergency circumstances. (i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:

(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.

(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.

(b) Standard: uses and disclosures for involvement in the individual's care and notification purposes. (1) Permitted uses and disclosures. (i) A covered entity may, in accordance with paragraphs (b)(2) or (3) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (3), or (4) of this section, as applicable.

(2) Uses and disclosures with the individual present. If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based the exercise of professional judgment, that the individual does not object to the disclosure.

(3) Limited uses and disclosures when the individual is not present. If the individual is not present for, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) Use and disclosures for disaster relief purposes. A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2) and (3) of this section apply to such uses and disclosure to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.
45 CFR § 164.512

§ 164.512 Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written consent or authorization of the individual as described in §§ 164.506 and 164.508, respectively, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) Standard: Uses and disclosures required by law. (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) Standard: uses and disclosures for public health activities. (1) Permitted disclosures. A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration:

(A) To report adverse events (or similar reports with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations if the disclosure is made to the person required or directed to report such information to the Food and Drug Administration;

(B) To track products if the disclosure is made to a person required or directed by the Food and Drug Administration to track the product;

(C) To enable product recalls, repairs, or replacement (including locating and ***82814** notifying individuals who have received products of product recalls, withdrawals, or other problems); or

(D) To conduct post marketing surveillance to comply with requirements or at the direction of the Food and Drug Administration;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides a health care to the individual at the request of the employer:

(1) To conduct an evaluation relating to medical surveillance of the workplace; or

(2) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance;

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(1) By giving a copy of the notice to the individual at the time the health care is provided; or

(2) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(2) Permitted uses. If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) Standard: Disclosures about victims of abuse, neglect or domestic violence. (1) Permitted disclosures. Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) Informing the individual. A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(d) Standard: Uses and disclosures for health oversight activities. (1) Permitted disclosures. A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) Exception to health oversight activities. For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) Joint activities or investigations. Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

(4) Permitted uses. If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

(e) Standard: Disclosures for judicial and administrative proceedings.

(1) Permitted disclosures. A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by ***82815** such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protecting health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);

(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and

(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:

(1) No objections were filed; or

(2) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

(vi) Nothwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient

to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(iv) of this section.

(2) Other uses and disclosures under this section. The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.

(f) Standard: Disclosures for law enforcement purposes. A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) Permitted disclosures: Pursuant to process and as otherwise required by law. A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(1) The information sought is relevant and material to a legitimate law enforcement inquiry;

(2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(3) De-identified information could not reasonably be used.

(2) Permitted disclosures: Limited information for identification and location purposes. Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;

(B) Date and place of birth;

(C) Social security number;

(D) ABO blood type and rh factor;

(E) Type of injury;

(F) Date and time of treatment;

(G) Date and time of death, if applicable; and

(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) Permitted disclosure: Victims of a crime. Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:

(ii) The individual agrees to the disclosure; or

(iii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and ***82816** adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) Permitted disclosure: Decedents. A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) Permitted disclosure: Crime on premises. A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

(6) Permitted disclosure: Reporting crime in emergencies. (i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

(A) The commission and nature of a crime;

(B) The location of such crime or of the victim(s) of such crime; and

(C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

(g) Standard: Uses and disclosures about decedents. (1) Coroners and medical examiners. A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.

(2) Funeral directors. A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes. A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) Standard: Uses and disclosures for research purposes. (1) Permitted uses and disclosures. A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) Board approval of a waiver of authorization. The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by § 164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc .107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(1) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(2) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(3) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) Reviews preparatory to research. The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) Research on decedent's information. The covered entity obtains from the researcher:

(A) Representation that the use or disclosure is sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) Documentation of waiver approval. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) Identification and date of action. A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than minimal risk to the individuals;

(B) The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;

(C) The research could not practicably be conducted without the alteration or waiver;

(D) The research could not practicably be conducted without access to and use of the protected health information;

(E) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

(F) There is an adequate plan to protect the identifiers from improper use and disclosure;

(G) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and

(H) There are adequate written assurances that the protected health ***82817** information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

(iii) Protected health information needed. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph (i)(2)(ii)(D) of this section;

(iv) Review and approval procedures. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14

CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) Required signature. The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

(j) Standard: Uses and disclosures to avert a serious threat to health or safety. (1) Permitted disclosures. A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or

(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:

(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or

(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.

(2) Use or disclosure not permitted. A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or

(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.

(3) Limit on information that may be disclosed. A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.

(4) Presumption of good faith belief. A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

(k) Standard: Uses and disclosures for specialized government functions. (1) Military and veterans activities. (i) Armed Forces personnel. A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the Federal Register the following information:

(A) Appropriate military command authorities; and

(B) The purposes for which the protected health information may be used or disclosed.

(ii) Separation or discharge from military service. A covered entity that is a component of the Departments of Defense or Transportation may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

(iii) Veterans. A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.

(iv) Foreign military personnel. A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the Federal Register pursuant to paragraph (k)(1)(i) of this section.

(2) National security and intelligence activities. A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, et seq.) and implementing authority (e.g., Executive Order 12333).

(3) Protective services for the President and others. A covered entity may disclose protected health ***82818** information to authorized federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056, or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or to for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

(4) Medical suitability determinations. A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:

(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12698;

(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or

(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.

(5) Correctional institutions and other law enforcement custodial situations. (i) Permitted disclosures. A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual

protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:

(A) The provision of health care to such individuals;

(B) The health and safety of such individual or other inmates;

(C) The health and safety of the officers or employees of or others at the correctional institution;

(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

(E) Law enforcement on the premises of the correctional institution; and

(F) The administration and maintenance of the safety, security, and good order of the correctional institution.

(ii) Permitted uses. A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.

(iii) No application after release. For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

(6) Covered entities that are government programs providing public benefits. (i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.

(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.

(l) Standard: Disclosures for workers' compensation. A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.
45 CFR § 164.514

§ 164.514 Other requirements relating to uses and disclosures of protected health information.
(a) Standard: de-identification of protected health information. Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(b) Implementation specifications: requirements for de-identification of protected health information. A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code; and ***82819**

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) Implementation specifications: re-identification. A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

(1) Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d)(1) Standard: minimum necessary requirements. A covered entity must reasonably ensure that the standards, requirements, and implementation specifications of § 164.502(b) and this section relating to a request for or the use and disclosure of the minimum necessary protected health information are met.

(2) Implementation specifications: minimum necessary uses of protected health information. (i) A covered entity must identify:

(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) Implementation specification: Minimum necessary disclosures of protected health information. (i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under § 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of § 164.512(i) have been provided by a person requesting the information for research purposes.

(4) Implementation specifications: Minimum necessary requests for protected health information. (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

(iii) For all other requests, a covered entity must review the request on an individual basis to determine that the protected health information sought is limited to the information reasonably necessary to accomplish the purpose for which the request is made.

(5) Implementation specification: Other content requirement. For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, discloses or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(e)(1) Standard: Uses and disclosures of protected health information for marketing. A covered entity may not use or disclose protected health information for marketing without an authorization that meets the applicable requirements of § 164.508, except as provided for by paragraph (e)(2) of this section.

(2) Implementation specifications: Requirements relating to marketing. (i) A covered entity is not required to obtain an authorization under § 164.508 when it uses or discloses protected health information to make a marketing communication to an individual that:

(A) Occurs in a face-to-face encounter with the individual;

(B) Concerns products or services of nominal value; or

(C) Concerns the health-related products and services of the covered entity or of a third party and the communication meets the applicable conditions in paragraph (e)(3) of this section.

(ii) A covered entity may disclose protected health information for purposes of such communications only to a business associate that assists the covered entity with such communications.

(3) Implementation specifications: Requirements for certain marketing communications. For a marketing communication to qualify under paragraph (e)(2)(i) of this section, the following conditions must be met:

(i) The communication must:

(A) Identify the covered entity as the party making the communication;

(B) If the covered entity has received or will receive direct or indirect remuneration for making the communication, prominently state that fact; and

(C) Except when the communication is contained in a newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad groups of individuals, contain instructions describing how the individual may opt out of receiving future such communications.

(ii) If the covered entity uses or discloses protected health information to target the communication to individuals based on their health status or condition:

(A) The covered entity must make a determination prior to making the communication that the product or service being marketed may be beneficial to the health of the type or class of individual targeted; and

(B) The communication must explain why the individual has been targeted ***82820** and how the product or service relates to the health of the individual.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future marketing communications, under paragraph (e)(3)(i)(C) of this section, are not sent such communications.

(f)(1) Standard: Uses and disclosures for fundraising. A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual; and

(ii) Dates of health care provided to an individual.

(2) Implementation specifications: Fundraising requirements. (i) The covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by § 164.520(b)(1)(iii)(B) is included in the covered entity's notice;

(ii) The covered entity must include in any fundraising materials it sends to an individual under this paragraph a description of how the individual may opt out of receiving any further fundraising communications.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.

(g) Standard: Uses and disclosures for underwriting and related purposes. If a health plan receives protected heath information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may not use or disclose such protected health information for any other purpose, except as may be required by law.

(h)(1) Standard: Verification requirements. Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.

(2) Implementation specifications: Verification. (i) Conditions on disclosures. If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by § 164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).

(ii) Identity of public officials. A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(iii) Authority of public officials. A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) Exercise of professional judgment. The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with § 164.512(j).

45 CFR § 164.520

§ 164.520 Notice of privacy practices for protected health information.

(a) Standard: notice of privacy practices. (1) Right to notice. Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) Exception for group health plans. (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan. ***82821**

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(3) Exception for inmates. An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) Implementation specifications: content of notice.

(1) Required elements. The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) Header. The notice must contain the following statement as a header or otherwise prominently displayed: “THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.”

(ii) Uses and disclosures. The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written consent or authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.

(E) A statement that other uses and disclosures will be made only with the individual's written authorization and that the individual may revoke such authorization as provided by § 164.508(b)(5).

(iii) Separate statements for certain uses or disclosures. If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement, as applicable, that:

(A) The covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual;

(B) The covered entity may contact the individual to raise funds for the covered entity; or

(C) A group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan.

(iv) Individual rights. The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction;

(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by § 164.524;

(D) The right to amend protected health information as provided by § 164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) Covered entity's duties. The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information and to provide individuals with notice of its legal duties and privacy practices with respect to protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) Complaints. The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) Contact. The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).

(viii) Effective date. The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) Optional elements. (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) Revisions to the notice. The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

(c) Implementation specifications: Provision of notice. A covered entity must make the notice required by this ***82822** section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(4) of this section, as applicable.

(1) Specific requirements for health plans. (i) A health plan must provide notice:

(A) No later than the compliance date for the health plan, to individuals then covered by the plan;

(B) Thereafter, at the time of enrollment, to individuals who are new enrollees; and

(C) Within 60 days of a material revision to the notice, to individuals then covered by the plan.

(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.

(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.

(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.

(2) Specific requirements for certain covered health care providers. A covered health care provider that has a direct treatment relationship with an individual must:

(i) Provide the notice no later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider;

(ii) If the covered health care provider maintains a physical service delivery site:

(A) Have the notice available at the service delivery site for individuals to request to take with them; and

(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and

(iii) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(ii) of this section, if applicable.

(3) Specific requirements for electronic notice. (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.

(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service.

(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.

(d) Implementation specifications: Joint notice by separate covered entities. Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:

(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;

(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and

(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and

(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.

(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.

(e) Implementation specifications: Documentation. A covered entity must document compliance with the notice requirements by retaining copies of the notices issued by the covered entity as required by § 164.530(j).

45 CFR § 164.522

§ 164.522 Rights to request privacy protection for protected health information.

(a)(1) Standard: Right of an individual to request restriction of uses and disclosures. (i) A covered entity must permit an individual to request that the covered entity restrict:

(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and

(B) Disclosures permitted under § 164.510(b).

(ii) A covered entity is not required to agree to a restriction.

(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.

(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.

(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §§ 164.502(a)(2)(i), 164.510(a) or 164.512.

(2) Implementation specifications: Terminating a restriction. A covered entity may terminate its agreement to a restriction, if :

(i) The individual agrees to or requests the termination in writing;

(ii) The individual orally agrees to the termination and the oral agreement is documented; or

(iii) The covered entity informs the individual that it is terminating its ***82823** agreement to a restriction, except that such termination is only effective with respect to protected health information created or received after it has so informed the individual.

(3) Implementation specification: Documentation. A covered entity that agrees to a restriction must document the restriction in accordance with § 164.530(j).

(b)(1) Standard: Confidential communications requirements. (i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the covered health care provider by alternative means or at alternative locations.

(ii) A health plan must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.

(2) Implementation specifications: Conditions on providing confidential communications.

(i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.

(ii) A covered entity may condition the provision of a reasonable accommodation on:

(A) When appropriate, information as to how payment, if any, will be handled; and

(B) Specification of an alternative address or other method of contact.

(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.

(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.
45 CFR § 164.524

§ 164.524 Access of individuals to protected health information.
(a) Standard: Access to protected health information. (1) Right of access. Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(i) Psychotherapy notes;

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(iii) Protected health information maintained by a covered entity that is:

(A) Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to the extent the provision of access to the individual would be prohibited by law; or

(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).

(2) Unreviewable grounds for denial. A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) Reviewable grounds for denial. A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) Review of a denial of access. If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) Implementation specifications: requests for access and timely action. (1) Individual's request for access. The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

(2) Timely action by the covered entity. (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section. ***82824**

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section.

(ii) If the request for access is for protected health information that is not maintained or accessible to the covered entity on-site, the covered entity must take an action required by paragraph (b)(2)(i) of this section by no later than 60 days from the receipt of such a request.

(iii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) or (ii) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) or (ii) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) Implementation specifications: Provision of access. If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) Providing the access requested. The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) Form of access requested. (i) The covered entity must provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.

(ii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(3) Time and manner of access. The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(4) Fees. If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;

(ii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

(iii) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.

(d) Implementation specifications: Denial of access. If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) Making other information accessible. The covered entity must, to the extent possible, give the individual access to any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) Denial. The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(3) Other responsibility. If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) Review of denial requested. If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) Implementation specification: Documentation. A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.
45 CFR § 164.526

§ 164.526 Amendment of protected health information.
(a) Standard: Right to amend. (1) Right to amend. An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) Denial of amendment. A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the ***82825** originator of protected health information is no longer available to act on the requested amendment;

(ii) Is not part of the designated record set;

(iii) Would not be available for inspection under § 164.524; or

(iv) Is accurate and complete.

(b) Implementation specifications: requests for amendment and timely action. (1) Individual's request for amendment. The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.

(2) Timely action by the covered entity. (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.

(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required by paragraphs (c)(1) and (2) of this section.

(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.

(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for an amendment.

(c) Implementation specifications: Accepting the amendment. If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) Making the amendment. The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.

(2) Informing the individual. In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.

(3) Informing others. The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:

(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and

(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

(d) Implementation specifications: Denying the amendment. If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) Denial. The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:

(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;

(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and

(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in § 164.530(d) or to the Secretary pursuant to the procedures established in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(2) Statement of disagreement. The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.

(3) Rebuttal statement. The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide a copy to the individual who submitted the statement of disagreement.

(4) Recordkeeping. The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.

(5) Future disclosures. (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.

(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.

(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.

(e) Implementation specification: Actions on notices of amendment. A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.

(f) Implementation specification: Documentation. A covered entity must document the titles of the persons or ***82826** offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by § 164.530(j).

45 CFR § 164.528

§ 164.528 Accounting of disclosures of protected health information.

(a) Standard: Right to an accounting of disclosures of protected health information. (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in § 164.502;

(ii) To individuals of protected health information about them as provided in § 164.502;

(iii) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;

(iv) For national security or intelligence purposes as provided in § 164.512(k)(2);

(v) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5); or

(vi) That occurred prior to the compliance date for the covered entity.

(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:

(A) Document the statement, including the identity of the agency or official making the statement;

(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.

(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

(b) Implementation specifications: Content of the accounting. The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) The accounting must include for each disclosure:

(i) The date of the disclosure;

(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;

(iii) A brief description of the protected health information disclosed; and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure; or, in lieu of such statement:

(A) A copy of the individual's written authorization pursuant to § 164.508; or

(B) A copy of a written request for a disclosure under §§ 164.502(a)(2)(ii) or 164.512, if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§ 164.502(a)(2)(ii) or 164.512, or pursuant to a single authorization under § 164.508, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(c) Implementation specifications: Provision of the accounting. (1) The covered entity must act on the individual's request for an accounting, no later than 60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) Implementation specification: Documentation. A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.
45 CFR § 164.530

§ 164.530 Administrative requirements.
(a)(1) Standard: Personnel designations. (i) A covered entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity.

(ii) A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.520.

(2) Implementation specification: Personnel designations. A covered entity must document the personnel designations in paragraph (a)(1) of this section as required by paragraph (j) of this section.

(b)(1) Standard: Training. A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart, as necessary and appropriate for the members of the workforce to ***82827** carry out their function within the covered entity.

(2) Implementation specifications: Training. (i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:

(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity;

(B) Thereafter, to each new member of the workforce within a reasonable period of time after the person joins the covered entity's workforce; and

(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart, within a reasonable period of time after the material change becomes effective in accordance with paragraph (i) of this section.

(ii) A covered entity must document that the training as described in paragraph (b)(2)(i) of this section has been provided, as required by paragraph (j) of this section.

(c)(1) Standard: Safeguards. A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

(2) Implementation specification: Safeguards. A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.

(d)(1) Standard: Complaints to the covered entity. A covered entity must provide a process for individuals to make complaints concerning the covered entity's policies and procedures required by this subpart or its compliance with such policies and procedures or the requirements of this subpart.

(2) Implementation specification: Documentation of complaints. As required by paragraph (j) of this section, a covered entity must document all complaints received, and their disposition, if any.

(e)(1) Standard: Sanctions. A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the covered entity or the requirements of this subpart. This standard does not apply to a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of § 164.502(j) or paragraph (g)(2) of this section.

(2) Implementation specification: Documentation. As required by paragraph (j) of this section, a covered entity must document the sanctions that are applied, if any.

(f) Standard: Mitigation. A covered entity must mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of this subpart by the covered entity or its business associate.

(g) Standard: Refraining from intimidating or retaliatory acts. A covered entity may not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against:

(1) Individuals. Any individual for the exercise by the individual of any right under, or for participation by the individual in any process established by this subpart, including the filing of a complaint under this section;

(2) Individuals and others. Any individual or other person for:

(i) Filing of a complaint with the Secretary under subpart C of part 160 of this subchapter;

(ii) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under Part C of Title XI; or

(iii) Opposing any act or practice made unlawful by this subpart, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of the opposition is reasonable and does not involve a disclosure of protected health information in violation of this subpart.

(h) Standard: Waiver of rights. A covered entity may not require individuals to waive their rights under § 160.306 of this subchapter or this subpart as a condition of the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.

(i)(1) Standard: Policies and procedures. A covered entity must implement policies and procedures with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of this subpart. The policies and procedures must be reasonably designed, taking into account the size of and the type of activities that relate to protected health information undertaken by the covered entity, to ensure such compliance. This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirement of this subpart.

(2) Standard: Changes to policies or procedures. (i) A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation specifications of this subpart;

(ii) When a covered entity changes a privacy practice that is stated in the notice described in § 164.520, and makes corresponding changes to its policies and procedures, it may make the changes effective for protected health information that it created or received prior to the effective date of the notice revision, if the covered entity has, in accordance with § 164.520(b)(1)(v)(C), included in the notice a statement reserving its right to make such a change in its privacy practices; or

(iii) A covered entity may make any other changes to policies and procedures at any time, provided that the changes are documented and implemented in accordance with paragraph (i)(5) of this section.

(3) Implementation specification: Changes in law. Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by § 164.520, the covered entity must promptly make the appropriate revisions to the notice in accordance with § 164.520(b)(3). Nothing in this paragraph may be used by a covered entity to excuse a failure to comply with the law.

(4) Implementation specifications: Changes to privacy practices stated in the notice. (i) To implement a change as provided by paragraph (i)(2)(ii) of this section, a covered entity must:

(A) Ensure that the policy or procedure, as revised to reflect a change in the covered entity's privacy practice as stated in its notice, complies with the standards, requirements, and implementation specifications of this subpart;

(B) Document the policy or procedure, as revised, as required by paragraph (j) of this section; and

(C) Revise the notice as required by § 164.520(b)(3) to state the changed practice and make the revised notice available as required by § 164.520(c). The covered entity may not implement a change to a policy or procedure prior to the effective date of the revised notice.

(ii) If a covered entity has not reserved its right under § 164.520(b)(1)(v)(C) to change a privacy practice that is stated in the notice, the covered entity is bound by the privacy practices as stated ***82828** in the notice with respect to protected health information created or received while such notice is in effect. A covered entity may change a privacy practice that is stated in the notice, and the related policies and procedures, without having reserved the right to do so, provided that:

(A) Such change meets the implementation the requirements in paragraphs (i)(4)(i)(A)-(C) of this section; and

(B) Such change is effective only with respect to protected health information created or received after the effective date of the notice.

(5) Implementation specification: Changes to other policies or procedures. A covered entity may change, at any time, a policy or procedure that does not materially affect the content of the notice required by § 164.520, provided that:

(i) The policy or procedure, as revised, complies with the standards, requirements, and implementation specifications of this subpart; and

(ii) Prior to the effective date of the change, the policy or procedure, as revised, is documented as required by paragraph (j) of this section.

(j)(1) Standard: Documentation. A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

(2) Implementation specification: Retention period. A covered entity must retain the documentation required by paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.

(k) Standard: Group health plans. (1) A group health plan is not subject to the standards or implementation specifications in paragraphs (a) through (f) and (i) of this section, to the extent that:

(i) The group health plan provides health benefits solely through an insurance contract with a health insurance issuer or an HMO; and

(ii) The group health plan does not create or receive protected health information, except for:

(A) Summary health information as defined in § 164.504(a); or

(B) Information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) A group health plan described in paragraph (k)(1) of this section is subject to the standard and implementation specification in paragraph (j) of this section only with respect to plan documents amended in accordance with § 164.504(f).
45 CFR § 164.532

§ 164.532 Transition provisions.
(a) Standard: Effect of prior consents and authorizations. Notwithstanding other sections of this subpart, a covered entity may continue to use or disclose protected health information pursuant to a consent, authorization, or other express legal permission obtained from an individual permitting the use or disclosure of protected health information that does not comply with §§ 164.506 or 164.508 of this subpart consistent with paragraph (b) of this section.

(b) Implementation specification: Requirements for retaining effectiveness of prior consents and authorizations. Notwithstanding other sections of this subpart, the following provisions apply to use or disclosure by a covered entity of protected health information pursuant to a consent, authorization, or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, if the consent, authorization, or other express legal permission was obtained from an individual before the applicable compliance date of this subpart and does not comply with §§ 164.506 or 164.508 of this subpart.

(1) If the consent, authorization, or other express legal permission obtained from an individual permits a use or disclosure for purposes of carrying out treatment, payment, or health care operations, the covered entity may, with respect to protected health information that it created or received before the applicable compliance date of this subpart and to which the consent, authorization, or other express legal permission obtained from an individual applies, use or disclose such information for purposes of carrying out treatment, payment, or health care operations, provided that:

(i) The covered entity does not make any use or disclosure that is expressly excluded from the a consent, authorization, or other express legal permission obtained from an individual; and

(ii) The covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.

(2) If the consent, authorization, or other express legal permission obtained from an individual specifically permits a use or disclosure for a purpose other than to carry out treatment, payment, or health care operations, the covered entity may, with respect to protected health information that it created or received before the applicable compliance date of this subpart and to which the consent, authorization, or other express legal permission obtained from an individual applies, make such use or disclosure, provided that:

(i) The covered entity does not make any use or disclosure that is expressly excluded from the consent, authorization, or other express legal permission obtained from an individual; and

(ii) The covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.

(3) In the case of a consent, authorization, or other express legal permission obtained from an individual that identifies a specific research project that includes treatment of individuals:

(i) If the consent, authorization, or other express legal permission obtained from an individual specifically permits a use or disclosure for purposes of the project, the covered entity may, with respect to protected health information that it created or received either before or after the applicable compliance date of this subpart and to which the consent or authorization applies, make such use or disclosure for purposes of that project, provided that the covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.

(ii) If the consent, authorization, or other express legal permission obtained from an individual is a general consent to participate in the project, and a covered entity is conducting or participating in the research, such covered entity may, with respect to protected health information that it created or received as part of the project before or after the applicable compliance date of this subpart, make a use or disclosure for purposes of that project, provided that the covered entity complies with all limitations placed by the consent, authorization, or other express legal permission obtained from an individual.

(4) If, after the applicable compliance date of this subpart, a covered entity agrees to a restriction requested by an individual under § 164.522(a), a subsequent use or disclosure of ***82829** protected health information that is subject to the restriction based on a consent, authorization, or other express legal permission obtained from an individual as given effect by paragraph (b) of this section, must comply with such restriction.
45 CFR § 164.534

§ 164.534 Compliance dates for initial implementation of the privacy standards.
(a) Health care providers. A covered health care provider must comply with the applicable requirements of this subpart no later than February 26, 2003.

(b) Health plans. A health plan must comply with the applicable requirements of this subpart no later than the following date, as applicable:

(1) Health plans other than small health plans—February 26, 2003.

(2) Small health plans—February 26, 2004.

(c) Health care clearinghouses. A health care clearinghouse must comply with the applicable requirements of this subpart no later than February 26, 2003.

[FR Doc. 00-32678 Filed 12-20-00; 11:21 am]

BILLING CODE 4150-04-P

Footnotes

1 The Principles are: (1) Notice; (2) Choice (i.e., consent); (3) Onward Transfer (i.e., subsequent disclosures); (4) Security; (5) Data Integrity; (6) Access; and (7) Enforcement. Department of Commerce, Safe Harbor Principles, July 21, 2000 ("Principles"). They do not apply to manually processed data.

2 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 298-299.

FN3 Health Privacy Working Group, "Best Principles for Health Privacy," Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, July 1999.

4 National Committee on Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations, "Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment," 1998, p. 25.

FN5 ASTM, "Standard Guide for Confidentiality, Privacy, Access and Data Security, Principles for Health Information Including Computer-Based Patient Records," E 1869-97, § 11.1.1.

6 Definition of Disease Management, October 1999 (from web site of Disease Management Association of America (www.dmaa.org/definition.html) accessed May 21, 2000. Other references used for our analysis include: Mary C. Gurnee, et al, Constructing Disease Management Programs, Managed Care, June 1997, accessed at http://managedcaremag.com, 5/19/2000; Peter Wehrwein, Disease Management Gains a Degree of Respectability, Managed Care, August 1997, accessed at www.managedcaremag.com, 5/18/00; John M. Harris, Jr., disease management: New Wine in Old Bottles, 124 Annals of Internal Medicine 838 (1996); Robert S. Epstein and Louis M. Sherwood, From Outcomes research to disease management: A Guide for the Perplexed, 124 Annals of Internal Medicine 832 (1996); Anne Mason et al, disease management, the Pharmaceutical Industry and the NHS, Office of Health Economics (United Kingdom), accessed at www.ohe.org, 5/19/2000; Thomas Bodenheimer, Disease Management—Promises and Pitfalls, 340 New Eng. J. Med, April 15, 1999, accessed at www.nejm.org, 4/20/99; Bernard Lo and Ann Alpers, Uses and Abuses of Prescription Drug information in pharmacy benefits Management Programs, 283 JAMA 801 (2000); Robert F. DeBusk, Correspondence, Disease Management, and Regina E. Herzlinger, Correspondence, Disease Management, 341 New Eng. J. Med, Sept 2, 1999, accessed 9/2/99; Letter, John A. Gans, American Pharmaceutical Association, to Health Care Financing Administration, Reference HCFA-3002-P, April 12, 1999, accessed at www.aphanet.org, 1/18/2000; Ronald M. Davis, et al, Editorial, Advances in Managing Chronic Disease, 320 BMJ 525 (2000), accessed at www.bmj.com, 2/25/00; Thomas Bodenheimer, Education and Debate, disease management in the American Market, 320 BMJ 563 (2000), accessed at www.bmj.com, 2/25/2000; David J. Hunter, disease management: has it a future?, 320 BMJ 530 (2000), accessed www.bmj.com 2/25/2000; Trisha Greenhalgh, Commercial partnerships in chronic disease management: proceeding with caution, 320 BMJ 566 (2000); Edmund X. DeJesus, disease management in a Warehouse, Healthcare Informatics, September 1999, accessed at www.healthcare-informatics.com, 5/19/00; Regulation, 42 CFR 422.112, Medicare+Choice Program, subpart C, Benefits and Beneficiary Protections, sec. 422.112, Access to Services; and Arnold Chen, Best Practices in Coordinated Care, Submitted by Mathematica Policy Research, Inc., to Health Care Financing Administration, March 22, 2000.

7 Confidentiality in Adolescent Health Care, a joint policy statement of the American Academy of Pediatrics; the American Academy of Family Physicians; the American College of Obstetricians and Gynecologists; NAACOG—The Organization for Obstetric, Gynecologic, and Neonatal Nurses; and the National Medical Association.

8 J. Merz, P. Sankar, S.S. Yoo, "Hospital Consent for Disclosure of Medical Records," Journal of Law, Medicine & Ethics, 26 (1998): 241-248.

9 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 306.

FN10 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, pp. 215-217.

FN11 Health Privacy Working Group, "Best Principles for Health Privacy," Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, July 1999, p. 19.

FN12 AMA Council on Ethical and Judicial Affairs, "Opinion E-5.05: Confidentiality," Issued December 1983, Updated June 1994.

13 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 196-197.

FN14 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 315.

FN15 ASTM, "Standard Guide for Confidentiality, Privacy, Access and Data Security, Principles for Health Information Including Computer-Based Patient Records," E 1869-97, § 12.1.4.

16 Confidentiality and Data Access Committee, Federal Committee on Statistical Methodology, Office of Management and Budget.

17 Sweeney, L. Guaranteeing Anonymity when Sharing Medical Data, the Datafly System. Masys, D., Ed. Proceedings, American Medical Informatics Association, Nashville, TN: Hanley & Belfus, Inc., 1997:51-55.

18 The U.S. Census Bureau's Recommendations Concerning the Census 2000 Public Use Microdata Sample (PUMS) Files [http://www.ipums.org/ centscensus2000/2000pums_bureau.pdf], Population Division, U.S. Census Bureau, November 3, 2000.

19 Figures derived from US Census data on 1990 Decennial Census of Population and Housing, Summary Tape File 3B (STF3B). These data are available to the public (for a fee) at http:// www.census.gov/mp/www/rom/msrom6af.html.

20 Statistical Policy Working Paper 22—Report on Statistical Disclosure Limitation Methodology (http://www.fcsm.gov/working-papers/wp22.html) (prepared by the Subcommittee on Disclosure Limitation Methodology, Federal Committee on Statistical Methodology, Office of Management and Budget).

FN21 The Geographic Component of Disclosure Risk for Microdata. Brian Greenberg and Laura Voshell. Bureau of the Census Statistical Research Division Report: Census/SRD/RR-90-13, October, 1990.

22 A Simulation Study of the Identifiability of Survey Respondents when their Community of Residence is Known. John Horm, Natonal Center for Health Statistics, 2000.

23 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 313.

FN24 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 192.

FN25 Health Privacy Working Group, "Best Principles for Health Privacy," Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, July 1999, p.19.

26 National Committee on Quality Assurance, "Surveyor Guidelines for the Accreditation of MCOs," effective July 1, 2000—June 30, 2001, p. 324.

FN27 ASTM, "Standard Guide for Confidentiality, Privacy, Access and Data Security, Principles for Health Information Including Computer-Based Patient Records," E 1869-97, § 9.2.

28 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, p. 300-303.

FN29 Health Privacy Working Group, "Best Principles for Health Privacy," Health Privacy Project, Institute for Health Care Research and Policy, Georgetown University, July 1999.

30 National Committee on Quality Assurance and the Joint Commission on Accreditation of Healthcare Organizations, "Protecting Personal Health Information: A Framework for Meeting the Challenges in a Managed Care Environment,"1998, p. 25.

FN31 ASTM, "Standard Guide for Confidentiality, Privacy, Access and Data Security, Principles for Health Information Including Computer-Based Patient Records," E 1869-97, § 11.1.1.

32 Privacy Protection Study Commission, "Personal Privacy in an Information Society," July 1977, pp. 306-307.

33 Janlori Goldman, Institute for Health Care Research and Policy, Georgetown University: @http://www.healthprivacy.org/resources>.

34 The proposed privacy rule provided an estimate for a five-year period. However, the Transactions Rule provided a cost estimate for a ten year period. The decision was made to provide the final privacy estimates in a ten year period so that it would be possible to compare the costs and benefits of the two regulations.

FN35 This based on a seven percent real discount rate, explained in OMB Circular A-94, and a projected 4.2 percent inflation rate projected over the ten-year period covered by this analysis.

FN36 The regulatory impact analysis in the Transactions Rule showed a net savings of $29.9 billion (net present value of $19.1 billion in 2002 dollars). The cost estimates included all electronic systems changes that would be necessitated by the HIPAA administrative standards (e.g., security, safeguards, and electronic signatures; eligibility for a health plan; and remittance advice and payment claim status), except privacy. At the time the Transactions Rule was developed, the industry provided estimates for the systems changes in the aggregate. The industry argued that affected parties would seek to make all electronic changes in one effort because that approach would be the most cost-efficient. The Department agreed, and therefore, it "bundled" all the system change cost in the Transactions Rule estimate. Privacy was not included because at the time the Department had not made a decision to develop a privacy rule. As the Department develops other HIPAA administrative simplification standards, there may be additional costs and savings due to the non-electronic components of those regulations, and they will be identified in regulatory impact analyses that accompany those regulations. The Department anticipates that such costs and savings will be relatively small compared to the privacy and Transactions rules. The Department anticipates that the net economic impact of the rules will be a net savings to the health care system.

37 Health spending projections from National Health Expenditure Projections 1998-2008 (January 2000), Health Care Financing Administration, Office of the Actuary, @http://hcfa.hhs.gov/stats/nhe-proj/>.

*Note: Numbers may not add due to rounding.

38 American Association of Health Plans, Code of Conduct; http:www.aahp.org.; American Dental Association, Principles of Ethics and Professional Conduct; http://www.ada.org.; American Hospital Association, "Disclosure of Medical Record Information," Management Advisory: Information Management; 1990, AHA: Chicago, IL.; American Medical Association, AMA Policy Finder—Current Opinions Council on Ethical and Judicial Affairs; several documents available through the Policy Finder at http:www.ama-assn.org.; American Psychiatric Association, "APA Outlines Standards Needed to Protect Patient's Medical Record"; Release No. 99-32, May 27, 1999; http:www.psych.org.

39 Ibid, Goldman, p. 6.

40 "Practice Briefs," Journal of AHIMA; Harry Rhodes, Joan C. Larson, Association of Health Information Outsourcing Service; January 1999.

41 Ibid, Goldman, p. 20.

42 Ibid, Goldman, p. 21.

43 "Medical records and privacy: Empirical effects of legislation; A memorial to Alice Hersh"; McCarthy, Douglas B; Shatin, Deborah; et al. Health Service Research: April 1, 1999; No. 1, Vol. 34; p. 417. The article details the effects of the Minnesota law conditioning disclosure of protected health information on patient authorization.

44 Source Book of Health Insurance Data: 1997-1998, Health Insurance Association of America, 1998. p. 33.

45 "Health plans," for purposes of the regulatory impact and regulatory flexibility analyses, include licensed insurance carriers who sell health products; third party administrators that will have to comply with the regulation for the benefit of the plan sponsor; and self-insured health plans that are at least partially administered by the plan sponsor.

46 Health Care Finance Administration, Office of the Actuary, 2000. Estimates for the national health care expenditure accounts are only available through 2008; hence, we are only able to make the comparison through that year.

47 These estimates were, in part, derived from a report prepared for the Department by the Gartner Group, consultants in health care information technology: "Gartner DHHS Privacy Regulation Study," by Jim Klein and Wes Rishel, submitted to the Office of the Assistant Secretary for Policy and Evaluation on October 20, 2000.

48 "Top Compensation in the Healthcare Industry, 1997", Coopers & Lybrand, New York, NY., }@http://www.pohly.com/salary/2.shtml>.

FN49 "A Unifif Survey of Compensation in Financial Services: 2000," July 2000, Unifi Network Survey unit, PriceWaterhouseCoopers LLP and Global HR Solutions LLC, Westport, Ct., @http:// public.wsj.com/careers/resources/documents/20000912-insuranceexecs-tab.htm>.

50 The cost for policies for minimum necessary, because they will be distinct and extensive, are presented separately, above.

51 "The Altman Weil 1999 Survey of Law Firm Economics," @http:// www.altmanweil.com/publications/survey/sife99/standard.htm>.

52 Equifax-Harris Consumer Privacy Survey, 1994.

53 Consumer Privacy Survey, Harris-Equifax, 1994, p vi.

FN54 Promoting Health: Protecting Privacy, California Health Care Foundation and Consumers Union, January 1999, p 12.

55 Health Information Survey, Harris-Equifax, 1993, pp 49-50.

56 American Cancer Society. http://4a2z.com/cgi/rfr.cgi?4CANCER-2-http:// www.cancer.org/frames.html

FN57 American Cancer Society. http:// www3.cancer.org/cancerinfo/sitecenter.asp?ctid= 8&scp= 0&scs = 0&scss= 0&scdoc = 40000.

FN58 Polednak, AP. "Estimating Prevalence of Cancer in the United States," Cancer 1997; 8-:136-41

FN59 Martin Brown, "The Burden of Illness of Cancer: Economic Cost and Quality of Life." Annual Review of Public Health, 2001:22:91-113.

FN60 Disease-Specific Estimates of Direct and Indirect Costs of Illness and NIH Support: Fiscal Year 2000 Update. Department of Health and Human Services, Naitonal Institutes of Health, Office of the Director, February 2000.

FN61 DALY scores for 10 cancer sites are presented in Brown, "The Burden of Illness of Cancer: Economic Cost and Quality of Life," figure 1.

62 Breast Cancer Information Service. http:// trfn.clpgh.org/bcis/FAQ/facts2.html

63 Jack S. Mandel, et al., "Reducing Mortality from Colorectal Cancer by Screening for Fecal Occult Blood," The New England Journal of Medicine, May 13, 1993, Vol, 328, No. 19.

64 Promoting Health: Protecting Privacy, California Health Care Foundation and Consumers Union, January 1999, p 13

FN65 For example, Roger Detels, M.D., et al., in "Effectiveness of Potent Anti-retroviral Therapy. * * *" JAMA, 1998; 280:1497-1503 note the impact of therapy on HIV persons with respect to lengthening the time to development of AIDS, not just delaying death in persons who already have AIDS.

FN66 John Hornberger et al., "Early treatment with highly active anti-retroviral therapy (HAART) is cost-effective compared to delayed treatment," 12th World AIDS conference, 1998.

67 Sexually Transmitted Diseases in America, Kaiser Family Foundation, 1998, p. 12.

FN68 Standard Medical information; see http://www.mayohealth.org for examples.

69 Substance Abuse and Mental Health Services Administration. http:// www.samhsa.gov/oas/srcbk/costs-02htm. Source of data: DP Rice, Costs of Mental Illness (unpublished data).

70 Department of Health and Human Services, Mental Health: A Report of the Surgeon General. Rockville, MD: 1999, page 408.

FN71 According to the Surgeon General's Report, 28 percent of the adult population have either a mental or addictive disorder, whether or not they receive services: 19 percent have a mental disorder alone, 6 percent have a substance abuse disorder alone, and 3 percent have both. Subtracting the 3 percent who have both, about three-quarters of the population with either a mental or addictive disorder have a mental disorder and one-quarter have a substance abuse disorder. We assume that this ratio (three-quarter to one-quarter) is the same for the adult population with either a mental or addictive disorder who do not receive services. [Thus, we assume that 15 percent of the population have an untreated mental disorder (three-quarters of 20 percent) and 5 percent have an untreated addictive disorder (one-quarter of 20 percent).

FN72 According to the Population Estimates Program, Population Division, U.S. Census Bureau, the U.S. population age 20 and older is 197.1 million on Sept. 1, 2000. This estimate of the adult population is used throughout this section.

73 The number of adults with mental illness is calculated by multiplying the U.S. Census Bureau estimate of the U.S. adult population—197.1 million—by the percent of the adult population with mental illness—22 percent, according to the Surgeon General's Report on Mental Health, which says that 19 percent of the population have a mental disorder alone and three percent have a mental and substance abuse disorder.

74 "Entities" and "establishments" are synonymous in this analysis.

75 "Entities" and "establishments" are used synonymously in this RFA.

FN76 "Small governments" were not included in this analysis directly; rather we have included the kinds of institutions within those governments that are likely to incur costs, such as government hospitals and clinics.

77 Entities are the physical location where an enterprise conducts business. An enterprise may conduct business in more than one establishment.

78 Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997.

FN79 Op.cit, 1997.

80 Office of Advocacy, U.S. Small Business Administration, from data provided by the Bureau of the Census, Statistics of U.S. Businesses, 1997.

FN81 Op.cit., 1997.

82 Health Care Financing Administration, OSCAR.

End of Document

89 FR 32976-01, 2024 WL 1801644(F.R.)

RULES and REGULATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Parts 160 and 164

RIN 0945-AA20

HIPAA Privacy Rule To Support Reproductive Health Care Privacy

Friday, April 26, 2024

AGENCY: Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services.

***32976** ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS or "Department") is issuing this final rule to modify the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). The Department is issuing this final rule after careful consideration of all public comments received in response to the notice of proposed rulemaking (NPRM) for the HIPAA Privacy Rule to Support Reproductive Health Care Privacy ("2023 Privacy Rule NPRM") and public comments received on proposals to revise provisions of the HIPAA Privacy Rule in the NPRM for the Confidentiality of Substance Use Disorder (SUD) Patient Records ("2022 Part 2 NPRM").

DATES:

Effective date: This final rule is effective on June 25, 2024.

Compliance date: Persons subject to this regulation must comply with the applicable requirements of this final rule by December 23, 2024, except for the applicable requirements of 45 CFR 164.520 in this final rule. Persons subject to this regulation must comply with the applicable requirements of 45 CFR 164.520 in this final rule by February 16, 2026.

FOR FURTHER INFORMATION CONTACT: Marissa Gordon-Nguyen at (202) 240-3110 or (800) 537-7697 (TDD), or by email at OCRPrivacy@hhs.gov.

SUPPLEMENTARY INFORMATION:

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Table of Acronyms

Term	Meaning
Part V	
AMA	American Medical Association.
API	Application Programming Interface.
CARES Act	Coronavirus Aid, Relief, and Economic Security Act.
CDC	Centers for Disease Control and Prevention.
CLIA	Clinical Laboratory Improvement Amendments of 1988.
CMS	Centers for Medicare & Medicaid Services.
DOD	Department of Defense.
Department or HHS	Department of Health and Human Services.
EHR	Electronic Health Record.
E.O.	Executive Order.
FDA	Food and Drug Administration.
FHIR®	Fast Healthcare Interoperability Resources®.
FTC	Federal Trade Commission.
GINA	Genetic Information Nondiscrimination Act of 2008.
Health IT	Health Information Technology.
HIE	Health Information Exchange.
HIPAA	Health Insurance Portability and Accountability Act of 1996.
HITECH Act	Health Information Technology for Economic and Clinical Health Act of 2009.
ICR	Information Collection Request.

IIHI	Individually Identifiable Health Information.
NCVHS	National Committee on Vital and Health Statistics.
NICS	National Instant Criminal Background Check System.
NPP	Notice of Privacy Practices.
NPRM	Notice of Proposed Rulemaking.
OCR	Office for Civil Rights.
OHCA	Organized Health Care Arrangement.
OMB	Office of Management and Budget.
ONC	Office of the National Coordinator for Health Information Technology.
PHI	Protected Health Information.
PRA	Paperwork Reduction Act of 1995.
RFA	Regulatory Flexibility Act.
RIA	Regulatory Impact Analysis.
SBA	Small Business Administration.
SSA	Social Security Act of 1935.
TPO	Treatment, Payment, or Health Care Operations.
UMRA	Unfunded Mandates Reform Act of 1995.

***32977**

I. Executive Summary

A. Overview

In this final rule, the Department of Health and Human Services (HHS or "Department") modifies certain provisions of the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule"), issued pursuant to section 264 of the Administrative Simplification provisions of title II, subtitle F, of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[FN1] The Privacy Rule [FN2] is one of several rules, collectively known as the HIPAA Rules,[FN3] that protect the privacy and security of individuals' protected health information [FN4] (PHI), which is individually identifiable health information [FN5] (IIHI) transmitted by or maintained in electronic media or any other form or medium, with certain exceptions.[FN6]

The Privacy Rule requires the disclosure of PHI only in the following circumstances: when required by the Secretary to investigate a regulated entity's compliance with the Privacy Rule and to the individual pursuant to the individual's right of access and the individual's right to an accounting of disclosures.[FN7] Any other uses or disclosures described in the Privacy Rule are either permitted or prohibited, as specified in the Privacy Rule. For example, the Privacy Rule permits, but does not require, a regulated entity to disclose PHI to conduct quality improvement activities when applicable conditions are met, and it prohibits a regulated entity from selling PHI except pursuant to and in compliance with 45 CFR 164.508(a)(4).[FN8]

In accordance with its statutory mandate, the Department promulgated the Privacy Rule and continues to administer and enforce it to ensure that individuals are not afraid to seek health care from, or share important information with, their health care providers because of a concern that their sensitive information will be disclosed outside of their relationship with their health care provider. Protecting privacy promotes trust between health care providers and individuals, advancing access to and improving the quality of health care. To achieve this goal, the Department generally has applied the same privacy standards to nearly all PHI, regardless of the type of health care at issue. Notably, special protections were given to psychotherapy notes, owing in part to the particularly ***32978** sensitive information those notes contain.[FN9]

Under its statutory authority to administer and enforce the HIPAA Rules, the Department may modify the HIPAA Rules as needed.[FN10] The Supreme Court decision in Dobbs v. Jackson Women's Health Organization [FN11] (Dobbs) overturned precedent that protected a constitutional right to abortion and altered the legal and health care landscape. This decision has far-reaching implications for reproductive health care beyond its effects on access to abortion.[FN12] This changing legal landscape increases the likelihood that an individual's PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system.[FN13] The threat that PHI will be disclosed and used to conduct such an investigation against, or to impose liability upon, an individual or another person is likely to chill an individual's willingness to seek lawful health care treatment or to provide full information to their health care providers when obtaining that treatment, and on the willingness of health care providers to provide such care.[FN14] These developments in the legal environment increase the potential that use and disclosure of PHI about an individual's reproductive health will undermine access to and the quality of health care generally.

In order to continue to protect privacy in a manner that promotes trust between individuals and health care providers and advances access to, and improves the quality of, health care, we have determined that the Privacy Rule must be modified to limit the circumstances in which provisions of the Privacy Rule permit the use or disclosure of an individual's PHI about reproductive health care for certain non-health care purposes, where such use or disclosure could be detrimental to privacy of the individual or another person or the individual's trust in their health care providers. This determination was informed by our expertise in administering the Privacy Rule, questions we have received from members of the public and Congress, comments we received on the 2023 HIPAA Privacy Rule to Support Reproductive Health Care Privacy notice of proposed rulemaking (NPRM) ("2023 Privacy Rule NPRM"),[FN15] and our analysis of the state of privacy for IIHI.

This final rule ("2024 Privacy Rule") amends provisions of the Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals' ability to obtain lawful reproductive health care. This final rule balances the interests of society in obtaining PHI for non-health care purposes with the interests of the individual, the Federal Government, and society in protecting individual privacy, thereby improving the effectiveness of the health care system by ensuring that persons are not deterred from seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided.

The Department carefully analyzed state prohibitions and restrictions on an individual's ability to obtain high-quality health care and their effects on health information privacy and the relationships between individuals and their health care providers after Dobbs; assessed trends in state legislative activity with respect to the privacy of PHI; and conducted a thorough review of the text, history, and purposes of HIPAA and the Privacy Rule. The Department also engaged in extensive discussions with HHS agencies and other Federal departments, including the Department of Justice; consulted with the National Committee on Vital and Health Statistics (NCVHS) and the Attorney General as required by section 264(d) of HIPAA, and with Indian Tribes as required by Executive Order 13175; [FN16] held listening sessions with and reviewed correspondence from stakeholders, including covered entities, states, individuals, and patient advocates; and reviewed correspondence to HHS from Members of Congress.[FN17] The modifications made to the Privacy Rule by this final rule are the result of this work.

B. Effective and Compliance Dates

1. 2023 Privacy Rule NPRM

In the 2023 Privacy Rule NPRM, the Department proposed an effective date for a final rule that would occur 60 days after publication, and a compliance date that would occur 180 days after the effective date.[FN18] Taken together, the two dates would give entities 240 days after publication to implement compliance measures. In the preamble to the proposed rule, the Department stated that it did not believe that the proposed rule would pose unique implementation challenges that would justify an extended compliance period (i.e., a period longer than the standard 180 days provided in 45 CFR 160.105).[FN19] The Department also asserted that adherence to the standard compliance period is necessary to timely address the circumstances described in the 2023 Privacy Rule NPRM.

2. Overview of Comments

A commenter urged the Department to move quickly to issue the final rule and to provide a 180-day compliance period ***32979** as proposed. Some commenters requested that the Department provide additional time for regulated entities to comply with the proposed modifications to the Privacy Rule. Several commenters requested that the Department coordinate compliance deadlines across its rulemakings, while a few commenters specifically encouraged the Department to provide additional time for compliance with the modifications to the Notice of Privacy Practices (NPP) requirements proposed in the 2023 Privacy Rule NPRM.

3. Final Rule

This final rule is effective on June 25, 2024. Covered entities and business associates of all sizes will have 180 days beyond the effective date of the final rule to comply with the final rule's provisions, with the exception of the NPP provisions, which we address separately below. We understand that some covered entities and business associates remain concerned that a 180-day period may not provide sufficient time to come into compliance with the modified requirements. However, we believe that providing a 180-day compliance period best comports with section 1175(b)(2) of the Social Security Act of 1935 (SSA), 42 U.S.C. 1320d-4, and our implementing provision at 45 CFR 160.104(c)(1), which require the Secretary to provide at least a 180-day period for covered entities to comply with modifications to standards and implementation specifications in the HIPAA Rules, and also that providing a 180-day compliance period best protects the privacy and security of individuals' PHI in a timely manner that reflects the urgency of addressing the changes in the legal landscape and their effects on individuals, regulated entities, and other persons, while balancing the burden imposed upon regulated entities of implementing this final rule.

Section 160.104(a) permits the Department to adopt a modification to a standard or implementation specification adopted under the Privacy Rule no more frequently than once every 12 months.[FN20] As discussed above, we are required to provide a minimum of a 180-day compliance period when adopting a modification, but we are permitted to provide a longer compliance period based on the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.[FN21] The Department makes every effort to consider the burden and cost of implementation for regulated entities when determining an appropriate compliance date.

While we recognize that regulated entities will need to revise and implement changes to their policies and procedures in response to the modifications in this final rule, we do not believe that these changes are so significant as to require more than a 180-day compliance period. This final rule narrowly tailors the application of its changes to certain limited circumstances involving lawful reproductive health care and clarifies that regulated entities are not expected to know or be aware of laws other than those with which they are required to comply. While it adds a condition to certain requests for uses and disclosures, the affected requests already require careful review by regulated entities for compliance with previously imposed conditions. Thus, we do not believe it will be difficult for regulated entities to adjust their policies and procedures to accommodate this new requirement. The other modifications finalized in this rule are in service of implementing the two changes above and impose minimal burden on regulated entities. Additionally, the Department believes, based on its evaluation of the evolving privacy landscape, that the changes made by this final rule are of particular urgency. Accordingly, we believe that a 180-day compliance period, combined

with a 60-day effective date, is sufficient for regulated entities to make the changes required by most of the modifications in this final rule, with the exception of the NPP provisions.

We separately consider the question of the compliance date for the modifications to the NPP provisions. In the 2022 Confidentiality of Substance Use Disorder (SUD) Patient Records NPRM ("2022 Part 2 NPRM"),[FN22] the Department proposed, among other things, to revise 45 CFR 164.520 as required by section 3221 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[FN23] The Department proposed to provide the same compliance date for both the proposed modifications to 45 CFR 164.520 and the more extensive modifications to 42 CFR part 2 ("Part 2").[FN24] The 2024 Confidentiality of Substance Use Disorder (SUD) Patient Records Final Rule ("2024 Part 2 Rule") explicitly noted that the Department was not finalizing the proposed modifications to the NPP provisions at that time, but that we planned to do so in a future HIPAA final rule.[FN25] The Department also acknowledged that some covered entities might have NPPs that would not reflect updated changes to policies and procedures addressing how Part 2 records are used and disclosed. Rather than requiring covered entities to revise their NPPs twice in a short period of time, the Department announced in the 2024 Part 2 Rule that it would exercise enforcement discretion related to the requirement that covered entities update their NPPs whenever material changes are made to privacy practices until the compliance date established by a future HIPAA final rule.[FN26] The Department is finalizing the modifications to the NPP required by section 3221 of the CARES Act in this rule and aligning the effective and compliance dates for all of the modified NPP requirements with those of the 2024 Part 2 Rule.

The compliance date of the 2024 Part 2 Rule is February 16, 2026, substantially later than the compliance date for most of this final rule, because of the significant changes required for compliance with the 2024 Part 2 Rule. Accordingly, in compliance with 45 CFR 160.104 and consistent with the NPP proposals included in the 2022 Part 2 NPRM and public comment, we are aligning the compliance date for the NPP changes required by this final rule with the compliance date for the 2024 Part 2 Rule so that covered entities regulated under both rules can implement all changes to their NPPs at the same time. Covered entities are expected to be in compliance with the modifications to 45 CFR 164.520 on February 16, 2026.

4. Response to Public Comments

Comment: One commenter expressed support for the proposal in the 2023 Privacy Rule NPRM to establish a 180-day compliance date and urged the Department to issue a final rule quickly. Some commenters sought an extension of the compliance date for twelve to eighteen months, explaining that extensive policy and legal work, process and software changes, documentation and training would be required to implement the 2023 Privacy Rule NPRM.

One commenter suggested phasing in the attestation requirement so that "downstream" regulated entities, such as business associates and managed care organizations, would have a later compliance date than health care providers.

***32980** Response: We appreciate the commenters' suggestions, but as discussed above, based on our assessment, we do not believe the modifications required by this final rule will require longer to implement.

Comment: Some commenters requested that the Department coordinate compliance deadlines of final rules that revise the Privacy Rule or publish one final rule addressing the proposals in the NPRMs to enable regulated entities to leverage the resources required to implement the changes to achieve compliance with all of the new requirements at one time.

One commenter explained that each NPRM would involve operational changes requiring significant resources and effort and expressed their belief that a single comprehensive final rule would allow regulated entities to make all of the required changes, including revisions to policies and procedures, development of new or revised workflows, electronic health record (EHR) updates, and technology enhancements.

Response: We appreciate the commenters' suggestion, but we do not believe that it is necessary to fully align the compliance dates for the 2024 Part 2 Rule and the 2024 Privacy Rule. By imposing separate compliance deadlines, we are able to act more quickly to protect the privacy of PHI.

However, consistent with 45 CFR 160.104 and as requested by public comment, we are applying the same compliance date for covered entities to revise their NPPs to address modifications made to 45 CFR 164.520 in response to and consistent with the CARES Act and to support reproductive health care privacy. The compliance date for the NPP provisions is February 16, 2026. [FN27] Part 2 programs, including those that are covered entities, can choose to implement the changes to their NPPs that are required by the 2024 Part 2 Rule prior to the compliance date, but there is no requirement that they do so.

II. Statutory and Regulatory Background

A. Statutory Authority and History

1. Health Insurance Portability and Accountability Act of 1996 (HIPAA)

In 1996, Congress enacted HIPAA [FN28] to reform the health care delivery system to "improve portability and continuity of health insurance coverage in the group and individual markets." [FN29] To enable health care delivery system reform, Congress included in HIPAA requirements for standards to support the electronic exchange of health information. According to section 261, "[i]t is the purpose of this subtitle to improve [. . .] the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information [. . .]." [FN30] Congress applied the Administrative Simplification provisions directly to three types of entities known as "covered entities"—health plans, health care clearinghouses, and health care providers who transmit information electronically in connection with a transaction for which HHS has adopted a standard.[FN31]

Section 262(a) of HIPAA required the Secretary to adopt uniform standards "to enable health information to be exchanged electronically." [FN32] Congress directed the Secretary to adopt standards for unique identifiers to identify individuals, employers, health plans, and health care providers across the nation [FN33] and standards for, among other things, transactions and data elements relating to health information,[FN34] the security of that information,[FN35] and verification of electronic signatures.[FN36]

Congress recognized that the standardization of certain electronic health care transactions required by HIPAA posed risks to the privacy of confidential health information and viewed individual privacy, confidentiality, and data security as critical for orderly administrative simplification.[FN37] Thus, as explained in the preamble to the 2023 Privacy Rule NPRM,[FN38] Congress provided the Department with the authority to regulate the privacy of IIHI. According to one Member of Congress, privacy standards would create an additional layer of protection beyond the oath pledged by health care providers to keep information secure and, as described by another Member, would further protect information from being used in a "malicious or discriminatory manner." [FN39] Congress intended for the law to enhance individuals' trust in health care providers, which required that the law provide additional protection for the confidentiality of IIHI. As described by a Member of Congress: "The bill would also establish strict security standards for health information because Americans clearly want to make sure that their health care records can only be used by the medical professionals that treat them. Often, we assume that because doctors take an oath of confidentiality that in fact all who touch their records operate by the same standards. Clearly, they do not." [FN40] Moreover, Congress considered that health care reform required an approach that would not compromise privacy as health information became more accessible.[FN41]

Accordingly, section 264(a) directed the Secretary to submit to Congress detailed recommendations for Federal "standards with respect to the privacy of [IIHI]" nationwide within one year of HIPAA's enactment.[FN42] The statute made clear that the Secretary had the authority to promulgate regulations if Congress did not enact legislation covering these matters within three years.[FN43] Congress directed the Secretary to ensure that the regulations promulgated "address at least" the following three subjects: (1) the rights that an individual who is a subject of IIHI should have; (2) the procedures that should be established for the exercise of such rights; and (3) the uses and disclosures of such information that should be authorized or required.[FN44]

Additionally, Congress provided a clear statement that HIPAA's provisions would "supersede any contrary ***32981** provision of State law," with certain limited exceptions.[FN45] One exception to this general preemption authority is for "state privacy laws that are contrary to and more stringent than the corresponding federal standard, requirement, or implementation specification." [FN46] Thus, Congress intended for the Department to create privacy standards to safeguard health information while respecting the ability of states to provide individuals with additional health information privacy.

Congress required the Secretary to consult with the NCVHS,[FN47] thereby ensuring that the Secretary's decisions reflected public and expert involvement and advice in carrying out the requirements of section 264.[FN48] NCVHS sent its initial recommendations to the Secretary in a letter to the Secretary on June 27, 1997. Importantly, NCVHS advised that "strong substantive and procedural protections" should be imposed if health information were to be disclosed to law enforcement, and, where identifiable health information would be made available for non-health purposes, individuals should be afforded assurances that their data would not be used against them.[FN49] Additionally, NCVHS "unanimously" recommended that "[. . .] the Secretary and the Administration assign the highest priority to the development of a strong position on health privacy that provides the highest possible level of protection for the privacy rights of patients." [FN50] NCVHS further noted that failure to do so would "undermine public confidence in the health care system, expose patients to continuing invasions of privacy, subject record keepers to potentially significant legal liability, and interfere with the ability of health care providers and others to operate the health care delivery and payment system in an effective and efficient manner," which would undermine what Congress intended.[FN51]

NCVHS further recommended that "any rules regulating disclosures of identifiable health information be as clear and as narrow as possible. Each group of users must be required to justify their need for health information and must accept reasonable substantive and procedural limitations on access." [FN52] According to NCVHS, this would allow for the disclosures that society deemed necessary and appropriate while providing individuals with clear expectations regarding their health information privacy.

As we noted in the 2023 Privacy Rule NPRM,[FN53] Congress contemplated that the Department's rulemaking authorities under HIPAA would not be static. Congress specifically built in a mechanism to adapt such regulations as technology and health care evolve, directing that the Secretary review and modify the Administrative Simplification standards as determined appropriate, but not more frequently than once every 12 months.[FN54] That statutory directive complements the Secretary's general rulemaking authority to "make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter." [FN55]

2. Health Information Technology for Economic and Clinical Health (HITECH) Act

On February 17, 2009, Congress enacted the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) [FN56] to promote the widespread adoption and standardization of health information technology (health IT). The HITECH Act included additional HIPAA privacy and security requirements for covered entities and business associates and expanded certain rights of individuals with respect to their PHI.

Congress understood the importance of a relationship between a connected health IT landscape, "a necessary and vital component of health care reform," [FN57] and privacy and security standards when it enacted the HITECH Act. The Purpose statement of an accompanying House of Representatives report [FN58] on the Energy and Commerce Recovery and Reinvestment Act [FN59] recognizes that "[i]n addition to costs, concerns about the security and privacy of health information have also been regarded as an obstacle to the adoption of [health IT]." The Senate Report for S. 336 [FN60] similarly acknowledges that "[i]nformation technology systems linked securely and with strong privacy protections can improve the quality and efficiency of health care while producing significant cost savings." [FN61] As the Department explained in the 2013 regulation referred to as the "Omnibus Rule" [FN62] and discussed in greater detail below, the HITECH Act's additional HIPAA privacy and security requirements [FN63] supported Congress' goal of promoting widespread adoption and interoperability of health IT by "strengthen[ing] the privacy and security protections for health information established by HIPAA." [FN64]

In passing the HITECH Act, Congress instructed the Department that any new health IT standards adopted under section 3004 of the Public Health Service Act (PHSA) must take into account the privacy and security requirements of the HIPAA Rules.[FN65] Congress also affirmed that the existing HIPAA Rules were to remain in effect to the extent that they are consistent with the HITECH Act and directed the Secretary to revise the HIPAA Rules as necessary for consistency with the ***32982** HITECH Act.[FN66] Congress confirmed that the new law was not intended to have any effect on authorities already granted under HIPAA to the Department, including section 264 of that statute and the regulations issued under that provision.[FN67] Congress thus affirmed the Secretary's ongoing rulemaking authority to modify the Privacy Rule's standards and implementation specifications as often as every 12 months when appropriate, including to strengthen privacy and security protections for IIHI.

B. Regulatory History

The Secretary has delegated the authority to administer the HIPAA Rules and to make decisions regarding their implementation, interpretation, and enforcement to the HHS Office for Civil Rights (OCR).[FN68] Since the enactment of the HITECH Act, the Department has exercised its authority to modify the Privacy Rule several times—in 2013, 2014, and 2016.[FN69]

1. 2000 Privacy Rule

As directed by HIPAA, the Department provided a series of recommendations to Congress for a potential new law that would address the confidentiality of IIHI.[FN70] Congress did not act within its three-year self-imposed deadline. Accordingly, the Department published a proposed rule on November 3, 1999,[FN71] and issued the first final rule establishing "Standards for Privacy of Individually Identifiable Health Information" ("2000 Privacy Rule") on December 28, 2000.[FN72]

The primary goal of the Privacy Rule was to provide greater protection to individuals' privacy to engender a trusting relationship between individuals and health care providers. As announced, the final rule set standards to protect the privacy of IIHI to "begin to address growing public concerns that advances in electronic technology and evolution in the health care industry are resulting, or may result, in a substantial erosion of the privacy surrounding" health information.[FN73] On the eve of that rule's issuance, the President issued an Executive Order recognizing the importance of protecting individual privacy, explaining that "[p]rotecting the privacy of patients' protected health information promotes trust in the health care system. It improves the quality of health care by fostering an environment in which patients can feel more comfortable in providing health care professionals with accurate and detailed information about their personal health." [FN74]

Since its promulgation, the Privacy Rule has protected PHI by limiting the circumstances under which covered entities and their business associates (collectively, "regulated entities") are permitted or required to use or disclose PHI and by requiring covered entities to have safeguards in place to protect the privacy of PHI. In adopting these regulations, the Department acknowledged the need to balance several competing factors, including existing legal expectations, individuals' privacy expectations, and societal expectations.[FN75] The Department noted in the preamble that the large number of comments from individuals and groups representing individuals demonstrated the deep public concern about the need to protect the privacy of IIHI and constituted evidence of the importance of protecting privacy and the potential adverse consequences to individuals and their health if such protections are not extended.[FN76] Through its policy choices in the 2000 Privacy Rule, the Department struck a balance between competing interests—the necessity of protecting privacy and the public interest in using identifiable health information for vital public and private purposes—in a way that was also workable for the varied stakeholders.[FN77]

In the 2000 Privacy Rule, the Department established "general rules" for uses and disclosures of PHI, codified at 45 CFR 164.502.[FN78] The 2000 Privacy Rule also specified the circumstances in which a covered entity was required to obtain an individual's consent,[FN79] authorization,[FN80] or the opportunity for the individual to agree or object.[FN81] Additionally, it established rules for when a covered entity is permitted to use or disclose PHI without an individual's consent, authorization, or opportunity to agree or object.[FN82] In particular, the Privacy Rule permits certain uses and disclosures of PHI, without the individual's authorization, for identified activities that benefit the community, such as public health activities, judicial and administrative proceedings, law enforcement purposes, and research.[FN83]

The Privacy Rule also established the rights of individuals with respect to their PHI, including the right to receive adequate notice of a covered entity's privacy practices, the right to request restrictions of uses and disclosures, the right to access (i.e., to inspect and obtain a copy of) their PHI, the right to request an amendment of their PHI, and the right to receive an accounting of disclosures.[FN84]

In the 2000 Privacy Rule, the Secretary exercised her statutory authority to adopt 45 CFR 160.104(a), which reserves the Secretary's ability to modify any standard or implementation specification adopted under the Administrative Simplification provisions.[FN85] The Secretary first invoked this modification authority to amend the Privacy Rule in 2002 [FN86] and made additional modifications in 2013,[FN87] and 2016,[FN88] as described below.

2. 2002 Privacy Rule

After publication of the 2000 Privacy Rule, the Department received many inquiries and unsolicited comments about the Privacy Rule's effects and operation. As a result, the Department opened the 2000 Privacy Rule for further comment in February 2001, less than one month before the effective date and 25 months before the compliance date for most covered entities, and issued clarifying guidance on its implementation.[FN89] NCVHS' Subcommittee on Privacy, Confidentiality and Security held public ***32983** hearings about the 2000 Privacy Rule. From those hearings, the Department obtained additional information about concerns related to key provisions and their potential unintended consequences for health care quality and access.[FN90] On March 27, 2002, the Department proposed modifications to the 2000 Privacy Rule to clarify the requirements and correct potential problems that could threaten access to, or quality of, health care.[FN91]

In response to comments on the proposed rule, the Department finalized modifications to the Privacy Rule on August 14, 2002 (“2002 Privacy Rule”).[FN92] This final rule clarified HIPAA's requirements while maintaining strong protections for the privacy of IIHI.[FN93] These modifications addressed certain workability issues, including but not limited to clarifying distinctions between health care operations and marketing; modifying the minimum necessary standard to exclude disclosures authorized by individuals and clarify its operation; eliminating the consent requirement for uses and disclosures of PHI for treatment, payment, or health care operations (TPO), and to otherwise clarify the role of consent in the Privacy Rule; and making other modifications and conforming amendments consistent with the proposed rule. The Department also included modifications to the provisions permitting the use or disclosure of PHI for public health activities and for research activities without consent, authorization, or an opportunity to agree or object.

3. 2013 Omnibus Rule

Following the enactment of the HITECH Act, the Department issued an NPRM, entitled “Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health [HITECH] Act” (“2010 NPRM”),[FN94] which proposed to implement certain HITECH Act requirements. In 2013, the Department issued the final rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health [HITECH] Act and the Genetic Information Nondiscrimination Act, and Other Modifications to the HIPAA Rules (“2013 Omnibus Rule”),[FN95] which implemented many of the new HITECH Act requirements, including strengthening individuals' privacy rights related to their PHI.

The Department also finalized regulatory provisions that were not required by the HITECH Act, but were necessary to address the workability and effectiveness of the Privacy Rule and to increase flexibility for and decrease burden on regulated entities.[FN96] In the 2010 NPRM, the Department noted that it had not amended the Privacy Rule since 2002.[FN97] It further explained that information gleaned from contact with the public since that time, enforcement experience, and technical corrections needed to eliminate ambiguity provided the impetus for the Department's actions to make certain regulatory changes.[FN98]

For example, the Department modified its prior interpretation of the Privacy Rule requirement at 45 CFR 164.508(c)(1)(iv) that a description of a research purpose must be study specific.[FN99] The Department explained that, under its new interpretation,

the research purposes need only be described adequately such that it would be reasonable for an individual to expect that their PHI could be used or disclosed for such future research.[FN100] In the 2013 Omnibus Rule, the Department explained that this change was based on the concerns expressed by covered entities, researchers, and other commenters on the 2010 NPRM that the former requirement did not represent current research practices. The Department provided a similar explanation for its modifications to the Privacy Rule that permit certain disclosures of student immunization records to schools without an authorization.[FN101] Additionally, based on a recommendation made at an NCVHS meeting, the Department requested comment on and finalized proposed revisions to the definition of PHI to exclude information regarding an individual who has been deceased for more than 50 years.[FN102] For the latter, the Department noted that it was balancing the privacy interests of decedents' living relatives and other affected individuals against the legitimate needs of public archivists to obtain records.[FN103]

None of the changes described in the paragraph above were required by the HITECH Act. Rather, the Department determined that it was necessary to promulgate these changes pursuant to its existing general rulemaking authority under HIPAA. NCVHS and the public also recommended other changes between the publication of the 2002 Privacy Rule and the 2013 Omnibus Rule, including the creation of specific categories of PHI, such as “Sexuality and Reproductive Health Information” that would allow for special protections of such PHI.[FN104] The Department declined to propose specific protections for certain categories of PHI at that time because of concerns about the ability of regulated entities to segment PHI and the effects on care coordination. Many of those concerns are still present and so, the Department did not propose and determined not to establish a specific category of particularly sensitive PHI in this rulemaking. Instead, as discussed more fully below, the Department is finalizing a purpose-based prohibition against certain uses and disclosures.

***32984 4. 2024 Privacy Rule**

On April 17, 2023, the Department issued an NPRM [FN105] to modify the Privacy Rule for the purpose of prohibiting uses and disclosures of PHI for criminal, civil, or administrative investigations or proceedings against persons for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided. To properly execute the HIPAA statutory mandate, and in accordance with the regulatory authority granted to it by Congress, the Department continually monitors and evaluates the evolving environment for health information privacy nationally, including the interaction of the Privacy Rule and state statutes and regulations governing the privacy of health information. In keeping with the Department's practice, this final rule accommodates state autonomy to the extent consistent with the need to maintain rules for health information privacy that serve HIPAA's objectives. The regulation thus preempts state law only to the extent necessary to achieve Congress' directive to establish a standard for the privacy of IIHI for the purpose of improving the effectiveness of the health care system. As discussed below, achieving that objective requires individuals to trust that their health care providers will maintain privacy of PHI about lawful reproductive health care. In addition, NCVHS held a virtual public meeting that included a discussion about the proposed rule on June 14, 2023,[FN106] and provided recommendations to the Department based on this discussion, briefings at their July 2022 [FN107] and December 2022 [FN108] meetings, and the expertise of its members.[FN109] The resultant public record and subsequent recommendations submitted to the Department by NCVHS, along with other public comments on the 2023 Privacy Rule NPRM, informed the development of these modifications.

III. Justification for This Rulemaking

A. HIPAA Encourages Trust and Confidence by Carefully Balancing Individuals' Privacy Interests With Others' Interests in Using or Disclosing PHI

1. Privacy Protections Ensure That Individuals Have Access to, and Are Comfortable Accessing, High-Quality Health Care

The goal of a functioning health care system is to provide high-quality health care that results in the best possible outcomes for individuals. To achieve that goal, a functioning health care system depends in part on individuals trusting health care providers. Thus, trust between individuals and health care providers is essential to an individual's health and well-being.[FN110] Protecting

the privacy of an individual's health information is "a crucial element for honest health discussions." [FN111] The original Hippocratic Oath required physicians to pledge to maintain the confidentiality of health information they learn about individuals. [FN112] Without confidence that private information will remain private, individuals—to their own detriment—are reluctant to share information with health care providers.

When proposing the 2000 Privacy Rule, the Department recognized that individuals may be deterred from seeking needed health care if they do not trust that their sensitive information will be kept private.[FN113] The Department described its policy choices as stemming from a motivation to develop and maintain a relationship of trust between individuals and health care providers. The Department explained that a fundamental assumption of the 2000 Privacy Rule was that the greatest benefits of improved privacy protection would be realized in the future as individuals gain increasing trust in their health care provider's ability to maintain the confidentiality of their health information.[FN114] As a result, the Privacy Rule strengthened protections for health information privacy, including the right of individuals to determine who has access to their health information.

Despite the Privacy Rule's rights and protections, individuals do not have confidence that their IIHI is being protected adequately. In a 2022 survey on patient privacy, the American Medical Association (AMA) found that, of 1,000 patients surveyed: (1) nearly 75% were concerned about protecting the privacy of their own health information; and (2) 59% of patients worried about health data being used by companies to discriminate against them or their loved ones.[FN115] According to the AMA, a lack of health information privacy raises many questions about circumstances that could put individuals and health care providers in legal peril, and that the "primary purpose of increasing [health information] privacy is to build public trust, not inhibit data exchange." [FN116]

The Federal Government also has a strong interest in ensuring that individuals have access to high-quality health care.[FN117] This is true at both an ***32985** individual and population level. In the 2000 Privacy Rule, the Department noted that high-quality health care depends on an individual being able to share sensitive information with their health care provider based on the trust that the information shared will be protected and kept confidential.[FN118] An effective health care system requires an individual to share sensitive health information with their health care providers. They do so with the reasonable expectation that this information is going to be used to treat them. The prospect of the disclosure of highly sensitive PHI by regulated entities can result in medical mistrust and the deterioration of the confidential, safe environment that is necessary to provide high-quality health care, operate a functional health care system, and improve the public's health generally.[FN119] High-quality health care cannot be attained without patient candor. Health care providers rely on an individual's health information to diagnose them and provide them with appropriate treatment options and may not be able to reach an accurate diagnosis or recommend the best course of action for the individual if the individual's medical records lack complete information about their health history. However, an individual may be unwilling to seek treatment or share highly sensitive PHI when they are concerned about the confidentiality and security of PHI provided to treating health care providers.[FN120] The Department has long recognized that health care professionals who lose the trust of their patients cannot deliver high-quality care.[FN121] Similarly, if a health care provider does not trust that the PHI they include in an individual's medical records will be kept private, the health care provider may leave gaps or include inaccuracies when preparing medical records, creating a risk that ongoing or future health care would be compromised. In contrast, heightened confidentiality and privacy protections enable a health care provider to feel confident maintaining full and complete medical records.

Incomplete medical records and health care avoidance not only inhibit the quality of health care an individual receives; they are also detrimental to efforts to improve public health. The objective of public health is to prevent disease in and improve the health of populations. Barriers that undermine the willingness of individuals to seek health care in a timely manner or to provide complete and accurate health information to their health care providers undermine the overall objective of public health. For example, individuals who are not candid with their health care providers because of concerns about potential negative consequences of a loss of privacy may withhold information about a variety of health matters that have public health implications, such as communicable diseases or vaccinations.[FN122] Experience also shows that medical mistrust—especially in communities of color and other communities that have been marginalized or negatively affected by historical and current

health care disparities—can create damaging and chilling effects on individuals' willingness to seek appropriate and lawful health care for medical conditions that can worsen without treatment.[FN123]

2. The Department's Approach to the Privacy Rule Has Long Sought To Balance the Interests of Individuals and Society

While recognizing the importance of preserving individuals' trust, the Department has consistently taken the approach of balancing the interests of the individual in the privacy of their PHI with society's interests, including in the free flow of information that enables the provision of effective and efficient health care services. Such an approach derives from Congress's direction, in 1996, to improve the efficiency and effectiveness of the health care system by encouraging the development of a health information system while taking into account the privacy of IIHI and the uses and disclosures of such information that should be authorized or required.[FN124] In past rulemakings, the Department has made revisions to the Privacy Rule to balance an individual's privacy expectations with a covered entity's need for information for reimbursement and quality purposes.[FN125] As the Department previously explained, "Patient privacy must be balanced against other public goods, such as research and the risk of compromising such research projects if researchers could not continue to use such data." [FN126] The 2000 Privacy Rule included permissions for regulated entities to disclose PHI under certain conditions, including for judicial and administrative proceedings and law enforcement purposes, because an individual's right to privacy in information about themselves is not absolute. For example, it does not prevent reporting of public health information on communicable diseases, nor does it prevent law enforcement ***32986** from obtaining information when due process has been observed.[FN127]

In more recent rulemakings revising the Privacy Rule, the Department has continued its efforts to build and maintain individuals' trust in the health care system while balancing the interests of individuals with those of others. For example, in explaining revisions made as part of the 2013 Omnibus Rule, the Department recognized that covered entities must balance protecting the privacy of health information with sharing health information with those responsible for ensuring public health and safety. [FN128] The Privacy Rule was also revised in 2016 ("2016 Privacy Rule") in accordance with an administration-wide effort to curb gun violence across the nation.[FN129] The 2016 Privacy Rule was tailored to authorize the disclosure of a limited set of PHI [FN130] for a narrow, specific purpose, that is, to permit only regulated entities that are state agencies or other entities designated by a state to collect and report information to the National Instant Criminal Background Check System (NICS) or a lawful authority making an adjudication or commitment as described by 18 U.S.C. 922(g)(4) to disclose to NICS the identities of individuals who are subject to a Federal "mental health prohibitor," that disqualifies them from shipping, transporting, possessing, or receiving a firearm. As explained in the 2016 Privacy Rule, the Federal mental health prohibitor applies only to the extent that the individual is involuntarily committed or determined by a court or other lawful authority to be a danger to self or others, or is unable to manage their own affairs because of a mental illness or condition.[FN131] Similar to this final rule, the 2016 Privacy Rule balanced public safety goals with individuals' privacy interests by clearly limiting permissible disclosures to those that are necessary to ensure that individuals are not discouraged from seeking lawful health care, in this case, voluntary treatment for mental health needs.[FN132] In the 2013 Omnibus Rule and 2016 Privacy Rule, the Department ensured that the disclosures were necessary for the public good and were not for the purpose of harming the individual. This approach is consistent with the NCVHS recommendations to the Secretary relating to health information privacy: "The Committee strongly supports limiting use and disclosure of identifiable information to the minimum amount necessary to accomplish the purpose. The Committee also strongly believes that when identifiable health information is made available for non-health uses, patients deserve a strong assurance that the data will not be used to harm them." [FN133]

Consistent with Congress's directive to promulgate "standards with respect to the privacy of [IIHI]" that, among other things, address the "uses and disclosures of such information that should be authorized or required," [FN134] the Department recognizes a variety of interests with respect to health information. These include individuals' interests in the privacy of their health information, society's interests in ensuring the effectiveness of the health care system, and other interests of society in using IIHI for certain non-health care purposes. As part of balancing these interests, the Department has also recognized that it may be necessary to afford additional protection to certain types of health information because those types of information are particularly sensitive and often involve highly personal health care decisions. For example, the Department affords special privacy protections to psychotherapy notes. These protections are afforded in part because of the particularly sensitive information those notes contain and in part because of the unique function of these records, which are by definition maintained

separately from an individual's medical record.[FN135] As we previously explained, the primary value of psychotherapy notes is to the specific provider, and the promise of strict confidentiality helps to ensure that the patient will feel comfortable freely and completely disclosing very personal information essential to successful treatment.[FN136] The Department elaborated that even the possibility of disclosure may impede development of the confidential relationship necessary for successful treatment because of the sensitive nature of the problems for which individuals consult psychotherapists and the potential embarrassment that may be engendered by the disclosure of confidential communications made during counseling sessions.[FN137] Therefore, to support the development and maintenance of an individual's trust and protect the relationship between an individual and their therapist, the Privacy Rule permits the disclosure of psychotherapy notes without an individual's authorization only in limited circumstances, such as to avert a serious and imminent threat to health or safety. Those limited circumstances do not include judicial and administrative proceedings or law enforcement purposes unless the disclosure is "necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public." [FN138]

Information about an individual's reproductive health and associated health care is also especially sensitive and has long been recognized as such. As stated in the AMA's Principles of Medical Ethics, the "decision to terminate a pregnancy should be made privately within the relationship of trust between patient and physician in keeping with the patient's unique values and needs and the physician's best professional judgment." [FN139] NCVHS first noted reproductive health information as an example of a category of health information commonly considered to contain sensitive information in ***32987** 2006.[FN140] Between 2005 and 2010, NCVHS held nine hearings that addressed questions about sensitive information in medical records and identified additional categories of sensitive information beyond those addressed in Federal and state law, including "sexuality and reproductive health information." In several letters to the Secretary during that period, NCVHS recommended that the Department identify and define categories of sensitive information, including "reproductive health." [FN141] In a 2010 letter to the Secretary, NCVHS elaborated that, after extensive testimony on sensitive categories of health information, "reproductive health" should be expanded to "sexuality and reproductive health information," because:

Information about sexuality and reproductive history is often very sensitive. Some reproductive issues may expose people to political controversy (such as protests from abortion proponents), and public knowledge of an individual's reproductive history may place [them] at risk of stigmatization." Additionally, individuals may wish to have their reproductive history segmented so that it is not viewed by family members who otherwise have access to their records. Parents may wish to delay telling their offspring about adoption, gamete donation, or the use of other forms of assisted reproduction technology in their conception, and, thus, it may be important to have the capacity to segment these records.[FN142]

The Department did not provide specific protections for certain categories of PHI upon receipt of the recommendation or as part of the 2013 Omnibus Rule because of concerns about the ability of regulated entities to segment PHI and the effects on care coordination. While we recognized the sensitive nature of reproductive health information before this rulemaking, the Department believed that the Supreme Court's recognition of a constitutional right to abortion coupled with the privacy protections afforded by the HIPAA Rules provided the necessary trust to promote access to and quality of health care. As a result of the changed legal landscape for reproductive health care broadly, including abortion, the range of circumstances in which PHI about legal reproductive health care could be sought and used in investigations or to impose liability expanded significantly. Now that states have much broader power to criminalize and regulate reproductive choices—and that some states have already exercised that power in a variety of ways [FN143]—individuals legitimately have a far greater fear that especially sensitive information about lawful health care will not be kept private. This changed environment requires additional privacy protections to help restore the Privacy Rule's carefully-struck balance between individual and societal interests. Because the concerns regarding segmentation and the negative impact on care coordination remain, the Department did not propose and is not establishing a new category of particularly sensitive PHI in this final rule. Instead, as discussed more fully below, the Department is finalizing its proposed purpose-based prohibition against certain uses and disclosures.

B. Developments in the Legal Environment Are Eroding Individuals' Trust in the Health Care System

The Supreme Court's decision in Dobbs overturned Roe v. Wade [FN144] and Planned Parenthood of Southeastern Pennsylvania v. Casey,[FN145] thereby enabling states to significantly restrict access to abortion.[FN146] Following the Supreme Court's

decision, the legal landscape has shifted as laws significantly restricting access to abortion have in fact become effective in some jurisdictions. This change has also led to questions about both the current and future lawfulness of other types of reproductive health care, and therefore, the ability of individuals to access such health care.[FN147] Thus, this shift may interfere with the longstanding expectations of individuals, established by HIPAA and the Privacy Rule, with respect to the privacy of their PHI.[FN148] For example, while the Privacy Rule currently permits, but does not require, uses and disclosures of PHI for certain purposes,[FN149] including when another law requires a regulated entity to make the use or disclosure,[FN150] regulated entities after Dobbs may feel compelled by other applicable law to use or disclose PHI to law enforcement or other persons who may use that health information against an individual, a regulated entity, or another person who has sought, obtained, provided, or facilitated reproductive health care, even when such health care is lawful in the circumstances in which the health care is obtained.[FN151]

As a consequence of these developments in Federal and state law, an individual's expectation of privacy of their health information (irrespective of whether an individual is or was pregnant) is threatened by the potential use or disclosure of PHI to identify persons who seek, obtain, provide, or facilitate lawful reproductive health care. Thus, these developments have created an environment in which individuals are more likely to fear that their PHI will be requested from regulated entities for use against individuals, health care providers, and others, merely because such persons sought, obtained, provided, or facilitated lawful reproductive health care.[FN152] The potential increased demand for PHI for these purposes is not limited to states in which providing or obtaining certain reproductive health care is no longer legal. Rather, the changes in the legal landscape have nationwide implications, not only because of their effects on the relationship between health care providers and individuals, but also because of the potential effects on the flow of health information across state lines. For example, an individual who travels out-of-state to obtain reproductive health care that is lawful under the circumstances in which it is provided may now be reluctant to have that information disclosed to a health care provider in their home state if they ***32988** fear that it may then be used against them or a loved one in their home state. A health care provider may be unable to provide appropriate health care if they are unaware of the individual's recent health history, which could have significant negative health consequences. Individuals and health care providers may also be reluctant to disclose PHI to health plans with a multi-state presence because of concerns that one of those states will seek to obtain that PHI to investigate or impose liability on the individual or the health care provider, even if there is no nexus with that state other than the presence of the health plan in that state. Such reluctance may have significant ramifications for access to reproductive health care, given the cost associated with obtaining such health care, and health care generally.

Additionally, PHI is more likely to be transmitted across state lines as the electronic exchange of PHI increases because it is easier and more efficient to send information electronically. For instance, the Trusted Exchange Framework and Common Agreement (TEFCA) initiative established under the 21st Century Cures Act and the Centers for Medicare & Medicaid Services (CMS) Interoperability and Prior Authorization Final Rule will spur greater use and disclosure of PHI by regulated entities and to health apps and others.[FN153] Different components of a health information exchange/health information network (HIE/HIN) may be located in different states, meaning that the PHI may be transmitted across state lines, and thus affected by laws severely restricting access to reproductive health care, even where both the health care and the recipient of the PHI are located in states where access to such health care is not substantially restricted.

According to commenters, individuals are increasingly concerned about the confidentiality of discussions with their health care providers. As a result, some individuals are not confiding fully in their health care providers, increasing the risk that their medical records will not be complete and accurate, leading to decreases in health care quality and safety. This lack of openness is also likely to affect the information and treatment recommendations health care providers provide to individuals because health care providers will not be sufficiently informed to provide thorough and accurate information and guidance.[FN154]

Individuals are not alone in their fears. Indeed, according to commenters, some health care providers are afraid to provide lawful health care because they are concerned that in doing so, they risk being subjected to investigation and possible liability.[FN155] The Department is aware that some health care providers, such as clinicians and pharmacies, are hesitant to provide lawful health care or lawfully prescribe or fill prescriptions for medications that can result in pregnancy loss, even when the health care or

those prescriptions are intended to treat individuals for other health matters, because of fear of law enforcement action.[FN156] Some health care providers are also not providing individuals with information to address concerns about their reproductive health, even where their communications would be lawful, out of fear of criminal prosecution, civil suit, or loss of their clinical license.[FN157] This may result in individuals making decisions about their health care with incomplete information, which could have serious implications for health outcomes. These fears also increase the risk that individual medical records will not be maintained with completeness and accuracy, which will in turn affect the quality of health care provided to individuals and their safety. Fears about potential prosecution, even when Federal law protects the actions of health care providers, are likely to negatively affect the accuracy of medical records maintained by health care providers and thereby harm individuals.

As explained by commenters and supported by research, these impingements on the privacy of health information about reproductive health care are likely to have a disproportionately greater effect on women, individuals of reproductive age, and individuals from communities that have been historically underserved, marginalized, or subject to discrimination or systemic disadvantage by virtue of their race, disability, social or economic status, geographic location, or environment.[FN158] Historically ***32989** underserved and marginalized individuals are also more likely to be the subjects of investigations and other activities to impose liability for seeking or obtaining reproductive health care, even where such health care is lawful under the circumstances in which it is provided.[FN159] They are also less likely to have adequate access to legal counsel to defend themselves from such actions.[FN160] These inequities may be exacerbated where individuals face multiple, intersecting disparities, such as having limited English proficiency [FN161] and disability.[FN162] Such individuals are thus especially likely to be concerned that information they share with their health care providers about their reproductive health care will not remain private. This is particularly true considering the historic lack of trust, negative experiences, and fear of discrimination that many members of historically underrepresented and marginalized communities and communities of color have in the health care system; [FN163] such individuals are more likely to be deterred from seeking or obtaining health care—or from giving their health care providers full information.

Congress contemplated that the Department would need to modify standards adopted under HIPAA's Administrative Simplification provisions and directed the Secretary to review standards adopted under 42 U.S.C. 1320d-2 periodically.[FN164] In accordance with this directive and based on the Department's expertise and analysis and the recent developments in the legal landscape, there is a compelling need to provide additional protections to PHI about lawful reproductive health care. Accordingly, consistent with Congress's directions to the Department, in HIPAA, as amended by Genetic Information Nondiscrimination Act (GINA) and the HITECH Act, to establish standards and requirements for the electronic transmission of certain health information, including the privacy thereof, for the development of a health information system, the Department is restricting certain uses and disclosures of PHI for particular non-health care purposes to provide such protections.

C. To Protect the Trust Between Individuals and Health Care Providers, the Department Is Restricting Certain Uses and Disclosures of PHI for Particular Non-Health Care Purposes

As discussed above, Congress enacted HIPAA to improve the efficiency and effectiveness of the health care system, which includes ensuring that individuals have trust in the health care system. Congress also directed the Department to develop standards with respect to the privacy of IIHI as part of its decision to encourage the development of a health information system. To preserve such trust, and to encourage the development and use of a nationwide health information system, it is appropriate and necessary for Federal law and policy to protect the confidentiality of medical records, especially those that are highly sensitive. Accordingly, to protect the trust between individuals and health care providers, this rule restricts certain uses and disclosures of PHI for particular non-health care purposes, i.e., for using or disclosing PHI to conduct a criminal, civil, or administrative investigation into or to impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating ***32990** lawful reproductive health care, or to identify any person to initiate such activities.

Information about reproductive health care is particularly sensitive and requires heightened privacy protection. The Department's approach is consistent with efforts across the Federal Government. For example, the Department of Defense (DOD) has recognized such privacy concerns. In a memorandum to DOD leaders, the Secretary of Defense directed the DOD to "[e]stablish additional privacy protections for reproductive health care information" for service members and "[d]isseminate

guidance that directs Department of Defense health care providers that they may not notify or disclose reproductive health information to commanders unless this presumption is overcome by specific exceptions set forth in policy." [FN165] The Federal Trade Commission (FTC) has also recognized that information about personal reproductive matters is "particularly sensitive" and has committed to using the full scope of its authorities to protect consumers' privacy, including the privacy of their health information and other sensitive data.[FN166] In business guidance, the FTC explained that "[t]he exposure of health information and medical conditions, especially data related to sexual activity or reproductive health, may subject people to discrimination, stigma, mental anguish, or other serious harms." [FN167]

As discussed above, the Department has long provided special protections for psychotherapy notes because of the sensitivity around this information. However, unlike psychotherapy notes, which by their very nature are easily segregated, reproductive health information is not easily segregated. Additionally, regulated entities generally do not have the ability to segment certain PHI such that regulated entities could afford special protections for specific categories of PHI.[FN168] Where such technology is available, it is generally cost prohibitive and burdensome to implement.[FN169] Therefore, the Department did not propose, and is not finalizing, a newly defined subset of PHI. Creating such a subset would create barriers to disclosing PHI for care coordination because the PHI would need to be segregated from the remaining medical record. Instead, consistent with the Privacy Rule's longstanding overall approach,[FN170] the Department is finalizing a purpose-based prohibition against certain uses and disclosures. This rule seeks to protect individuals' privacy interests in their PHI about reproductive health care and the interests of society in an effective health care system by enabling individuals and licensed health care professionals to make decisions about reproductive health care based on a complete medical record, while balancing those interests with other interests of society in obtaining PHI for certain non-health care purposes.

To assist in effectuating this prohibition, the Department is also requiring regulated entities to obtain an attestation in certain circumstances from the person requesting the use or disclosure stating that the use or disclosure is not for a prohibited purpose. A person (including a regulated entity or someone who requests PHI) who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual would be subject to potential criminal liability.[FN171] Thus, a person who knowingly and in violation of HIPAA falsifies an attestation (e.g., makes a material misrepresentation about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could be subject to the criminal penalties provided by the statute.[FN172] Additionally, a regulated entity is subject to potential civil penalties for violations of the HIPAA Rules, including a failure to obtain a valid attestation before disclosing PHI, where an attestation is required.[FN173] The purpose-based prohibition, in concert with the attestation, will restrict the use and disclosure of PHI about lawful reproductive health care where the use or disclosure could harm HIPAA's overall goals of increasing trust in the health care system, improving health care quality, and protecting individual privacy. At the same time, it will allow uses and disclosures that either support those goals or do not substantially interfere with their achievement.

Consistent with the Privacy Rule's approach, the Department is clarifying that the purpose-based prohibition applies only in certain circumstances, recognizing the interests of both the Federal Government and states while also protecting the information privacy interests of persons who seek, obtain, provide, or facilitate lawful reproductive health care. Thus, the Department is finalizing a Rule of ***32991** Applicability that balances the privacy interests of individuals and the interests of society in an effective health care system with those of society in the use of PHI for other non-health care purposes by limiting the new prohibition to certain circumstances.

The Department's experience administering the Privacy Rule, research cited below, our assessment of the needs of individuals and health care providers in light of recent developments to the legal landscape, public comments, and the Regulatory Impact Analysis, in Section VI below, all provide support for the changes finalized in this rulemaking. These changes will improve individuals' confidence in the confidentiality of their PHI and their trust in the health care system, creating myriad benefits for the health care system. Balancing the privacy interests of individuals and the use of PHI for other societal priorities will continue to support an effective health care system, as Congress intended. This final rule will deter the creation of inaccurate and incomplete medical records, which will help to support the provision of appropriate lawful health care. Health care providers base their treatment recommendations on PHI contained within existing medical records, as well as information shared with them

directly by the individual. Thus, where individuals withhold information from their health care providers about lawful health care, health care providers may not be in possession of all of the necessary information to make an informed recommendation for an appropriate treatment plan, which may result in negative health outcomes at both the individual and population level. It will also improve the confidence of individuals, including among the Nation's most vulnerable communities, that they can securely seek or obtain or share that they sought or obtained lawful reproductive health care without that information being used or disclosed for the purpose of investigating or imposing liability on them for seeking or obtaining that lawful health care. By improving individuals' confidence and trust in their relationships with their health care providers, it will make individuals more likely to, for example, comply with preventative health screening recommendations, which will protect against a decline in individual and population health outcomes related to missed preventative health screenings. Additional intangible benefits from increased privacy protections in this area include enhanced support for survivors of rape, incest, and sex trafficking. The new attestation requirement discussed in greater detail below will help to assure regulated entities of their ability to operationalize these changes and avoid exposure to HIPAA liability for impermissible disclosures.

IV. General Discussion of Public Comments

The Department received more than 25,900 comments in response to its proposed rule. Overall, these comments represent the views of approximately 51,500 individuals and 350 organizations. Slightly more than half of the individuals and organizations who shared their views expressed general support for the 2023 Privacy Rule NPRM and its objectives. Less than one percent expressed mixed views. Organizational commenters included professional and trade associations, including those representing medical professionals, health plans, health care providers, health information management professionals, health information management system vendors, release-of-information vendors, employers, epidemiologists, and attorneys. The Department also received comments from advocacy organizations, including those representing patients, privacy advocates, faith-based organizations, and civil rights organizations. The NCVHS also provided comments, as did members of Congress, state, local, and Tribal government officials and public health authorities. Other commenters included health care systems, hospitals, and health care professionals.

A. General Comments in Support of the Proposed Rule

Comment: Many commenters expressed general support for the proposed rule and urged the Department to protect the privacy of individuals by limiting uses and disclosures of PHI for certain purposes where the use or disclosure of information is about reproductive health care that is lawful under the circumstances in which such health care is provided.

Many health care providers and individuals emphasized the importance of trusting relationships between individuals and their health care providers. According to individual commenters, a trusting relationship permits individuals to participate in sensitive and difficult conversations with their health care providers and enables health care providers to furnish high-quality and appropriate health care and to maintain accurate and complete medical records, including records that contain information about reproductive health care.

Many organizations also submitted comments that expressed agreement with the Department's position on the importance of the relationship between HIPAA and the HIPAA Rules and trust between individuals and health care providers. For example, an organization commented that privacy has long been a “hallmark” of medical care and agreed with the Department that Congress recognized this principle when it enacted HIPAA. Some organizations commented that the HIPAA framework of law and rules provides individuals with the necessary trust and confidence to seek reproductive health care without fear of being prosecuted or targeted by law enforcement, including in medical emergencies.

Other commenters stated that a trusting confidential relationship between an individual and a health care provider is an essential prerequisite to the delivery of high-quality health care. They also asserted that protective privacy laws, including HIPAA, help to ensure that individuals do not forgo health care.

Many individuals asserted that the proposed safeguards are urgently needed to provide individuals with the confidence to seek health care. According to the commenters, the proposal would increase the likelihood that pregnant individuals would receive essential health care, thus improving their overall well-being. One commenter expressed support for the proposal because they believe people should not be held liable or face punishment for seeking, obtaining, providing, or facilitating lawful health care. Another commenter expressed concerns that the increase in state legislation targeting reproductive health care has placed significant burdens on physicians and increased the risk of maternal morbidity and mortality for individuals.

A few commenters also expressed agreement with the Department's assertion that the proposed restrictions would clarify legal obligations of regulated entities with respect to the disclosure of PHI for certain non-health related purposes and would enable persons requesting PHI, including health plans, to better understand when such disclosures are permitted.

Response: The Department appreciates these comments and is finalizing the proposed rule with modification, as described in greater detail below. Consistent with HIPAA's goals, this final rule will support the development and maintenance of trust between individuals and their health care providers, encouraging individuals ***32992** to be forthright with health care providers regarding their health history and providing valuable clarity to the regulated community and individuals concerning their privacy rights with respect to lawfully provided health care. In so doing, the Department helps to support access to health care by increasing individuals' confidence in the privacy of their PHI about lawfully provided reproductive health care. We are taking these actions as a result of our ongoing evaluation of the environment, including the legal landscape, and consistent with the Privacy Rule's longstanding balance of individual privacy and societal interests in PHI for non-health care purposes.

Comment: A wide cross-section of commenters, including individuals, health care providers, patient advocacy organizations, reproductive rights organizations, state law enforcement agencies, and others all agreed that individuals who frequently experience discrimination generally also experience it when seeking health care.

Many of these commenters urged the Department to recognize that there is a trust deficit in relationships between individuals and health care providers in communities that frequently experience discrimination. Many commenters cited scholarly journals and research articles showing that women of color especially suffer poorer medical outcomes, including higher maternal mortality and denial of medical interventions or treatments.

Commenters who answered the Department's request for comment about whether members of “historically underserved and minority communities” are more likely to be the subject of investigations into or proceedings against persons in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care unanimously responded in the affirmative. Some commenters expressed concern about the current legal environment's disproportionately negative effect on the privacy of women and members of marginalized and historically underserved communities and communities of color, such as immigrants who might avoid obtaining health care because of fears that their PHI could be shared with government officials. In general, commenters encouraged the Department to consider the likely negative implications of reduced health information privacy when combined with these disparities on health outcomes for members of marginalized and historically underserved communities and communities of color when crafting the final rule.

Some commenters expressed concern about the current legal environment's disproportionately negative effect on the privacy of members of marginalized and historically underserved communities and communities of color, such as women of color, immigrants and American Indians and Alaska Natives, who might withhold information from health care providers or avoid obtaining health care because of fears that their PHI could be shared with government officials or used to investigate or impose liability on them.

Among commenters that addressed this topic, many supported the Department's proposed purpose-based prohibition. Commenters stated that the proposed rule would help to mitigate medical mistrust of individuals in marginalized and historically underserved communities and communities of color and reduce the racial disparities that result from the increased criminalization of reproductive health care.

Several commenters also addressed the issue of the availability of legal counsel among these communities. A few commenters asserted that individuals who are members of marginalized and historically underserved communities and communities of color are less likely to have access to legal counsel, despite being more likely to be subjects of investigations into or proceedings against persons in connection with obtaining providing or facilitating lawful sexual and reproductive health care and cited to related studies.

Response: We appreciate these comments and thank commenters for sharing these important considerations. As we discussed in the 2023 Privacy Rule NPRM and again here, the experiences of individuals from communities that have been historically underserved, marginalized, or subject to discrimination or systemic disadvantage by virtue of their race, disability, social or economic status, geographic location, or environment have significant negative effects on their relationships with health care providers and their willingness to seek necessary health care. We agree that the current legal landscape has exacerbated the health inequities that these individuals encounter when seeking reproductive health care services. The Department expects that the steps we have taken in this rule will meaningfully strengthen the privacy of PHI about lawful reproductive health care, and as a result, will help to mitigate the exacerbation of health disparities for members of marginalized and historically underserved communities and communities of color.

The Department is actively working to reduce health disparities. In recent months, we released a new plan to address language barriers and strengthen language access in health care,[FN174] and issued three proposed rules to address health disparities: one to revise existing regulations to strengthen prohibitions against discrimination on the basis of a disability in health care and human services programs; [FN175] another to issue new regulations to advance non-discrimination in health and human service programs for the LGBTQI+ community; [FN176] and a third to revise existing regulations to prohibit discrimination on the basis of race, color, national origin, sex, age, and disability in a range of health programs.[FN177] The Department will continue to work to address these concerns, ensure that individuals have access to and do not forgo necessary health care, and build individuals' trust that health care providers can and will protect the privacy of individuals' sensitive health information.

Comment: A few commenters agreed with the Department's position that the proposed rule would appropriately protect individuals against growing threats to their privacy with respect to PHI about reproductive health care while permitting states to conduct law enforcement activities.

Response: The Privacy Rule always has and continues to balance privacy interests and other societal interests by permitting disclosures of PHI to support ***32993** public policy goals, including disclosures to support certain criminal, civil, and administrative law enforcement activities; the operation of courts and tribunals; health oversight activities; the duties of coroners and medical examiners; and the reporting of child abuse, domestic violence, and neglect to appropriate authorities. We appreciate these comments that recognized the growing threat to the privacy of PHI and the need to strike an appropriate balance between ensuring health care privacy and conducting law enforcement activities. We are finalizing the proposed rule with modification as described in greater detail below.

B. General Comments in Opposition to the Proposed Rule

Comment: Several commenters generally opposed the proposed rule because of their opposition to certain types of reproductive health care. Many commenters opposed the proposed rule generally because they believed that it would harm women and children. Other commenters expressed concern that the proposals would increase administrative burdens and costs for health care providers; impede parental rights; prevent mandatory reporting of child abuse or abuse, domestic violence, and neglect; infringe upon states' rights; thwart law enforcement investigations; inhibit disclosures for public health activities; and protect those who engage in unlawful activities.

Response: The modifications to the Privacy Rule in this final rule directly advance Congress' directive in HIPAA to improve the efficiency and effectiveness of the health care system by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information,[FN178] including

a standard for the privacy of IIHI that, among other things, addresses the "uses and disclosures of such information that should be authorized or required." [FN179] As discussed in greater detail elsewhere in this final rule, a trusting relationship between individuals and health care providers is the foundation of effective health care. A primary goal of the Privacy Rule is to ensure the privacy of an individual's PHI while permitting necessary uses and disclosures of PHI that enable high-quality health care and protect the health and well-being of all individuals, including women and children, and the public.

From the outset, the Department structured the Privacy Rule to ensure that individuals do not forgo lawful health care when needed—or withhold important information from their health care providers that may affect the quality of health care they receive out of a fear that their sensitive information would be revealed outside of their relationship with their health care provider. The Department has long been committed to protecting the privacy of PHI and providing the opportunity for an authentic, trusting relationship between individuals and health care providers. As we discussed in the 2023 Privacy Rule NPRM and again here, this final rule will help engender trust between individuals and health care providers and confidence in the health care system. We believe that this confidence will eliminate some of the burdens health care providers face in providing high-quality health care, encourage health care providers to accurately document PHI in an individual's medical record, and encourage individuals to provide health care providers with their complete and accurate health history, all of which will ultimately support better health outcomes. Nothing in this final rule sets forth a particular standard of care or affects the ability of health care providers to exercise their professional judgment.

This final rule protects the relationship between individuals and health care providers by protecting the privacy of PHI in circumstances where recent legal developments have increased concerns about that information being used and disclosed to harm persons who seek, obtain, provide, or facilitate reproductive health care under circumstances in which such health care is lawful, while continuing to permit uses and disclosures that confer other social benefits. It is narrowly tailored and respects the interests of both states and the Department. The final rule continues to permit regulated entities to use or disclose PHI to comply with certain mandatory reporting laws, for public health activities, and for law enforcement purposes when the uses and disclosures are compliant with the applicable provisions of the Privacy Rule.

Further, consistent with the longstanding operation of the Privacy Rule, this final rule requires that, in certain circumstances, regulated entities obtain information from persons requesting PHI, such as law enforcement, before the regulated entities may use or disclose the requested PHI. The Department recognizes that this final rule may increase the burden on those persons making requests for PHI, such as federal and state law enforcement officials, by requiring, in certain circumstances, that regulated entities obtain more information from such persons than previously required, and may, at times, prevent regulated entities from using or disclosing PHI that they previously would have been permitted to use or disclose. For example, the Department recognizes that situations may arise where a regulated entity reasonably determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (e.g., law enforcement) reasonably believes otherwise. In such circumstances, where the regulated entity provided the reproductive health care, and upon receiving a request for the PHI for a purpose that implicates the prohibition, reasonably determines that the provision of reproductive health care was lawful, the final rule would prohibit the regulated entity from disclosing PHI for certain types of investigations into the provision of such health care. This constitutes a change from the current Privacy Rule, under which a regulated entity is permitted, but not required, to make a use or disclosure under 45 CFR 164.512(f) of information that is "relevant and material to a legitimate" law enforcement inquiry, provided that certain conditions are met; these conditions include, for example, that the request is specific and limited in scope to the extent reasonably practicable given the purpose for which the information is sought.[FN180] Similarly, the Department acknowledges that, where the regulated entity did not provide the reproductive health care that is the subject of the investigation or imposition of liability, the Rule of Applicability and Presumption, discussed below, may require regulated entities to obtain additional information, that is, factual information that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided, from persons requesting PHI before using or disclosing the requested PHI.

Consistent with HIPAA and the Department's longstanding approach in the Privacy Rule, the Department is finalizing an approach that strikes an appropriate balance between the privacy interests of individuals and the interests of law enforcement,

and private parties afforded legal rights of action, in ***32994** obtaining PHI for certain non-health care purposes. While this approach may adversely affect particular interests of law enforcement, and private parties afforded legal rights of action, in some cases, the Department believes that the final rule best balances these competing interests by enhancing privacy protections without unduly interfering with legitimate law enforcement activities and does so in a manner that is consistent with the approach taken elsewhere in the Privacy Rule. As explained above, individual privacy interests are especially strong where individuals seek lawful reproductive health care. In particular, individuals may forgo lawful health care or avoid disclosing previous lawful health care to providers because they fear that their PHI will be disclosed. The Department believes these concerns are exacerbated by the prospect of state investigations into, and resulting intimidation and criminalization of, health care providers for providing lawful reproductive health care, as well as state laws encouraging state residents to sue persons who facilitate individuals' access to legal health care. The final rule addresses these interests by protecting privacy in situations where the reproductive health care at issue is especially likely to be lawful under the circumstances in which such health care was provided. Where a regulated entity receives a request for PHI about reproductive health care that the regulated entity provided, such health care is likely to be lawful where the regulated entity reasonably determines, based on all information in its possession, that such health care was lawful under the circumstances in which it was provided. Similarly, where a regulated entity receives a request for PHI about reproductive health care that the regulated entity did not provide, such health care is likely to be lawful where law enforcement is unable to provide factual information that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

The Department recognizes that, in some cases, the approach adopted in this final rule may inadvertently prohibit the disclosure of PHI about reproductive health care that was unlawfully provided, such as where a health care provider reasonably but incorrectly determines that the reproductive health care it provided was lawful under the circumstances in which such health care was provided. This is similar to how the Privacy Rule has always potentially prevented the use or disclosure of PHI that could be useful to law enforcement in certain circumstances because the request for PHI does not meet the conditions of the applicable permission. Nevertheless, given the importance of protecting individual privacy in this area, the Department has determined that the final rule adopts the appropriate balance between individual privacy and the interests of other persons, such as law enforcement. Specifically, the Department believes that the benefits to individual privacy of a broadly protective rule outweigh the benefits to societal interests in the use or disclosure of PHI from a narrower rule. While a narrower rule would more broadly permit disclosures related to PHI that might concern reproductive health care that is not lawful under the circumstances in which it is provided, such a rule would inadvertently permit more disclosures of PHI about lawful reproductive health care. Accordingly, the Department concludes that the final rule must be sufficiently broad to protect against such disclosures, given the paramount importance of individual privacy in this area.

Moreover, as explained above, individual privacy interests are paramount to promote free and open communication between individuals and their health care providers, thereby ensuring that individuals receive high-quality care based on their accurate medical history. Society has long recognized that information exchanged as part of a specific relationship for which trust is paramount should be entitled to heightened protection (e.g., marital privilege, attorney-client privilege, doctor-patient privilege). Similarly, this final rule seeks to address situations where privacy interests are especially important, based both on the content of the information that is protected from disclosure (concerning lawful reproductive health care) and the context in which that information is shared (concerning a trust-based relationship between individuals and their health care providers).

In contrast, the potential adverse effects of this final rule on other interests, such as those of law enforcement, are limited by the narrow scope of this final rule. This final rule does not seek to prohibit disclosures of PHI where the request is for reasons other than investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. For example, as explained in the NPRM and below, the final rule does not prohibit the use or disclosure of PHI for investigating alleged violations of the Federal False Claims Act or a state equivalent; conducting an audit by an Inspector General aimed at protecting the integrity of the Medicare or Medicaid program where the audit is not inconsistent with this final rule; investigating alleged violations of Federal nondiscrimination laws or abusive conduct, such as sexual assault, that occur in connection with reproductive health care; or determining whether a person or entity violated 18 U.S.C. 248 regarding freedom of access to clinic entrances. In each of these

cases, the request is not made for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

Even when the request is for the purpose of investigating or imposing liability on the mere act of seeking, obtaining, providing, or facilitating reproductive health care, this final rule does not seek to prohibit disclosures of PHI about reproductive health care that is not lawful under the circumstances in which it was provided. Thus, in most situations involving reproductive health care that is not lawful under the circumstances in which it is provided, this final rule will not prevent the use or disclosure of PHI to investigate or impose liability on persons for such legal violations, provided such disclosures are otherwise permitted by the Privacy Rule. Moreover, where a regulated entity did not provide the reproductive health care at issue, this final rule prohibits the use or disclosure of PHI where the person making the request does not provide sufficient information to overcome the presumption of legality. In such cases, law enforcement agencies and other persons have a reduced interest in obtaining such PHI where the information does not demonstrate to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided.

This final rule does not prohibit the use or disclosure of PHI to investigate or impose liability on persons where reproductive health care is unlawful under the circumstances in which it is provided. Instead, the final rule prohibits the use or disclosure of PHI in narrowly tailored circumstances (i.e., where the use or disclosure is to conduct an investigation or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that ***32995** is lawful under the circumstances in which such health care is provided, or to identify a person for such activities). For example, once this final rule is in effect, a covered health care provider may still disclose PHI to a medical licensing board investigating a health care provider's actions related to their obligation to report suspected elder abuse, assuming the disclosure meets the conditions of an applicable Privacy Rule permission. This is because the final rule does not bar the use or disclosure of PHI for health oversight purposes, which is unrelated to the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

Additionally, even where the final rule prohibits the use or disclosure of PHI to investigate potentially unlawful reproductive health care (i.e., where a regulated entity reasonably determines that the reproductive health care they provided was lawful, or where the presumption of legality is not overcome), law enforcement retains other ways of investigating reproductive health care that they suspect may have been unlawfully provided. For example, law enforcement retains the use of other traditional and otherwise lawful investigatory means for obtaining information, such as conducting witness interviews and accessing other sources of information not covered by HIPAA. The final rule is therefore tailored to protect the relationship between individuals and their health care providers specifically, while leaving unaffected law enforcement's ability to conduct investigations using information from other sources.

With respect to commenters' concerns about parental rights, this final rule also does not interfere with the ability of states to define the nature of the relationship between a minor and a parent or guardian.

Comment: A few commenters that expressed negative views asserted that the proposed rule exceeded the Department's statutory authority under HIPAA or was beyond the Department's rulemaking authority. Some commenters stated that the rulemaking was arbitrary and capricious and would make it difficult for law enforcement to investigate reproductive health care and engage in health oversight activities and would require health care providers to provide certain types of health care against which they have objections. Some commenters expressed concern about the balance of powers between the states and the federal government. Other commenters suggested that the proposals preempt state laws serving public health, safety, and welfare.

Response: As discussed above, Congress explicitly stated that the purpose of HIPAA's Administrative Simplification provisions was to improve the efficiency and effectiveness of the health care system. For the health care system to be effective, individuals must trust that information that they share with health care providers about lawful health care will remain private. Accordingly, since their inception, the HIPAA Rules have required that regulated entities narrowly tailor disclosures to law enforcement to protect an individual's privacy.[FN181] While the Department is adopting an approach in this final rule that is more protective of privacy interests than the current Privacy Rule in certain circumstances, these changes are necessary to appropriately

balance privacy interests and the interests of law enforcement, and private parties afforded legal rights of action, in light of the changing legal environment. This is discussed in detail above. In both the 2023 Privacy Rule NPRM and this final rule, the Department cited to multiple studies documenting the real-world harm to health and health care in the changing legal environment. As explained above, the Department acknowledges that this final rule may affect certain state interests in obtaining PHI to investigate potentially unlawful reproductive health care, but the Department has tailored the final rule to strike the appropriate balance between privacy interests and state interests. This final rule limits the potential harm to individuals, health care providers, and others resulting from the disclosure of PHI to investigate or punish individuals for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. We emphasize that nothing in this rule or any of the HIPAA Rules requires a health care provider to provide any type of health care, including any type of reproductive health care.

Comment: Several commenters asserted that the proposed rule would impede states' enforcement of their own laws, including those concerning sexual assault and sex trafficking. Many commenters opposed the proposed rule because they believed it would inhibit the ability of states to investigate or enforce laws prohibiting minors from obtaining certain types of health care and prevent the commenters from reporting minors who they believe are coerced into obtaining such health care to authorities.

Response: This rule does not prohibit the disclosure of PHI for investigating allegations of or imposing liability for sexual assault, sex trafficking, or coercing minors into obtaining reproductive health care. Rather, this final rule modifies the existing HIPAA Privacy Rule standards by prohibiting uses and disclosures of PHI to investigate or impose liability on individuals, regulated entities, or other persons for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such reproductive health care is provided, or to identify any person to investigate or impose liability on them for such purposes. Accordingly, requests for the disclosure of PHI to investigate such allegations of or impose liability for such crimes do not fall within the final rule's prohibition, and the presumption of lawfulness likewise would not be triggered because the prohibition would not apply. A regulated entity therefore would not be prohibited from disclosing an individual's PHI when subpoenaed by law enforcement for the purpose of investigating such allegations, assuming that law enforcement provided a valid attestation and met the other conditions of the applicable permission.

Moreover, as explained above, the final rule is tailored to prohibit disclosures related to lawful reproductive health care, thereby reducing the interference with law enforcement interests to create an appropriate balance with privacy interests.

Comment: Some states expressed concern that the proposed rule would intrude into areas where the HIPAA Rules have previously acknowledged state control, such as enforcement of state and local laws, regulation of the practice of health care, and reporting of abuse.

Response: This final rule balances the interests of individuals in the privacy of their PHI and of society in an effective health care system with those of society in obtaining PHI for certain non-health care purposes. The Privacy Rule always has and continues to permit disclosures of PHI to support public policy goals, including disclosures to support criminal, civil, and administrative law enforcement activities; the operation of courts and tribunals; health oversight activities; the duties of coroners and medical examiners; and the reporting of child abuse, domestic violence, and neglect to appropriate authorities. As explained above, while the final rule adopts an approach that is more ***32996** protective of privacy interests in certain circumstances than the previous Privacy Rule, the final rule continues to balance the interests that HIPAA Rules have long sought to protect with those of society in PHI.

C. Other General Comments on the Proposed Rule

Comment: Commenters urged the Department to provide enhanced privacy protections for health information that is not covered by existing frameworks or specifically addressed in the proposed rule. A few professional associations expressed support for revising the Privacy Rule to provide stronger protection for the privacy of reproductive health care information and urged the Department to modify the Privacy Rule to provide even stronger protections than those proposed in the 2023 Privacy Rule NPRM.

Response: The Department's authority under HIPAA is limited to protecting the privacy of IIHI that is maintained or transmitted by covered entities and, in some cases, their business associates. Specific modifications to the Privacy Rule to protect the privacy of PHI are described in greater detail below. Consistent with the Department's longstanding approach with respect to the Privacy Rule, the modifications we are finalizing in this rule strike a balance between protecting an individual's right to health information privacy with the interests of society in permitting the disclosure of PHI to support the investigation or imposition of liability for unlawful conduct. In particular, the final rule does not prohibit the disclosure of PHI about reproductive health care that was unlawfully provided, because an individual's privacy interests in reproductive health care that is not lawful (e.g., a particular type of reproductive health care that is provided by a nurse practitioner in a state that requires that type of reproductive health care to be provided by a physician) are comparatively lower than a state's interests in investigating and imposing liability on persons for unlawful reproductive health care. We will continue to monitor legal developments and their effects on individual privacy as we consider the need for future modifications to the Privacy Rule.

Comment: Several commenters questioned how the proposed rule would affect their current business associate and data exchange agreements.

Response: The modifications in this final rule may require regulated entities to revise existing business associate agreements where such agreements permit regulated entities to engage in activities that are no longer permitted under the revised Privacy Rule. Regulated entities must be in compliance with the provisions of this rule by December 23, 2024.

Comment: A few commenters requested clarification of whether minors and legal adults have the same protections under the Privacy Rule and whether this rule would alter existing protections.

Response: The final rule does not change how the Privacy Rule applies to adults and minors. Thus, all of the protections provided to PHI by this final rule apply equally to adults and minors. For example, under this final rule, a regulated entity is prohibited from using or disclosing a minor's PHI for the purposes prohibited under 45 CFR 164.502(a)(5)(iii). The Privacy Rule generally permits a parent to have access to the medical records about their child as their minor child's personal representative when such access is consistent with state or other law, with limited exceptions.[FN182] Additional information about how the Privacy Rule applies to minors can be found at 45 CFR 164.502(g) and on the OCR website.[FN183]

Comment: Many commenters urged the Department to take an educational approach, rather than a punitive one, with respect to enforcement against regulated entities. In addition, many commenters addressed the need for resources and education for successful implementation of the proposed changes to the Privacy Rule. They called for the Department to collaborate with and educate regulated entities, individuals, and others affected by the proposed revisions, such as law enforcement, as well as for the Department to partner with other Federal agencies and state governments to conduct the education. Some suggested that educational resources should include multiple media formats and a centralized platform.

Response: The Department frequently issues non-binding guidance and conducts outreach to help regulated entities achieve compliance. We appreciate these recommendations and will consider these topics for future guidance. Regulated entities are expected to comply with the Privacy Rule as revised once the compliance date has passed.

V. Summary of Final Rule Provisions and Public Comments and Responses

The Department is modifying the Privacy Rule to strengthen privacy protections for individuals' PHI by adding a new category of prohibited uses and disclosures of PHI. This final rule prohibits a regulated entity from using or disclosing an individual's PHI for the purpose of conducting a criminal, civil, or administrative investigation into or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided, meaning that it is either: (1) lawful under the circumstances in which such health care is provided and in the state in which it is provided; or (2) protected, required, or authorized by Federal law, including the United States Constitution, regardless of the state in which such health care is provided. In both of these circumstances,

as explained above, the interests of the individual in the privacy of their PHI and of society in ensuring an effective health care system outweighs those of society in the use of PHI for non-health care purposes. To operationalize this modification, the Department is revising or clarifying certain definitions and terms that apply to the Privacy Rule, as well as other HIPAA Rules. This final rule also prohibits a regulated entity from using or disclosing an individual's PHI for the purpose of identifying an individual, health care provider, or other person for the purpose of initiating such an investigation or proceeding against the individual, a health care provider, or other person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided.

To effectuate these proposals, the Department is finalizing conforming and clarifying changes to the HIPAA Rules. These changes include, but are not limited to, clarifying the definition of "person" to reflect longstanding statutory language defining the term; adopting new definitions of "public health" surveillance, investigation, or intervention, and "reproductive health care"; adding a new category of prohibited uses and disclosures; clarifying that a regulated entity may not decline to recognize a person as a personal representative for the purposes of the Privacy Rule because they provide or facilitate reproductive health care for an individual; imposing a new ***32997** requirement that, in certain circumstances, regulated entities must first obtain an attestation that a requested use or disclosure is not for a prohibited purpose; and requiring modifications to covered entities' NPPs to inform individuals that their PHI may not be used or disclosed for a purpose prohibited under this final rule.

The Department's section-by-section description of the final rule is below.

A. Section 160.103 Definitions

1. Clarifying the Definition of "Person"

HIPAA does not define the term "person." [FN184] The HIPAA Rules have long defined "person" to mean "a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private." [FN185] This meaning was based on the definition of "person" adopted by Congress in the original SSA, as an "individual, a trust or estate, a partnership, or a corporation." [FN186]

In 2002, Congress enacted 1 U.S.C. 8, which defines "person," "human being," "child," and "individual." [FN187] The statute specifies that these definitions shall apply when "determining the meaning of any Act of Congress, or of any ruling, regulation, or interpretation of the various administrative bureaus and agencies of the United States." [FN188] The Department understands 1 U.S.C. 8 to provide definitions of "person," "individual," and "child" that do not include a fertilized egg, embryo, or fetus, and are consistent with the Department's understanding of those terms, as used in the SSA, HIPAA, and the HIPAA Rules.

The Department proposed to clarify the term "natural person" in a manner consistent with 1 U.S.C. 8.[FN189] Thus, the Department proposed to clarify that all terms subsumed within the definition of "natural person," such as "individual," [FN190] are limited to the confines of the term "person." [FN191] As discussed in the 2023 Privacy Rule NPRM, the purpose of this proposal was to better explain to regulated entities and other stakeholders the parameters of an "individual" whose PHI is protected by the HIPAA Rules.

Many individuals and organizations commented on the proposal to clarify the definition "person." Organizational commenters, including professional associations representing health care providers, advocacy groups, and academic departments, generally supported the proposal. Several commenters applauded the proposed clarification because they believed it would limit disclosures of PHI in cases where no individual has been harmed.

Most opponents of the proposed clarification were individuals participating in form letter campaigns who expressed concern that the proposal might diminish access to prenatal care. Others asserted that the proposed clarification would contradict or conflict with existing laws, such as mandatory reporting laws and Federal statutes that rely upon a different definition of "person."

The final rule adopts the proposed clarification of the definition of person, to mean a "natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private." Therefore, an "individual," "child," or "victim" (e.g., a victim of crime) under the HIPAA Rules must be a natural person. As we explained in the 2023 Privacy Rule NPRM, this clarification is consistent with the SSA, HIPAA, and 1 U.S.C. 8. This clarification applies only to regulations issued pursuant to the Administrative Simplification provisions of HIPAA.[FN192]

This clarification is consistent with the Privacy Rule's longstanding definitions of "person" [FN193] and "individual," [FN194] as applied to Privacy Rule provisions permitting certain types of reports or other disclosures of PHI. For example, a regulated entity is permitted to disclose PHI about an individual who the regulated entity reasonably believes to be a victim of abuse, neglect, or domestic violence only where the individual is a "natural person." [FN195] In addition, because a "victim" necessarily is a natural person, the permission to disclose PHI to avert a serious threat to health or safety at 45 CFR 164.512(j)(i) does not permit disclosures when the perceived threat does not involve the health or safety of a natural person or the public, or when an individual has not caused serious physical harm to a natural person.

Comment: Many organizational commenters expressed support for the proposal to clarify the definition of "person."

One commenter stated that this clarification should prevent law enforcement from attempting to avoid the proposed prohibition. According to another commenter, this proposed clarification is crucial as stakeholders adapt to the current reproductive health landscape.

Several commenters expressed support for the Department's proposal but requested additional clarifications. For example, one commenter recommended that the Department clarify whether the definition would preempt state laws.

Response: We take the opportunity to emphasize here that the clarification only applies to the HIPAA Rules and explains certain terms that apply to the permissions for uses and disclosures of PHI by regulated entities. We do not believe it is necessary to further clarify the final regulatory text because the current definition remains unchanged other than to incorporate the plain wording of 1 U.S.C. 8.

Comment: A few commenters expressed opposition to the Department's proposed clarification of "person" as tantamount to eliminating legal protections for and recognition of categories of human beings based on developmental stage. Some commenters maintained that the proposed clarification of "person" was inaccurate.

Several commenters opposed the proposed clarification of "person" because it would affect the provision of prenatal care.

A few commenters asserted that the proposed clarification would prevent the collection of medical information about reproductive health care for ***32998** important purposes, such as public health and research.

Response: We are clarifying the definition of person consistent with applicable Federal law only for the purpose of applying HIPAA's Administrative Simplification provisions. This clarification will not affect how the term "person" is applied for purposes of other laws, affect any rights or protections provided by any other law, or affect standards of health care, including prenatal care.

This final rule does not affect the reporting of vital statistics, nor does it affect the ability of regulated entities to use and disclose PHI for research. The Privacy Rule's standards for uses and disclosures for public health surveillance, investigations, and interventions, or for health oversight activities, are discussed elsewhere.

Comment: Several commenters requested additional clarifications to the Department's proposed clarification of "person." A few commenters asserted that the proposed clarification would be overly expansive. Most of these same commenters disagreed with

the Department's interpretation of 1 U.S.C. 8.[FN196] Commenters asserted that the clarification was inconsistent or conflicted with other laws.

Response: The clarified definition of person that we are finalizing in this rule does not change the Department's interpretation of the term or change definitions under other law, such as state law. It also is consistent with Federal law, including 1 U.S.C. 8, which specifically applies to Federal regulations, and other examples cited by commenters. For example, both GINA and the Privacy Rule protect the genetic information of a fetus carried by a pregnant individual as the PHI of the pregnant individual.[FN197]

The other laws cited by commenters address policy concerns that are different from those health information privacy issues addressed under HIPAA and do not address personhood. Even if those statutes did adopt different understandings of who is a "person," the Department has the authority to clarify or define terms that apply to the Administrative Simplification regulations issued pursuant to HIPAA. Additionally, the definition in the final rule of 1 U.S.C. 8 is appropriate because it is consistent with the Department's longstanding interpretation of the term in the context of HIPAA's Administrative Simplification provisions and associated regulations. Many Federal and state laws operate with differing definitions of common terms, to which existing legal standards that govern how such differences are to be interpreted would apply.[FN198]

Comment: A few commenters asserted that the proposal would expand minors' access to hormone therapy or surgeries without requiring parental consent.

Response: The final rule's clarification to define the term "person" does not affect the ability of a parent to make decisions related to health care for an individual who is an unemancipated minor,[FN199] and nothing in this rule dictates a standard of care. The application of this definition is limited to the HIPAA Rules.

Comment: A few commenters asserted that the proposed clarification would help to prevent the misapplication of child abuse laws to individuals who engage in certain behaviors while pregnant (e.g., use of an illicit substance or alcohol). Several other commenters expressed concern that this definition would limit the ability of a regulated entity to apply the Privacy Rule permission to use or disclose PHI to prevent a serious and imminent threat to a fertilized egg, embryo, or fetus.

Response: Under this final rule, a regulated entity would continue to be permitted to disclose PHI about an individual who the covered entity reasonably believes is a victim of child abuse or neglect, consistent with 45 CFR 164.512(b)(1)(ii), or a victim of abuse, neglect, or domestic violence, consistent with 45 CFR 164.512(c), to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence under the circumstances set forth under 45 CFR 164.512(c) where the individual meets the clarified definition of person. The Privacy Rule permission concerning serious and imminent threats [FN200] applies to threats to a person, consistent with the definition as clarified by this final rule, or the public.

2. Interpreting Terms Used in Section 1178(b) of the Social Security Act Reporting of Disease or Injury, Birth, or Death

Section 1178(a) of the SSA provides that HIPAA generally preempts contrary state laws with certain limited exceptions, such as those described in section 1178(b).[FN201] Specifically, section 1178(b) excepts from HIPAA's general preemption authority laws that provide for certain public health reporting, such as the reporting of disease or injury, birth, or death.[FN202] HIPAA does not define the terms in section 1178(b) that govern the scope of this exception to HIPAA's general preemption authority, nor has the Department previously defined such terms through rulemaking.

The Department recognizes that such public health reporting activities are an important means of identifying threats to the health and safety of the public. Accordingly, when a public health authority [FN203] has furnished documentation of its authority [FN204] to collect or receive such information, the Privacy Rule permits a regulated entity, without an individual's authorization, to use or disclose PHI to specified persons for public health activities.[FN205] These activities include all of the vital statistics reporting activities described in section 1178(b), including reporting of diseases and injuries, birth, or death.[FN206]

The Department proposed to interpret in preamble key terms used in section 1178(b) to clarify when HIPAA's general preemption authority applies. Specifically, the Department proposed an interpretation of section 1178(b) that would clarify that HIPAA's general preemption authority applies to laws that require regulated entities to use or disclose PHI for a purpose that would be prohibited under the proposed rule. Under this interpretation, the Privacy Rule permission to use or disclose PHI without an individual's authorization for the reporting of disease or injury, birth, or death [FN207] would not permit the use or disclosure of PHI for a criminal, civil, or administrative investigation into or proceeding against a person in connection with seeking, obtaining, ***32999** providing, or facilitating reproductive health care. The Department did not intend this clarification to prevent disclosures of PHI from regulated entities to public health authorities for public health purposes that have been and continue to be permitted under the Privacy Rule. Nor did the Department intend for this proposed clarification to prevent disclosures of PHI by regulated entities under other permissions in the Privacy Rule, such as for law enforcement purposes,[FN208] when made consistent with the conditions of the relevant permission and where the purpose of the disclosure is not one for which a use or disclosure would have been prohibited under 45 CFR 164.502(a)(5)(iii) as proposed.

The Department did not propose to define “disease or injury,” “birth,” or “death,” because we believed that these terms, when read with the definition of “person” and in the broader context of HIPAA, would exclude information about reproductive health care without the need for further clarification.[FN209] However, the Department invited public comment on whether it would be beneficial to make such clarification.

Few commenters addressed interpretation of these terms. Some commenters expressed concern that the Department's interpretation would prevent beneficial public health reporting about certain types of reproductive health care, while others requested that the Department prohibit public health reporting about certain types of reproductive health care. Some commenters on this issue agreed with the Department's interpretation and clarification of the terms used in 1178(b). Several of these commenters requested that the Department define or clarify these terms because reporting standards are inconsistent across states.

The Department declines to add definitions for “disease or injury,” “birth,” or “death” to the Privacy Rule in this final rule. However, we offer the discussion below to provide additional context on our interpretation of these terms.

At the time of HIPAA's enactment, state laws provided for the reporting of disease or injury, birth, or death by covered health care providers and other persons.[FN210] State public health reporting systems were well established and involved close collaboration between the state, local, or territorial jurisdiction and the Federal Government.[FN211] Reports generally were made to public health authorities or, in some specific cases, law enforcement (e.g., reporting of gunshot wounds).[FN212] Similar public health reporting systems continue to exist today.

Reporting of “disease or injury” commonly refers to diagnosable health conditions reported for limited purposes such as workers' compensation, tort claims, or communicable or other disease or injury tracking efforts. States, territories, and Tribal governments require health care providers (e.g., physicians, laboratories) and some others (e.g., medical examiners, coroners, veterinarians, [FN213] local boards of health) to report cases of certain diseases or conditions that affect public health, such as coronavirus disease 2019 (COVID-19), malaria, and foodborne illnesses.[FN214] Such reporting enables public health practitioners to study and explain diseases and their spread, along with determining appropriate actions to prevent and respond to outbreaks.[FN215] States also require health care providers to report incidents of certain types of injuries, such as those caused by gunshots, knives, or burns.[FN216] Various Federal statutes use the phrase “disease or injury” similarly to refer to events such as workplace injuries for purposes of compensation.[FN217]

The limited meaning given to the terms “disease” and “injury” for purposes of public health reporting is clear from HIPAA's broader context. For instance, interpreting “injury” reporting to include disclosures about all instances of suspected criminal abuse would render the specific permission to report “child abuse” superfluous.[FN218] And interpreting “disease” reporting to include disclosures about any sort of disease for any purpose would both eviscerate HIPAA's general provisions protecting

PHI and make superfluous the statutory requirement to not invalidate laws providing for public health surveillance, or public health investigation or intervention. For example, "disease management activities" constitute "health care" under the Privacy Rule. As such, a broad interpretation of "disease or injury" reporting could make potentially all the health records detailing a particular individual's treatment for any disease or injury disclosable to a public health authority or others unrelated to the health care.[FN219] Consequently, the Department has long understood "disease or injury" to narrowly refer to diagnosable health conditions reported for limited purposes such as workers' compensation, tort claims or in compliance with Federal laws that require states to conduct surveillance of specific diseases and injuries related to public health or Federal funding.[FN220]

With respect to reporting of "births" and "deaths," such vital statistics are reported by health care providers to the vital registration systems operated in ***33000** various jurisdictions [FN221] legally responsible for the registration of vital events. [FN222] State laws require birth certificates to be completed for all births, and Federal law mandates the national collection and publication of births and other vital statistics data.[FN223] Tracking and reporting death is a complex and decentralized process with a variety of systems used by more than 6,000 local vital registrars.[FN224] When HIPAA was enacted, the Model State Vital Statistics Act and Regulations, which is followed by most states,[FN225] included distinct categories for "live births," "fetal deaths," and "induced terminations of pregnancy," with instructions that abortions "shall not be reported as fetal deaths." [FN226] In light of that common understanding at the time of HIPAA's enactment, it is clear that the reporting of abortions is not included in the category of reporting of deaths for the purposes of HIPAA and does not fall within the scope of state death reporting activities that Congress specifically designated as excepted from preemption by HIPAA.

More generally, while Congress exempted certain "[p]ublic health" laws from preemption,[FN227] Congress chose not to create a general exception for criminal laws or other laws that address the disclosure of information about similar types of activities outside of the public health context.

For all these reasons, state laws requiring the use or disclosure of PHI for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities, are subject to HIPAA's general preemption provision. Similarly, the Privacy Rule's public health provisions that permit the disclosure of PHI for the reporting of disease or injury, birth, or death do not include permission to use or disclose PHI for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities. This general distinction between public health activities and investigation and enforcement activities is not limited to reproductive health care. Nevertheless, as discussed elsewhere in this final rule, the Department has chosen to strike a balance between privacy interests and other public policy interests. Consistent with the Department's longstanding approach that has allowed disclosures for law enforcement purposes in certain circumstances, the new prohibitions set forth in this rule apply only to lawful reproductive health care. State authorities cannot rely on the Privacy Rule's permissions for disclosures related to disease or injury, birth, or death to obtain PHI for the purpose of investigating or imposing liability for the provision of reproductive health care. However, as discussed above, state authorities may be able to invoke other permissions, such as the permission for disclosures for law enforcement purposes, to obtain such PHI where such disclosure is to investigate or impose liability on a person when the reproductive health care at issue is unlawful under the circumstances in which it is provided.

Comment: A few commenters expressed support for the Department's interpretation and clarification of the terms used in section 1178(b) of the SSA. A few commenters recommended that the Department define, rather than clarify, these terms. Some commenters requested that the Department further clarify the terms "disease or injury," "birth," and "death," to explicitly exclude information about reproductive health care. Other commenters expressed opposition to the Department's clarifications.

Response: We decline to define "disease or injury," "birth," or "death" in this final rule. The Department's understanding of these terms is consistent with the Model State Vital Statistics Act and Regulations and its application in the context of the passage of HIPAA. We believe that the 2023 Privacy Rule NPRM preamble discussion is sufficient to clarify that such reporting does not include the use or disclosure of PHI for investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, including reproductive health care, or to identify a person for such activities.

Defining "Public health," as used in the terms "public health surveillance," "public health investigation," and "public health intervention."

Section 1178(b) also excepts state laws providing for "public health surveillance, or public health investigation or intervention" from HIPAA's general preemption authority.[FN228] Neither HIPAA nor the Privacy Rule currently defines "public health surveillance" or "public health investigation or intervention." Consistent with the statute, the Privacy Rule expressly permits a regulated entity to use or disclose PHI for "public health" surveillance, investigation, or intervention.[FN229] The Department proposed to define public health, as used in the terms "public health surveillance," "public health investigations," and "public health interventions," to mean population-level activities to prevent disease and promote health of populations. In preamble to the 2023 Privacy Rule NPRM, the Department described public health surveillance as the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice.[FN230] The Department explained that public health investigations or interventions include monitoring real-time health status and identifying patterns to develop strategies to address chronic diseases and injuries, as well as using real-time data to identify and respond to acute outbreaks, emergencies, and other health hazards.[FN231] Public health surveillance, investigations, or interventions safeguard the health of the community by addressing ongoing or prospective population-level issues such as the spread of communicable diseases, even where these activities involve ***33001** individual-level investigations or interventions.

The Department also proposed to expressly exclude certain activities from the definition of public health to distinguish between public health activities and certain criminal investigations. Specifically, the Department proposed to provide in regulatory text that the Privacy Rule's permissions to use and disclose PHI for the "public health" activities of surveillance, investigations, or interventions do not include criminal, civil, or administrative investigations into, or proceedings against, any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, nor do they include identifying any person for the purpose of initiating such investigations or proceedings. The Department stated that any such actions are not public health activities that would be subject to the exception to HIPAA's general preemption authority for state laws providing for "public health surveillance, or public health investigation or intervention." [FN232]

Commenters expressed mixed views on the proposal to define "public health" in the context of "public health surveillance," "public health investigations" or "public health interventions." Commenters expressing opposition to the proposal either disagreed with the Department's assertion that public health activities do not involve uses and disclosures that would be prohibited by the rule or asserted that the proposal would prevent public health reporting of reproductive health care. Some commenters generally supported the goal of the proposal but expressed concern that inclusion of the proposed language about "population-level" activities could prevent essential public health activities that involve specific persons, such as reporting data about specific health care services provided to specific persons that have a "population-level" effect and investigating the spread of communicable diseases.

Some commenters asserted that the proposal would frustrate states' ability to enforce their laws not related to public health, such as laws banning health care such as abortion. Supporters asserted that the proposal would help to prevent PHI from being disclosed for a purpose that would be prohibited under the proposed rule. Supportive commenters also expressed concern about states obtaining PHI based on an interpretation of "public health investigations" that includes the mandatory reporting of pregnant individuals who engage in certain activities, such as substance use. Other commenters asserted that disclosures of PHI to public health authorities should be limited because of the potential for PHI to be redisclosed for purposes that otherwise would be prohibited under the Privacy Rule.

The final rule adopts the proposed definition with some modifications. The final rule maintains the proposed rule's focus on activities aimed at preventing disease and improving the health of populations. This definition does not prevent disclosures of PHI by covered entities to public health authorities for public health activities that have long been permitted under the Privacy Rule. As discussed in the 2023 Privacy Rule NPRM, since the time of HIPAA's enactment, public health activities related to surveillance, investigation, or intervention have been widely understood to refer to activities aimed at improving the health of a

population. For example, legal dictionaries define "public health" as "[t]he health of the community at large," or "[t]he healthful or sanitary condition of the general body of people or the community en masse; esp., the methods of maintaining the health of the community, as by preventive medicine or organized care for the sick." [FN233] Stedman's Medical Dictionary defines "public health" as "the art and science of community health, concerned with statistics, epidemiology, hygiene, and the prevention and eradication of epidemic diseases; an effort organized by society to promote, protect, and restore the people's health; public health is a social institution, a service, and a practice." [FN234] The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry have described "public health surveillance" as "the ongoing systematic collection, analysis and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice." [FN235] And many states similarly define "public health" to mean activities to support population health.[FN236] The Department likewise has used the term public health in this way since it first adopted the Privacy Rule.[FN237]

Public health surveillance, public health investigations, and public health interventions are activities that address population health concerns and have generalized public benefit [FN238] to the health of a population, including activities that involve specific persons. Examples of activities that prevent disease in and promote the health of populations include vaccination campaigns to eradicate communicable disease, surveillance of a community's use of emergency services after a natural disaster to improve allocation of resources to meet health needs, and investigation of the source of an outbreak of food poisoning. As explained in the preamble to the 2023 Privacy Rule NPRM,[FN239] there is a widely recognized distinction between public health activities, which primarily focus on improving the health of populations, and criminal investigations, which primarily focus on identifying and imposing liability on persons who have ***33002** violated the law.[FN240] States and other local governing authorities maintain criminal codes that are distinct and separate from public health reporting laws,[FN241] although some jurisdictions enforce required public health reporting through criminal statutes. Different governmental bodies are responsible for enforcing these separate codes, and public health officials do not typically investigate activities enforced under criminal statutes or laws.[FN242] Federal laws also generally treat public health investigations as distinct from criminal investigations.[FN243] Maintaining a clear distinction between public health investigations and criminal investigations serves HIPAA's broader purposes.[FN244]

The Department concludes that neither section 1178(b) nor the Privacy Rule's permissions to use and disclose PHI for the "public health" activities of surveillance, investigation, or intervention include conducting criminal, civil, or administrative investigations into, or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, including reproductive health care, nor do they include the identification of any person for such purposes. Such actions are not public health activities. As described above, this distinction between public health activities and other investigation and enforcement activities is not limited to reproductive health care. Public health surveillance, investigations, or interventions ensure the health of the community as a whole by addressing ongoing or prospective population-level issues such as the spread of communicable diseases, even where they involve interventions involving specific individuals. Such surveillance systems provide the necessary data to examine and potentially develop interventions to improve the public's health, such as providing education or resources to support individuals' access to health care and improve health outcomes and are not affected by this final rule.[FN245] U.S. states, territories, and Tribal governments participate in bilateral agreements with the Federal Government to share data on conditions that affect public health.[FN246] The CDC's Division of Reproductive Health collects reproductive health data in support of national and state-based population surveillance systems to assess maternal complications, mortality and pregnancy-related disparities, and the numbers and characteristics of individuals who obtain legal induced abortions.[FN247] This final rule does not affect CDC's ability to collect this information now or in the future. Importantly, disclosures to public health authorities permitted by the Privacy Rule are limited to the "minimum necessary" to accomplish the public health purpose.[FN248] In some cases, regulated entities need disclose only de-identified data [FN249] to meet the public health purpose.

By contrast, efforts to conduct criminal, civil, and administrative investigations or impose criminal, civil, and administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care generally target specific persons for particular conduct; they are not designed to address population-level health concerns and are not limited to information authorized to be collected by a public health or similar government authority for a public health activity. Thus, the

exceptions in section 1178(b) for "public health" investigations, interventions, or surveillance do not limit the Department's ability to prohibit uses or disclosures of PHI for other purposes, such as judicial and administrative proceedings or law enforcement purposes. While the Department has chosen as a policy matter to continue to permit uses or disclosures of PHI for law enforcement and other purposes in certain contexts, it is adopting a different balance where such uses or disclosures are about reproductive health care that is lawful under the circumstances in which it was provided.

While retaining the focus on activities to prevent disease and promote the health of populations, this final rule clarifies that population-level activities "include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information." This clarification addresses commenters' concerns that regulated entities would no longer be able to report information that states need to conduct public health functions intended to protect against prospective or ongoing threats at the population level, even if at times they necessarily will focus on individuals while doing so (through contact tracing, quarantine or isolation, and the like). The Department does not intend this clarification to prevent disclosures of PHI from covered entities to public health authorities for public health activities that have long been and continue to be permitted under the Privacy Rule. These changes clarify that public health, as used in the specified terms, broadly includes activities to prevent disease in and promote the health of populations. The changes also confirm that the Department does not require a public health authority to supply an attestation to a covered entity to receive PHI of an individual where that disclosure is intended to prevent disease in or promote the health of populations.

The intended purpose of including "population-level" was to facilitate ***33003** public health activities that protect large numbers of people from epidemics, environmental hazards, and the like. However, we believe that the language that clarifies that population-level activities "include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information," sufficiently serves this purpose of addressing uses and disclosures of PHI that are necessary to accomplish the overarching goals of public health.

The last sentence of the proposed definition, which described what are not public health activities, is also revised in the final rule for consistency with the general distinction between activities of public health surveillance, investigation, and intervention and activities of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying a person for such activities, as well as the standard the Department is adopting at 45 CFR 164.502(a)(5)(iii), which is discussed further in that section of this rule. Thus, while a state might assert that investigating or imposing liability on persons for the mere act of seeking, obtaining, providing, or facilitating health care satisfies the definition of "public health," their interpretation would not supersede the definition of "public health" in the context of public health surveillance, investigations, or interventions that the Department is adopting under its own Federal statutory authority to administer the HIPAA Rules.

Comment: A few organizations expressed support for the proposed definition of "public health" without further elaboration. Several commenters expressed support for the proposed definition of "public health" because it would prevent PHI from being disclosed for a prohibited purpose. A few commenters expressed support for the proposal because they believed that information reported for public health purposes could be requested, re-identified (in the case of de-identified information), or further disclosed to law enforcement for purposes for which the Department proposed to prohibit uses and disclosures.

Several commenters expressed support for the proposed definition of "public health" and the existing standard that limits public health disclosures of PHI to the minimum necessary information to achieve the purpose.

Response: Consistent with the NPRM, the Department agrees with the commenters who stated that it is important to define "public health" in the context of public health surveillance, investigation, or intervention to ensure that PHI is not disclosed for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). Disclosures of PHI for public health purposes continue to be subject to the minimum necessary standard, which limits the use and disclosure of PHI to the minimum necessary to achieve the specified purpose; in some circumstances, de-identified information may suffice. However, many public health activities do

require identifiable data, such as for interventions involving individuals, to protect against prospective or ongoing threats to health or safety at the population level, and the Privacy Rule does not prohibit such uses and disclosures.

When making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose, regulated entities are permitted, but not required, to rely on that representation, if such reliance is reasonable under the circumstances.[FN250] Such reliance may not be reasonable where the request appears to be overly broad when compared to the stated purpose of the request (e.g., where a public health authority requests the disclosure of PHI of all individuals who received treatment for uterine bleeding when the stated purpose is to investigate infection control practices by an obstetrician/gynecologist in a state where law enforcement has publicly announced its intention to investigate individuals for traveling out of state to seek or obtain reproductive health care that is lawful under the circumstances in which it is provided).

Comment: A few commenters asserted that law enforcement generally interprets public health investigations to include criminal investigations and prosecutions and the NPRM proposed definition would complicate such investigations by limiting the amount of PHI that could be disclosed to law enforcement.

Response: The Department has adopted a definition of "public health" in the context of public health surveillance, investigation, and intervention that sets clear parameters between such activities and law enforcement activities conducted to impose liability for the mere act of seeking, obtaining, providing, or facilitating health care. Public health surveillance, investigation, and intervention do not include efforts to attach liability to persons for specific acts of seeking, obtaining, providing, or facilitating health care.

This definition is consistent with the longstanding distinction made by the Department between public health activities and law enforcement activities as described above.

Comment: Several commenters expressed support for the Department's proposal generally but recommended further clarifications or revisions to it, especially regarding the limitation to "population-level" activities. A few commenters raised questions about the difference between the proposed definition of "public health" and the permission for public health activities under 45 CFR 164.512(b)(1)(i) and recommended that the Department clarify the definition to ensure that public health agencies are able to obtain health information for administrative or civil proceedings, such as quarantine or isolation in cases involving infectious diseases.

Response: The Department has modified the definition of "public health" in the context of public health surveillance, investigation, or intervention to clarify that such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of PHI. This change addresses commenters' concerns that under the proposed definition, regulated entities would no longer be able to report PHI that is required to address population-level concerns.

Comment: Several commenters raised concerns that the proposed definition of "public health" would circumvent states' interests related to public health. A few commenters expressed opposition to the Department's clarification of public health because they believed that states should have the ability to conduct surveillance, investigations, or interventions concerning certain types of health care for public health purposes. Several commenters asserted that the proposal would frustrate the ability of states to enforce their laws prohibiting access to certain types of health care. Conversely, a commenter requested that the Department explicitly exclude reproductive health care from the proposed definition of "public health," so it would not be reportable to public health agencies.

Response: We disagree with commenters' assertions that this final rule will prevent the reporting of vital statistics or other public health ***33004** activities. A covered entity may continue to use or disclose PHI for all the public health activities and purposes listed in section 1178(b). We also decline to explicitly exclude reproductive health care from the definition of "public health"

because doing so could hinder beneficial public health activities. Instead, this definition supports this final rule's prohibition against certain uses and disclosures of PHI by clarifying that public health surveillance, investigation, and intervention exclude conducting a criminal, civil, or administrative investigation into any person, or the imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying any person for such activities. Such excluded activities include those with the purposes that are prohibited at 45 CFR 164.502(a)(5)(iii).

Comment: A few commenters believed that defining "investigation," "intervention," or "surveillance" was unnecessary or recommended against doing so and requested that the Department clarify that such terms do not encompass any prohibited purposes. One commenter requested that the Department define these terms to expressly exclude information related to reproductive health care.

Response: We are not defining the terms "investigation," "intervention," or "surveillance" in this rule. However, we are providing extensive interpretation in the preamble to clarify that such activities in the public health context do not encompass conducting a criminal, civil, or administrative investigation into any person, or imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care, or identifying any person for such activities, including those for which use or disclosure of PHI is prohibited by 45 CFR 164.502(a)(5)(iii).

Reporting of Child Abuse

In accordance with section 1178(b) of HIPAA, the Privacy Rule permits a regulated entity to use or disclose PHI to report known or suspected child abuse or neglect if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports.[FN251] The Privacy Rule limits disclosures of PHI made pursuant to this permission to the minimum necessary to make the report.[FN252]

As the Department explained in the 2023 Privacy Rule NPRM, at the time HIPAA was enacted, "most, if not all, states had laws that mandated reporting of child abuse or neglect to the appropriate authorities." [FN253] Additionally, when Congress enacted HIPAA, it had already addressed child abuse reporting in other laws, such as the Victims of Child Abuse Act of 1990 [FN254] and the Child Abuse Prevention and Treatment Act.[FN255] For example, 34 U.S.C. 20341(a)(1), a provision of the original Victims of Child Abuse Act of 1990 that is still in place today, requires certain professionals to report suspected abuse when working on Federal land or in a federally operated (or contracted) facility.[FN256] As used in these statutes, the term "child abuse" does not include activities related to reproductive health care, such as abortion.

In the 2023 Privacy Rule NPRM, the Department discussed that it has long interpreted "child abuse," as used in the Privacy Rule and section 1178(b) of HIPAA, to exclude conduct based solely on a person seeking, obtaining, providing, or facilitating reproductive health care.[FN257] This interpretation is consistent with the public health aims of improving access to health care for individuals, including reproductive health care, and with relevant statutes at the time HIPAA was enacted, as described above. The Department also stated that this interpretation prohibits a regulated entity from disclosing PHI in reliance on the permission for reporting "child abuse" where the alleged victim does not meet the definition of "person" or "child," consistent with both 1 U.S.C. 8 and section 1178(b). Additionally, consistent with previous rulemaking under HIPAA, the Department clarified in the preamble that it did not intend for the interpretation to disrupt longstanding state or Federal child abuse reporting requirements that apply to regulated entities.[FN258]

The Department also made several clarifications in preamble concerning our interpretation of section 1178(b) and the Privacy Rule's public health permission and how we distinguish between public health reporting and disclosures for law enforcement purposes or judicial and administrative proceedings.

Comment: Many commenters supported the Department's clarification and agreed that it would preserve trust between individuals and health care providers, but also requested additional clarification from the Department on its implementation. Few opposed the clarification; those who did expressed concerns about the potential for the clarification to prevent state-mandated reporting in certain circumstances. Many commenters expressed mixed views about the Department's interpretation.

Response: The Department is moving forward with its interpretation as described in the NPRM. As noted above, this final rule does not alter the Privacy Rule's reliance on other applicable law with respect to determining who has the authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, including lawful reproductive health care.[FN259] The Privacy Rule does not permit a regulated entity to disclose PHI as part of a report of suspected child abuse based solely on the fact that a parent seeks reproductive health care (e.g., treatment for a sexually transmitted infection) for a child. However, the regulated entity is permitted to make such disclosure where there is suspicion of sexual abuse that could be the basis of permitted reporting.

Congress defined the term “child” in 1 U.S.C. 8, and the term “child” in the Privacy Rule is consistent with that definition. As such, the Department believes that to the extent this clarification prohibits a regulated entity from disclosing PHI to report “child abuse” under this permission in the Privacy Rule where the alleged victim does not meet the definition of “person,” it is consistent with both 1 U.S.C. 8 and section 1178(b).

The Department also reaffirms its clarification that the Privacy Rule permission to report known or suspected child abuse or neglect permits a disclosure only for the purpose of making a report, and the PHI disclosed must be limited to the minimum necessary information for the purpose of making a report.[FN260] These provisions do not permit the covered entity to disclose PHI in response to a request for the use or disclosure of PHI to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on a ***33005** person based on suspected child abuse. Instead, as we explained in the 2023 Privacy Rule NPRM, any disclosure of PHI in response to this type of request from an investigator, must meet the applicable Privacy Rule conditions for disclosures for judicial and administrative proceedings or law enforcement purposes, as applicable.[FN261] That is the case whether such disclosure is in follow up to the report made by the covered entity (other than to clarify the PHI provided on the report) or part of an investigation initiated based on an allegation or report made by a person other than the covered entity.[FN262]

Moreover, this clarification does not affect the ability of state authorities to invoke other permissions for disclosure under the Privacy Rule, such as the permission for disclosures for law enforcement purposes, where they are seeking PHI related to unlawful reproductive health care.[FN263] Thus, the Department's interpretation of “child abuse” continues to support the protection of children while also serving HIPAA's objectives of protecting the privacy of PHI to promote individuals' trust in the health care system and preserving the relationship between individuals and their health care providers.

Comment: A few commenters recommended that the Department expand the clarification of child abuse to broadly address providing or facilitating all health care, rather than just reproductive health care.

Response: It is beyond the scope of this rule making to expand the clarification to include the provision or facilitation of all lawful health care. We appreciate the recommendations of commenters and will take them under advisement for potential future rulemaking.

3. Adding a Definition of “Reproductive Health Care”

Section 160.103 of the HIPAA Rules defines “health care” as “care, services, or supplies related to the health of an individual.” [FN264] The definition clarifies that the term “includes but is not limited to” several identified types of care, services, and procedures [FN265] and includes examples such as therapeutic, rehabilitative, or maintenance care, as well as sale or dispensing of drugs or devices.

The Department proposed to add and define a new term, “reproductive health care,” that would be a subset of the term “health care.” [FN266] The Department proposed to define “reproductive health care” as “care, services, or supplies related to the reproductive health of the individual.” The Department noted in the NPRM preamble that the HIPAA Rules define “health care” broadly.[FN267]

Consistent with the definition of "health care" in the HIPAA Rules, the proposed definition of "reproductive health care" would have applied broadly and included not only reproductive health care and services furnished by a health care provider and supplies furnished in accordance with a prescription, but also care, services, or supplies furnished by other persons and non-prescription supplies purchased in connection with an individual's reproductive health. The Department proposed to use the term "reproductive health care" rather than "reproductive health services" to ensure that the term was interpreted broadly to capture all health care that could be furnished to address reproductive health, including the provision of medications and devices, whether prescription or over-the-counter.

The Department discussed in preamble some of the types of care, services, and supplies that were included in the proposed term. In keeping with the Department's intention for "reproductive health care" to be inclusive of all types of health care related to an individual's reproductive system, the 2023 Privacy Rule NPRM preamble indicated that the term would include, but not be limited to: contraception, including emergency contraception; pregnancy-related health care; fertility or infertility-related health care; and other types of care, services, or supplies used for the diagnosis and treatment of conditions related to the reproductive system. We also provided a non-exhaustive list of examples of health care within each of these categories of reproductive health care.

Consistent with the definition of "health care" adopted in 2000 in the HIPAA Rules, the Department did not propose a specific definition of "reproductive health" but invited comment on whether including a particular definition of "reproductive health" would be beneficial.

Many commenters supported the proposal and agreed that it would provide the necessary protections for individuals and others. Some referenced existing definitions used by other legal authorities and recommended the Department consider adopting or incorporating them in some manner.

Some commenters opposed the proposal to provide an inclusive definition of reproductive health care. Some commenters asserted that the proposal lacked clarity and was too open-ended, making it difficult to operationalize. Other commenters expressed concern that the proposed definition would permit minors to consent to reproductive health care without parental consent.

The final rule adopts the new term "reproductive health care" and definition with three modifications. First, we replace "care, services, or supplies related to the reproductive health of the individual" with "health care" and add a citation to the HIPAA Rules' definition of that term to clarify that reproductive health care is a subset of "health care."

Second, we specify that the term means health care "that affects the health of the individual in all matters relating to the reproductive system and to its functions and processes." In keeping with the Department's intention for "reproductive health care" to be interpreted broadly and inclusive of all types of health care related to an individual's reproductive system, this additional language clarifies that the definition encompasses the full range of health care related to an individual's reproductive health.

Third, we add a statement reaffirming that the definition should not be construed to establish a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

As discussed in the NPRM, this approach is consistent with the approach the Department took when it adopted the definition of "health care" in the HIPAA Rules. At that time, the Department explained that listing specific activities would create the risk that important activities would be left out and could also create confusion.[FN268]

By describing more fully the breadth of reproductive health care, the definition may decrease the perceived burden to regulated entities of complying with the rule by helping them determine whether a request for ***33006** the use or disclosure of PHI includes PHI that is implicated by this final rule.

To further clarify what is included in reproductive health care for regulated entities, we provide a non-exclusive list of examples that fit within the definition: contraception, including emergency contraception; preconception screening and counseling; management of pregnancy and pregnancy-related conditions, including pregnancy screening, prenatal care, miscarriage management, treatment for preeclampsia, hypertension during pregnancy, gestational diabetes, molar or ectopic pregnancy, and pregnancy termination; fertility and infertility diagnosis and treatment, including assisted reproductive technology and its components [FN269] (e.g., in vitro fertilization (IVF)); diagnosis and treatment of conditions that affect the reproductive system (e.g., perimenopause, menopause, endometriosis, adenomyosis); and other types of care, services, and supplies used for the diagnosis and treatment of conditions related to the reproductive system (e.g., mammography, pregnancy-related nutrition services, postpartum care products).

Additionally, the language in the definition stating that the definition should not be construed to set forth a standard of care or regulate what constitutes clinically appropriate reproductive health care should not be read as limiting "reproductive health care" to only health care that is determined to be appropriate by a health care professional. Rather, it may be the individual who determines whether the health care they receive, such as over-the-counter contraceptives, is appropriate. Like the definition of "health care," the definition of reproductive health care is intended to be broad. Finally, we clarify that meeting the definition is not sufficient for information about such health care to be protected under the HIPAA Rules or this final rule. Rather, the information about such health care still needs to meet the definition of PHI.[FN270]

Comment: Some commenters expressed support for the proposed definition of "reproductive health care." Several commenters specifically expressed their support for a broad definition of the term for various reasons, including: ensuring that providers of reproductive health care can continue to serve vulnerable communities and reduce health care disparities; providing clarity; and mitigating the need for clinical expertise and interpretation for each request for reproductive health information. Other commenters expressed support for the term because it would improve access to care and better reflect the breadth of services that support an individual's reproductive health, enable health care providers to continue to maintain appropriate data safeguards, and enable individuals to feel comfortable disclosing their information without fear of incrimination.

Many other commenters expressed opposition to the proposed definition because it was too expansive and would encompass procedures that they did not consider to be reproductive health care. Many commenters explicitly requested that the definition exclude certain types of health care. A few commenters recommended that the Department narrow the proposed definition to apply only to records directly involving certain specified services and clarify that the final definition does not include other procedures or treatments related to pregnancy or contraception. Another commenter expressed opposition to the proposed definition of "reproductive health care" because they believe that reproductive health information is no more sensitive than other medical information and should not be treated differently.

One commenter opposed the proposed definition of "reproductive health care" because they thought it would prevent health care providers from disclosing PHI to other health care providers for treatment, which would erode individual trust.

Several commenters requested that the Department expand the proposed definition, be more specific in its meaning (e.g., provide additional information about the types of care, services, or supplies included in the definition), or replace it with a more expansive term (e.g., "sensitive personal health care" meaning "care, services, or supplies related to the health of the individual which could expose any person to civil or criminal liability for the mere act of seeking, obtaining, providing, or facilitating such health care"). A commenter urged the Department to define the term "sexual and reproductive health care" to ensure that individuals have reproductive health care privacy, regardless of their sexual orientation or gender identity.

Commenters offered several alternative definitions or terms, such as "including but not limited to services related to contraception, sterilization, preconception care, maternity care, abortion care, and counseling regarding reproductive health care"; the definition of "reproductive health care services" at 18 U.S.C. 248(e)(5); "reproductive and sexual health care services" as defined in California Health and Safety Code section 1367.31; and limiting the definition to capture only health care that

is at risk of being investigated or prosecuted because of Dobbs. Other commenters requested additional precision or clarity in the definition. For example, a commenter recommended that the definition include the specific codes and data points that would constitute reproductive health care that would be prohibited from disclosure under the proposed rule (e.g., International Classification of Diseases (ICD) codes related to reproductive health, ABO blood type and Rh factor).

Several commenters urged the Department to narrow the proposed definition because of operational concerns, including the redirection of resources to making or obtaining legal determinations about whether a particular type of care was reproductive health care. Some explained that health information management staff generally do not have the clinical expertise to determine what would constitute "reproductive health care," while another stated that physicians would also have trouble discerning what health care would meet the proposed definition. Another commenter recommended that the Department include only PHI that is already reliably segregated in EHRs in the definition.

Many commenters requested that the Department further explain the proposed definition either in preamble or the regulatory text. One commenter suggested that in lieu of a definition of "reproductive health care," the Department include an extensive discussion of examples in the preamble and provide entities flexibility to implement policies or procedures that may be affected by the definition of "reproductive health care" in accordance with their operational structures. A few commenters also recommended that the Department provide examples in preamble discussion, rather than regulatory text. One commenter recommended that the Department provide specific examples to illustrate its meaning where there could be ambiguity. Several commenters recommended that examples be included in the regulatory text and provided specific examples of the types ***33007** of health care they thought should be included. Some commenters recommended the Department include examples but did not specify whether they should be in the preamble or in the regulatory text, while other commenters requested that the Department include a non-exhaustive list of examples of reproductive health care in both the regulation and preamble.

Response: After consideration, we have finalized a definition grounded in the Privacy Rule's long-established term "health care." We provide a non-exhaustive list of examples in preamble above. We do not explicitly address all of the many types of health care suggested in comments to avoid creating the impression of a complete list. This is also consistent with our approach regarding the definition of "health care." We emphasize that this definition does not set or affect standards of care, nor does it affect uses and disclosures of PHI for treatment purposes. Operational concerns expressed by some commenters are addressed in response to comments on the prohibition.

4. Whether the Department Should Define Any Additional Terms

The Department requested comments about whether it would be helpful for the Department to define "reproductive health" or any additional terms.[FN271]

Comment: Several commenters recommended that the Department define "reproductive health" because it would ensure that all covered entities would be required to implement changes, or that the PHI of individuals receiving certain types of health care would not be disclosed to states where individuals who receive such health care is being penalized.

Several commenters urged the Department to add the definition of reproductive health adopted by the United Nations and World Health Organization, while others recommended the adoption of the definition articulated by the International Conference on Population and Development in 1994. One commenter expressed opposition to adding a definition of reproductive health as unnecessary, and another instead recommended adoption of a precise definition of "reproductive health care."

Another commenter recommended expanding the definition of PHI to include certain digital data of entities not regulated under HIPAA (e.g., information from period tracking apps). One commenter recommended revising the definition of "health oversight agency" to exclude agencies that investigate or prosecute activities related to reproductive health care. Some commenters requested that the Department define additional terms or clarify existing terms.

Rather than define additional terms, one commenter recommended that the Department ensure that all the proposed definitions would be aligned with the Office of the National Coordinator for Health Information Technology (ONC) and CMS-mandated data elements for Certified Electronic Health Record Technology products and in the electronic clinical quality measures that health care providers are required to report to CMS.

Response: We appreciate the feedback from commenters, but upon further consideration, have concluded that defining any of the additional terms or clarifying additional existing ones is not necessary to support the implementation of this final rule. We also clarify that because HIPAA only authorizes the Department to protect IIHI used or disclosed by covered entities and their business associates, we are not able to regulate information that individuals themselves store and share using consumer health apps.

B. Section 164.502—Uses and Disclosures of Protected Health Information: General Rules

Section 164.502 of the Privacy Rule contains the general rules governing uses and disclosures of PHI. Paragraph (a)(1) of this section sets forth the list of permitted uses and disclosures.

1. Clarifying When PHI May Be Used or Disclosed by Regulated Entities

Section 164.502(a)(1)(iv) generally permits a regulated entity to use or disclose PHI pursuant to and in compliance with a valid authorization under 45 CFR 164.508, except for uses and disclosures of genetic information by a health plan for underwriting purposes prohibited under 45 CFR 164.502(a)(5)(i). Thus, an authorization that purports to allow a health plan to use or disclose PHI for that prohibited purpose is not valid under the Privacy Rule.

The Department proposed to modify 45 CFR 164.502(a)(1)(iv) to incorporate an additional limitation on the ability of a regulated entity to use and disclose PHI pursuant to an individual's authorization.[FN272] Specifically, the Department's proposal would prohibit a regulated entity from using or disclosing PHI pursuant to an individual's authorization where the purpose of the disclosure is for a criminal, civil, or administrative investigation or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or to identify any person for the purpose of initiating such activities. As explained in the 2023 Privacy Rule NPRM, the proposed modification was intended to prevent the misuse of the general permission for a regulated entity to use or disclose PHI pursuant to an individual's authorization to bypass the proposed prohibition against using and disclosing PHI for purposes that would be prohibited by proposed 45 CFR 164.502(a)(5)(iii).

The Department explained in the proposed rule that this change to the authorization permission was necessary to protect individuals' privacy by precluding any possibility that a third party, such as a law enforcement official, could coerce or attempt to coerce an individual into signing an authorization, thereby enabling the third party to circumvent the prohibition proposed at 45 CFR 164.502(a)(5)(iii).

The Department also proposed to modify the general rules in 45 CFR 164.502(a)(1)(vi) to expressly condition certain uses and disclosures made under 45 CFR 164.512 on the receipt of an attestation pursuant to proposed 45 CFR 164.509, which is discussed below in greater detail. For clarity, the Department proposed to revise 45 CFR 164.502(a)(1)(vi) by replacing the sentence containing the conditions for certain permitted uses and disclosures with a lettered list.

Public comments about the use of authorization to use and disclose PHI for the purposes the Department proposed to prohibit in the 2023 Privacy Rule NPRM were generally divided between opposing views and supportive views, although only a few comments expressed full support for the proposal, as drafted. While many commenters shared the Department's concerns about the potential for individuals to be coerced into providing an authorization, some of these commenters nonetheless opposed the proposal because it could limit beneficial disclosures, cause uncertainty about the validity of an authorization, increase the burden on regulated entities, or seem to conflict with state laws that permit the disclosure of certain health information with the individual's explicit written consent.

The Department received no comments on its proposal to replace the ***33008** sentence at 45 CFR 164.502(a)(1)(vi) with a lettered list. Comments on the Department's proposal to condition certain disclosures made under 45 CFR 164.512 on the receipt of an attestation as required by proposed 45 CFR 164.509 are discussed below in greater detail.

The Department is not finalizing its proposal to prohibit a regulated entity from using or disclosing an individual's PHI for the specified purposes pursuant to and in compliance with an individual's authorization. We agree with the majority of public comments discussed in detail below that generally expressed the view that the Privacy Rule's authorization requirements empower individuals to make decisions about who has access to their PHI. We acknowledge that maintaining the permission for regulated entities to obtain an individual's authorization to use and disclose PHI could leave an individual exposed to the potential for duress or coercion by a third party. It could also expose a health care provider or other person who provides or facilitates reproductive health care to liability in the event the authorization is used to affect a disclosure for a prohibited purpose in connection with lawful reproductive health care. However, we believe that continuing to permit uses and disclosures pursuant to an individual's authorization best preserves individual autonomy concerning uses and disclosures of their PHI. Consistent with our practice described above, the Department will monitor closely the interaction of the revised Privacy Rule and the evolving legal landscape to ensure an appropriate balance of protecting the privacy interests of individuals and permitting access to PHI for non-health care purposes.

As we discussed in the proposed rule, there is a relationship between the provision allowing an individual to authorize a regulated entity to use or disclose the individual's PHI to a third party and the HITECH Act requirement that a regulated entity comply with an individual's direction to transmit to another person an electronic copy of the individual's PHI in an EHR ("individual access right to direct").[FN273] Both enhance an individual's autonomy by providing them with the ability to determine who can access the individual's PHI as specified in the authorization or access request. Both also create an opportunity for coercion or attempted coercion of an individual by another person (e.g., a law enforcement official could attempt to coerce an individual into providing the law enforcement official with access to the individual's PHI by offering the individual a reduced sentence for an alleged crime). And while we remain concerned about the potential for coercion or attempted coercion, even if the Department were to finalize the proposed limitation on uses and disclosures with an authorization, the individual would retain the individual access right to direct, which is enshrined in statute. We also believe it would be inconsistent with the spirit of individual access right to direct for the Department to limit the ability of an individual to authorize a regulated entity to disclose their PHI to another person.

For the foregoing reasons, we are not finalizing this proposal, and the language in 45 CFR 164.502(a)(1)(iv) remains unchanged.

Comment: While some commenters expressed concern about the potential for coercion described in the proposed rule, they did not all agree that it would be appropriate to address this concern by prohibiting such disclosures pursuant to an authorization. Some commenters asserted that coercion concerns would not be eliminated by curtailing the ability of individuals to authorize disclosures of their PHI in certain circumstances.

Some commenters explained that prohibiting individuals from requesting disclosures of their PHI pursuant to an authorization for prohibited purposes would create a significant burden for regulated entities, primarily because of the frequent failure of persons requesting the use or disclosure of PHI to provide sufficient detail regarding the purpose of the request to allow them to determine if it would be for a prohibited purpose.

A few commenters asserted that a HIPAA authorization is the safest approach to ensuring an individual is aware of and agrees to the use or disclosure of their PHI. One of those commenters recommended that the Department permit a regulated entity to disclose PHI pursuant to a valid authorization unless the covered entity has actual knowledge that an authorization was not voluntary. A commenter recommended adding a disclaimer or warning to the authorization to provide assurances that an individual was not coerced into disclosing their PHI to law enforcement or other third party that might seek to use the PHI for improper purposes. Still another commenter recommended that the Department require the authorization to indicate the types

of sensitive information the individual intends to share. One commenter recommended that certain disclosures be accompanied by a notice of the individual's rights under the Privacy Rule.

Response: We appreciate comments concerning this proposal and the restriction of individuals' ability to maintain control over their PHI by prohibiting the use of written authorization. The Privacy Rule's written authorization requirements are the most objective means by which an individual can provide direction to a regulated entity about the use and disclosure of their PHI known to a regulated entity. The right of individuals to access their PHI and choose to disclose their PHI to another person is a cornerstone of HIPAA, and as such, we are not proceeding with this proposal. The Department will continue to monitor complaints we receive and the outcome of enforcement actions to identify potential coercion and the effect of permitting individuals to authorize the disclosure of PHI for purposes that are prohibited under 45 CFR 164.502(a)(5)(iii) on the relationship between health care providers and individuals.

We also appreciate the comments that asserted that restricting the ability of regulated entities to use an authorization to obtain PHI for the purposes prohibited in this rulemaking could create a burden for the regulated entities.

To the extent that individuals wish to authorize the use and disclosure of their PHI, particularly when a request is not clear, or when a request seeks only partial parts of a record, a written authorization provides the regulated entity with the opportunity to clarify, with both the individual and the person requesting the disclosure, the PHI that will be disclosed. State laws that require regulated entities to obtain an individual's written consent are generally considered more privacy protective, and thus are not preempted.

Comment: Several commenters expressed support for eliminating the ability of regulated entities to use or disclose PHI pursuant to an authorization in certain circumstances because of the potential for harm to individuals as proposed. One commenter described the potential negative effects of permitting uses and disclosures pursuant to an authorization in certain circumstances on individuals from historically marginalized communities. Another commenter asserted that individuals frequently do not read consent forms provided to them for signature for a variety of reasons, including proficiency. Some commenters expressed concerns that individuals who are the subject of a ***33009** criminal investigation or prosecution would be placed in situations where it would not be possible to obtain a voluntary authorization (e.g., a custodial situation), or that law enforcement could seek to persuade an individual to provide them with access to the individual's PHI through improper means.

Response: We continue to share the concern expressed by commenters about the potential for coercion or harassment of individuals, particularly those in marginalized or underserved communities, to provide authorization for the use or disclosure of their PHI. According to many reports and data cited by the Department and commenters, such individuals more often experience negative interactions with law enforcement or other prosecutorial authorities. We urge HIPAA regulated entities to be mindful of Privacy Rule requirements that could help mitigate the potential for harm resulting from coercion or difficulties individuals may experience in understanding an authorization. For example, 45 CFR 164.508(b)(2)(v) holds invalid authorizations that include "material information [. . .] known by the covered entity to be false"; 45 CFR 164.508(c)(1)(iv) requires that every authorization include a description of each purpose of the requested use or disclosure; and 45 CFR 164.508(c)(3), requires the authorization be written in plain language.[FN274] The Department will continue to monitor complaints, questions, and enforcement outcomes for potential harm from disclosures resulting from authorizations.

Comment: A few commenters requested clarifications of how the proposal would affect other disclosures made pursuant to the Privacy Rule, including disclosures to the individual's attorney, and whether the Department intended it to apply to other consumer-initiated requests, such as part of an Application Programming Interface (API).

A commenter recommended that health care providers be permitted to refuse to release PHI to any consumer health app when the information could lead to civil or criminal repercussions for the health care provider unless the app developer signs a binding agreement that protects them.

Response: We are not finalizing the proposal, but state here that the Department did not intend to affect or disrupt the ability of covered entities to make other disclosures of PHI pursuant to a written authorization under the Privacy Rule. Additionally, as discussed above, individuals have the right to obtain a copy of their PHI and the individual access right to direct, which could involve releasing PHI to a consumer health app or an API. With respect to EHR and technology vendors and other third parties who facilitate the exchange of PHI on behalf of covered entities, we continue to stress that valid business associate agreements are required by the Privacy Rule and necessary to protect the privacy of the individuals who are the subject of the PHI. ONC also has made clear that it intends to advance technologies that support requirements already extant under the HIPAA Privacy Rule. [FN275] Additionally, the Department continues to urge covered entities that have direct contact with individuals to educate such individuals on the risks of disclosing their PHI to persons that are not regulated by HIPAA.[FN276] We will continue to ensure that regulated entities enter into business associate agreements as required by the Privacy Rule.[FN277] We will continue to monitor complaints, questions, and enforcement outcomes.

Comment: Many commenters addressed the relationship between the Department's proposal to eliminate the option for an individual to request disclosure of their information for the prohibited purposes pursuant to an authorization and the individual right of access, particularly, the right of an individual to direct a regulated entity to transmit to a third party an electronic copy of their PHI in an EHR. Several commenters recommended that the Department curtail the individual access right to direct. Some commenters expressed concern about the potential for individuals to be coerced into providing access to their PHI to third parties. A few commenters expressed concerns that some third parties sell PHI for purposes adverse to individuals' interests, including some of the purposes described in the 2023 Privacy Rule NPRM.

A few commenters provided recommendations for ways to educate individuals regarding their rights under the Privacy Rule.

Response: Although we appreciate the comments on this topic, any modifications to the individual access right to direct are beyond the scope of this rulemaking. We reiterate here that covered entities and their technology vendors that meet the definition of business associates must ensure that valid business associate agreements are in place,[FN278] and we urge them to facilitate individuals' awareness of the risks of using third-party consumer apps that are not regulated by HIPAA.[FN279] The Department continues to appreciate the identification of better education resources for individuals and health care providers and commits to providing educational resources through its website, regional offices, and webinars.

2. Adding a New Category of Prohibited Uses and Disclosures

Generally, the Privacy Rule prohibits the use or disclosure of PHI except as permitted or required by the Privacy Rule. Paragraph (a)(5) of section 164.502 contains specific purposes for which the Privacy Rule explicitly prohibits the use and disclosure of PHI. Section 164.502(a)(5)(i) prohibits most health plans from using or disclosing PHI that is genetic information for underwriting purposes, while 45 CFR 164.502(a)(5)(ii) prohibits a regulated entity from selling PHI, except when they have obtained a valid authorization from the individual who is the subject of the PHI.

The Department proposed to add a new paragraph, 45 CFR 164.502(a)(5)(iii), to prohibit regulated entities from using or disclosing an individual's PHI for certain additional purposes, and to describe the scope, applicability, and limitations of the prohibition. Similar to most other ***33010** prohibitions within the Privacy Rule, this prohibition would be purpose-based, rather than a blanket prohibition against uses and disclosures of certain types of PHI.[FN280] The Department's rationale for this approach was four-fold: (1) to be consistent with the existing Privacy Rule permissible use and disclosure structure with which regulated entities are familiar, including the permission to disclose to law enforcement for certain purposes; (2) to avoid imposing a requirement on regulated entities that would necessitate the adoption and implementation of costly technology upgrades to enable data segmentation; [FN281] (3) to recognize that PHI about an individual's reproductive health care may be used or disclosed for a wide variety of purposes, and permitting the use or disclosure of PHI for some of those purposes would erode individuals' ability to trust in the health care system; and (4) to avoid any misperception that the Department is setting a standard of care or substituting its judgment for that of individuals and licensed health care professionals.

Proposed 45 CFR 164.502(a)(5)(iii)(A) would establish a new prohibition against the use or disclosure of PHI. Section (a)(5)(iii)(A)(1) would prohibit the use or disclosure of PHI where the use or disclosure is for a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care. Section 164.502(a)(5)(iii)(A)(2) would prohibit the use or disclosure of PHI to identify any person for the purpose of initiating a criminal, civil, or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care.

The Department proposed 45 CFR 164.502(a)(5)(iii)(B) to explain that "seeking, obtaining, providing, or facilitating" would include, but not be limited to, expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same. As the Department explained in the 2023 Privacy Rule NPRM, the proposed prohibition would apply to any request for PHI to facilitate a criminal, civil, or administrative investigation or proceeding against any person, or to identify any person to initiate an investigation or proceeding, where the basis for the investigation, proceeding, or identification is that the person sought, obtained, provided, or facilitated reproductive health care that is lawful under the circumstances in which such health care is provided. The Department further explained that, consistent with its HIPAA authority, the prohibition would preempt state or other laws requiring a regulated entity to use or disclose PHI in response to a court order or other type of legal process for a purpose prohibited under the proposed rule. Conversely, the prohibition would not preempt laws that require the use or disclosure of PHI for other purposes, such as: public health activities; [FN282] investigations of sexual assault committed against an individual where such use or disclosure is conditioned upon the receipt of an attestation; or investigations into human and sex trafficking, child abuse, or professional misconduct or licensing inquiries.[FN283]

The Department also proposed to subject this prohibition to a Rule of Applicability in 45 CFR 164.502(a)(5)(iii)(C). As the Department explained, the proposed prohibition in 45 CFR 164.502(a)(5)(iii) would prohibit a regulated entity from using or disclosing PHI for certain purposes against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is "lawful under the circumstances in which such health care is provided." [FN284] The Department further explained that it proposed a framework for regulated entities to determine whether the reproductive health care at issue was lawful under the circumstances in which such health care was provided. The proposed language of the Rule of Applicability under this rule would apply where one or more of three specified conditions exist.

The first condition, as proposed in 45 CFR 164.502(a)(5)(iii)(C)(1), addressed reproductive health care provided outside of the state that authorized the investigation or proceeding where such health care is lawful in the state where it is provided. In the proposed rule, we also clarified that the proposal would apply the prohibition in a situation in which the health care is ongoing, has been completed, or has not yet been obtained, provided, or facilitated. The proposed prohibition would recognize that any interest of society in conducting an investigation or proceeding against a person would require balancing with, and generally be outweighed by, the interests of society in protecting the privacy interests of individuals when they access lawful health care. As discussed above, privacy interests are heightened with respect to reproductive health care that is lawful under the circumstances in which it is provided as compared to the interests of law enforcement, and private parties afforded legal rights of action, in investigating or imposing liability for actions related to lawful reproductive health care.

The second condition, proposed in 45 CFR 164.502(a)(5)(iii)(C)(2), addressed reproductive health care protected, required, or authorized by Federal law, regardless of the state in which such health care is provided. It would apply the prohibition to reproductive health care that is lawful under the applicable Federal law and where the investigation or proceeding is against any person in connection with seeking, obtaining, providing, or facilitating reproductive health care. It would apply, for example, where the underlying reproductive health care continues to be protected by the Constitution, such as contraception, or is expressly required or authorized under Federal law.[FN285]

The third condition, proposed in 45 CFR 164.502(a)(5)(iii)(C)(3), would apply the prohibition when the relevant criminal, civil, or administrative investigation or proceeding is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care that is provided in a state consistent with and permitted by the law of that same state.

The Department also proposed a Rule of Construction in 45 CFR 164.502(a)(5)(iii)(D) that provided that the proposed prohibition should not be construed to prohibit a use or disclosure of PHI otherwise permitted by the Privacy Rule unless such use or disclosure is primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.[FN286] The Department proposed the Rule of Construction to avoid an erroneous interpretation of the prohibition ***33011** standard, which otherwise could have been construed to prevent regulated entities from using or disclosing PHI for the purpose of defending themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care that was not lawful under the circumstances in which it was provided.

Most of the comments addressing the proposed prohibition expressed support for the Department's purpose-based approach and the principle that the Privacy Rule should prohibit the use and disclosure of PHI for a criminal, civil, or administrative investigation into or proceeding against any person, or to identify any person to initiate a criminal, civil, or administrative investigation into or proceeding against any person, in connection with seeking, obtaining, providing, or facilitating lawful reproductive health care. At the same time, the Department received many comments that expressed concern about the proposal's clarity and regulated entities' ability to operationalize the Rule of Applicability and Rule of Construction. For example, commenters asserted that to the extent the proposed rule would require regulated entities to determine whether the requested PHI was about reproductive health care that was lawful under the circumstances in which it was provided, making such a determination could be unduly burdensome when the request was about reproductive health care that was not provided by the regulated entity that received the request and could expose them to legal risk in the absence of additional guidance or a safe harbor. Other commenters expressed concern that applying the prohibition would undermine the ability of states to enforce their own health care laws.

Commenters who addressed the proposed Rule of Construction also expressed confusion about how the Department intended "primarily" or "primarily for the purpose of" to be interpreted. Many either requested examples of uses and disclosures that were "primarily" for the underlying prohibited purposes. In lieu of the proposal to avoid liability based on "the mere act of" seeking, obtaining, providing, or facilitating reproductive health care, a few commenters suggested expanding the proposed definition or modifying existing permissions to explicitly exclude conduct based solely on seeking, obtaining, providing, or facilitating certain types of health care.

The Department is finalizing the proposed prohibition that restricts the ability of regulated entities to use or disclose PHI for activities with the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it was provided, or to identify any person for such purposes, with modifications to improve clarity and ease implementation for regulated entities.

The Department is retaining its purpose-based approach in the final rule in light of concerns about the ability of regulated entities to segment certain types of data and in recognition that PHI about an individual's reproductive health may be reflected throughout an individual's longitudinal health record, in addition to being maintained by a wide variety of regulated entities.

As we discussed in the 2023 Privacy Rule NPRM, the Department recognizes that diseases and conditions that are not directly related to an individual's reproductive health may be affected by or have bearing on the individual's reproductive health and the reproductive health care they are eligible to receive, and vice versa. Thus, it may be necessary for all types of health care providers to maintain complete and accurate medical records to ensure that subsequent health care providers are adequately informed in making diagnoses or recommending courses of treatment. For example, an individual with a chronic cardiac or endocrine condition may become pregnant, placing additional strain on the individual's cardiovascular or endocrine system. In such cases, it is essential that their cardiologist or endocrinologist be informed of the pregnancy and consulted as necessary to ensure appropriate health care is provided to the individual because such conditions may have bearing on their pregnancy.

Additionally, the final rule revises the prohibition standard at 45 CFR 164.502(a)(5)(iii) by incorporating language from the proposed Rule of Construction to clarify the purposes for which the Department prohibits uses or disclosures of PHI. In 45 CFR 164.502(a)(5)(iii)(A)(1) and (2), the Department incorporates the "mere act of" language of the proposed Rule of Construction to clarify that the prohibited uses and disclosures of PHI are tied to imposing criminal, civil, or administrative liability for the "mere act of" seeking, obtaining, providing, or facilitating reproductive care and not just "in connection to" such acts.[FN287] Section 164.502(a)(5)(iii)(A)(1) combines the criminal, civil, or administrative investigations language from the proposed prohibition standard with the proposed Rule of Construction to prohibit regulated entities from using or disclosing PHI for activities conducted for the purpose of a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Section 164.502(a)(5)(iii)(A)(2) separates and replaces the "or proceeding against" language from the first condition of the proposed prohibition standard with "to impose criminal, civil, or administrative liability on" and incorporates language from the proposed Rule of Construction to prohibit regulated entities from using or disclosing PHI for activities conducted for the purpose of imposing criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Similar to proposed 45 CFR 164.502(a)(5)(iii)(A)(2), 45 CFR 164.502(a)(5)(iii)(A)(3) now addresses the use or disclosure of PHI to identify any person for the activities described in the other conditions of the prohibition standard. To the extent the purpose in 45 CFR 164.502(a)(5)(iii)(A)(1) relates to activities conducted for an investigation, the purpose in 45 CFR 164.502(a)(5)(iii)(A)(2) relates to the activities to impose liability, including activities that would flow from that investigation, whether it be in the form of proceedings to consider censure, medical license revocation, the imposition of fines or other penalties, or detainment or imprisonment, or the actual imposition of such liability.

The prohibition against the uses and disclosures of PHI finalized in 45 CFR 164.502(a)(5)(iii)(A) is subject to the Rule of Applicability that the Department is finalizing in 45 CFR 164.502(a)(5)(iii)(B). As discussed in the proposed rule and finalized herein, the Rule of Applicability modifies the prohibition standard to make clear that the prohibition encompasses the use or disclosure of PHI for any activities conducted for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that the regulated entity that has received the request for PHI has reasonably determined is lawful under the circumstances in which such health care is provided. The prohibition's ***33012** reference to the "mere act" of seeking, obtaining, providing, or facilitating lawful reproductive health care includes the reasons that the reproductive health care was sought or provided (e.g., an investigation into whether a particular abortion was necessary to save a pregnant person's life would constitute an investigation into the "mere act" of seeking, obtaining, providing, or facilitating reproductive health care). The reference to "mere act" operates the same way with respect to activities conducted to identify any individual for the purposes described above. This includes but is not limited to law enforcement investigations, third party investigations in furtherance of civil proceedings, state licensure proceedings, criminal prosecutions, and family law proceedings. Examples of criminal, civil, or administrative investigations or activities to impose liability for which regulated entities would be prohibited from using or disclosing PHI would also include a civil suit brought by a person exercising a private right of action provided for under state law against an individual or health care provider who obtained, provided, or facilitated a lawful abortion, or a law enforcement investigation into a health care provider for lawfully providing or facilitating the disposal of an embryo at the direction of the individual.

The Department acknowledges that this final rule will not prohibit the use or disclosure of PHI in all instances in which persons request the use or disclosure of PHI for an investigation or to impose liability on a person for seeking, obtaining, providing, or facilitating reproductive health care. As discussed extensively in Section III of this rule, the Privacy Rule has long balanced the privacy interests of individuals with that of society in obtaining PHI for certain non-health care purposes. Accordingly, we acknowledge that in some circumstances, an individual's privacy interest in obtaining lawful care will outweigh law enforcement's interests in the PHI for certain non-health care purposes, while in others, law enforcement's interests in the PHI will outweigh the privacy interests of individuals. As we discussed above in Section III and in the proposed rule, recent developments in the legal landscape have made information about an individual's reproductive health more likely to be sought for punitive non-health care purposes, such as targeting individuals for seeking lawful reproductive health care outside of their home state, and therefore more likely to be subject to disclosure by regulated entities if the requested disclosure is permitted under the Privacy Rule. The Department's approach in this rulemaking limits the application of the prohibition to situations in

which reproductive health care meets one of the conditions of the Rule of Applicability. Accordingly, the prohibition applies only where individuals' privacy interests outweigh the interests of law enforcement, and private parties afforded legal rights of action, in obtaining individuals' PHI for the non-health care purpose of investigating or imposing liability for reproductive health care that was not lawful under the circumstances in which it was provided.

We also acknowledge, as we did in the proposed rule, that in some circumstances, the Privacy Rule imposes greater restrictions on uses and disclosures of PHI than state privacy laws, and the prohibition may delay or hamper enforcement of certain other state laws (e.g., laws governing access to reproductive health care). Such circumstances were contemplated by Congress when it enacted HIPAA.[FN288] For example, a state law might require a covered entity to disclose PHI to law enforcement in furtherance of an investigation, while the final rule may prohibit such a disclosure. In such cases, the provisions of the Privacy Rule would preempt the application of contrary provisions of state law, and the regulated entity could not disclose the PHI.[FN289] However, as discussed above in section III, we reiterate that not all methods to investigate the lawfulness of reproductive health care are foreclosed by this rule.

The Department emphasizes that the prohibition does not apply in circumstances that fall outside of its terms. Where a person requesting PHI identifies a legal basis for the request beyond the mere act of a person having sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which it was provided, the prohibition at 45 CFR 164.502(a)(5)(iii) would not apply. Similarly, if a person obtains reproductive health care that was unlawful, such health care would not be lawful under the circumstances in which it was provided, and the prohibition would not apply. Where the prohibition does not apply, the Privacy Rule permits the requested PHI to be used or disclosed, provided that the use or disclosure is otherwise permitted by the Privacy Rule (i.e., the request meets the requirements of an applicable permission and is accompanied by a valid attestation as described by 45 CFR 164.509, where required). The Department reminds the public that persons who request PHI under false pretenses may be subject to criminal penalties under HIPAA.[FN290]

The Rule of Applicability, as discussed below, vests the determination of whether the reproductive health care was lawful under the circumstances it was provided with the regulated entity that receives the request for PHI and requires that such determination be reasonable. The regulatory presumption, also discussed below, replaces the proposed requirement that a regulated entity make a determination regarding the lawfulness of the reproductive health care where someone other than the regulated entity that receives the request provided such health care. The new language requires that the reproductive health care at issue be presumed lawful under the circumstances in which such health care is provided when provided by a person other than the regulated entity receiving the request. This helps to ensure that the regulated entity is not required to make a determination about the lawfulness of such health care. The presumption may be overcome if certain conditions are met.

In the proposed rule, the Department provided examples that remain helpful in illustrating the operation of the clarified prohibition and how it continues to permit uses and disclosures for legitimate interests.[FN291] For example, the prohibition does not restrict a regulated entity from using or disclosing PHI to a health oversight agency conducting health oversight activities, such as investigating whether reproductive health care was actually provided or appropriately billed in connection with a claim for such services, or investigating substandard medical care or patient abuse.[FN292] However, as discussed above, investigating substandard medical care ***33013** or patient abuse may not be used as a pretext for investigating reproductive health care for purposes that are otherwise prohibited by this final rule. In another example, the rule does not bar a regulated entity from using or disclosing PHI to investigate an alleged violation of the Federal False Claims Act or a state equivalent based on unusual prescribing or billing patterns for erectile dysfunction medication.

This final rule also does not prohibit the use or disclosure of PHI where the PHI is sought to investigate or impose liability on a person for submitting a false claim for reproductive health care for payment to the government. In such a case, the request is not made for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. Instead, the purpose of the request for PHI is to investigate or impose liability on a person for an alleged violation of the Federal False Claims Act or a state equivalent.[FN293] As another example, the revised prohibition standard generally does not prohibit the disclosure of PHI to an Inspector General where the PHI is sought to conduct

an audit aimed at protecting the integrity of the Medicare or Medicaid Program where the audit is not inconsistent with this final rule. This is because the request is generally not being made for the purpose of investigating or imposing liability on a person for the mere act of providing the reproductive health care itself. The prohibition also makes clear that the use or disclosure of PHI is permitted where the purpose of the use or disclosure is to investigate alleged violations of Federal nondiscrimination laws or abusive conduct, such as sexual assault, that may occur in connection with reproductive health care. The prohibition likewise makes clear that the use or disclosure of PHI is permitted where the purpose of the use or disclosure is to penalize the provision of reproductive health care that is not lawful, as defined by the Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B), as long as a Privacy Rule permission applies.

Under the prohibition, a regulated entity could respond to a request for relevant records in a criminal or civil investigation pursuant to 18 U.S.C. 248 regarding freedom of access to clinic entrances. Investigations under this provision are conducted for the purpose of determining whether a person physically obstructed, intimidated, or interfered with persons providing "reproductive health services," [FN294] or attempted to do so. Thus, they do not involve investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that was reasonably determined to be lawful under the circumstances in which such health care was provided by the regulated entity that received the request for PHI.

The final rule retains the proposal's prohibition against the use or disclosure of PHI for activities conducted for the purpose of investigating or imposing liability on "any person" for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or for identifying "any person" for such activities. "Any person" means, based on the HIPAA Rules' definition of "person," [FN295] that the prohibition is not limited to use or disclosure of PHI for use against the individual; rather, the prohibition applies to the use or disclosure of PHI against a regulated entity, or any other person, including an individual or entity, who may have obtained, provided, or facilitated lawful reproductive health care.[FN296]

The Department has always and continues to recognize that there may be a public interest and benefit in disclosing PHI for limited non-health care purposes, including enforcing duly enacted laws. The Department has also always sought to balance competing interests in individual privacy and the use and disclosure of PHI for particular purposes in the Privacy Rule. We balance these competing interests by considering both the harm to individuals that results from the use or disclosure of PHI (e.g., loss of trust in the health care system, potential for financial liability or detainment) and the countervailing interests in disclosure. As discussed above, the Department finds that the final rule reflects the appropriate balance between these interests by prohibiting the use and disclosure of PHI for activities conducted for the purpose of investigating or imposing liability on "any person" for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, or for identifying "any person" for such activities.

Accordingly, the final rule adopts, with modifications discussed below, the proposed Rule of Applicability and re-designates it as 45 CFR 164.502(a)(5)(iii)(B). The final rule text also adds the word "only" in 45 CFR 164.502(a)(5)(iii)(B) to make clear that the prohibition's application is limited to the use or disclosure of PHI "only" where one or more of the conditions set forth in the Rule of Applicability exists.

To address concerns from commenters about how to determine whether reproductive health care is "lawful," the Department finalizes a revised Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B). Specifically, the Rule of Applicability, as finalized, requires that a regulated entity that receives a request for PHI make a reasonable determination about the lawfulness of the reproductive health care in the circumstances in which such health care was provided, where lawfulness is described by 45 CFR 164.502(a)(5)(iii)(B)(1)-(3). Thus, a regulated entity that receives the request for PHI must decide whether it would be reasonable for a similarly situated regulated entity to determine, as provided in the Rule of Applicability, that the reproductive health care is lawful under the circumstances in which such health care is provided.

To make the reasonableness determination, that is, to determine whether it would be reasonable for a similarly situated regulated entity to determine that one or more of the conditions of the Rule of Applicability applies, a regulated entity receiving the request for PHI must evaluate the facts and circumstances under which the reproductive health care was provided. Such facts and circumstances include but are not limited to the individual's diagnosis and prognosis, the time such health care was provided, the location where such health care was provided, and the particular health care provider who provided the health care. This approach is consistent with the current and longstanding practice under the Privacy Rule, whereby a covered entity is responsible for determining whether a requested use or disclosure is permitted under one or more of the permissions set forth in the Privacy Rule. For example, a regulated entity is permitted to make a use or disclosure of PHI where "required by law" pursuant to 45 CFR 164.512(a). To make a use or disclosure under that permission, the regulated entity cannot rely on assertions from the person making the request, but rather, must itself evaluate the relevant law to determine whether ***33014** the use or disclosure is "required by law" and thus permitted under that permission. As discussed above, the Department recognizes that this approach may prevent uses or disclosures in support of some law enforcement investigations (e.g., where a health care provider reasonably determines that its provision of reproductive health care was lawful, but where law enforcement reasonably disagrees or does not provide sufficient factual information for a regulated entity to determine that there is a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided). However, we believe that, in these narrow circumstances, the interests of law enforcement, and private parties afforded legal rights of action, are outweighed by privacy interests and that the current approach strikes the appropriate balance between these competing interests.

The Department is retaining the proposed framework for identifying the circumstances in which reproductive health care is lawful, and thus the prohibition applies. However, we are modifying the regulatory text of the Rule of Applicability to clarify its conditions. As revised, the regulatory text combines the first and third conditions of the Rule of Applicability into a revised 45 CFR 164.502(a)(5)(iii)(B)(1) that focuses on whether the reproductive health care at issue is lawful under the circumstances in which such health care is provided. Under the revised condition, the circumstances in which the prohibition applies are determined by the law of the state in which the health care is provided.

As proposed in the 2023 Privacy Rule NPRM, the first and third conditions, when considered together, would have given the impression that the Department was drawing a distinction between reproductive health care provided in-state or out-of-state, although outcomes would have been the same. As the Department explained in the proposed rule, both the first and third conditions would have prohibited a regulated entity from using or disclosing PHI where the reproductive health care was permitted by the law of the state in which it was provided (e.g., for pregnancy termination that occurs before a state-specific gestational limit or under a relevant exception in a state law restricting pregnancy termination such as when the pregnancy is the result of rape or incest or because the life of the pregnant individual is endangered, for reproductive health care that is generally permitted but must be provided by a specific type of health care professional or in a certain place of service). The outcome of the analysis remains the same under this final rule, which combines the first and third conditions of the Rule of Applicability into one condition. Thus, the revision improves the clarity of the Rule of Applicability by focusing solely on whether the reproductive health care was lawful under the circumstances in which it was provided.

Additionally, the final rule modifies the regulatory text in 45 CFR 164.502(a)(5)(iii)(B)(2) to include an express reference to the U.S. Constitution as a source of Federal law for determining whether reproductive health care is lawful under the circumstances in which such health care is provided. The Department has always intended to include the U.S. Constitution as a source of Federal law, and the final regulatory text now explicitly reflects this. The regulatory text also makes clear that the U.S. Constitution is not the sole source of Federal law and that Federal statutes, regulations, and policies may be the relevant legal authority for determining whether the reproductive health care is protected, required, or authorized under Federal law. This final rule in no way supersedes applicable state law pertaining to the lawfulness of reproductive health care.

To address commenters' concerns about obligating regulated entities to determine whether reproductive health care that occurred outside of the regulated entity is lawful, the Department is adding a new presumption provision at 45 CFR 164.502(a)(5)(iii)(C). It presumes the reproductive health care at issue was lawful under the circumstances in which such health care was provided when it was provided by a person other than the regulated entity receiving the request. The presumption can be overcome

where the regulated entity has either actual knowledge, or factual information supplied by the person requesting the use or disclosure, that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided. The first ground to overcome the presumption—concerning "actual knowledge"—accounts for situations where the regulated entity has actual knowledge that the reproductive health care was not lawful. The second ground to overcome the presumption—concerning "factual information"—accounts for situations where the person making the request has demonstrated to the regulated entity that there is a substantial factual basis that the reproductive health care was unlawful under the circumstances in which such health care was provided. To satisfy the second ground, the regulated entity must obtain from the person making the request sufficient threshold factual evidence that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided.

For example, an investigator requests information from a health plan about claims for coverage of certain reproductive health care provided by a particular health care provider. The health plan must presume that the reproductive health care was lawful unless the health plan has actual knowledge that the reproductive health care was not lawful or the investigator supplied information that demonstrates a substantial factual basis to believe that the reproductive health care was not lawful under these circumstances. The latter condition could be met where the investigator provides the regulated entity with various types of documentation. For example, persons requesting PHI could provide the regulated entity with affidavits supplied by complainants that contain the circumstances under which the reproductive health care was provided. In this example, the presumption would be overcome, and the health plan would be permitted to use or disclose the PHI, assuming that all applicable conditions of the Privacy Rule were otherwise met. In contrast, if the investigator requests the same information but only provides an anonymous report of a particular health care provider providing reproductive health care that is not lawful under the circumstances in which it is provided, the health plan would not have a substantial factual basis to believe that the reproductive health care was not lawful. Accordingly, this final rule would prohibit the health plan from disclosing the requested PHI unless the investigator provides sufficient information to overcome the presumption and the use or disclosure is otherwise permitted by the Privacy Rule. The conditions of making the use or disclosure would include, as described elsewhere in this final rule, obtaining a valid attestation if the relevant permission requires one.

The Department emphasizes that, as demonstrated by the numerous comments on this issue, this regulatory presumption is necessary for workability by the regulated entities subject to this final rule. We recognize that when a regulated entity did not provide the reproductive health care at ***33015** issue, it may not have access to all of the relevant information, including medical records with the necessary information, to determine whether prior reproductive health care obtained by an individual was lawful. We clarify that regulated entities are not expected to conduct research or perform an analysis of an individual's PHI to determine whether prior reproductive health care was lawful under the circumstances in which it was provided when such health care was provided by someone other than the regulated entity that receives the request for the use or disclosure of PHI.

We also reiterate that this final rule is intended to support and clarify the privacy interests of individuals availing themselves of lawful reproductive health care, and not to thwart the interests of states in conducting lawful investigations or imposing liability on the provision of unlawful reproductive health care. While this new regulatory presumption may make it more difficult for a state to investigate whether reproductive health care was unlawful under the circumstances in which it was provided (e.g., when other sources of information that is not PHI are unavailable), as discussed above, the Department has considered those interests and determined that the effects are justified by countervailing privacy benefits. Moreover, as also explained above, society's interest in obtaining PHI in such circumstances is reduced, particularly in light of its continued ability to obtain information from other sources. The Department also emphasizes that it is not applying a blanket presumption that all reproductive health care reflected in a regulated entity's records was lawful under the circumstances in which it was provided. Instead, the presumption applies only where the reproductive health care at issue is provided by someone other than the regulated entity that received the request for the use or disclosure of PHI, and it may be overcome in the circumstances identified above.

In contrast, where a request for PHI is made to the regulated entity that provided the relevant reproductive health care, the regulated entity is responsible for determining whether it provided reproductive health care that was lawful under the

circumstances in which it was provided, including, as discussed above, a review of all available relevant evidence bearing on whether the reproductive health care was lawful under the circumstances in which it was provided. If the regulated entity reasonably determines that the health care was lawfully provided, the prohibition applies, and the regulated entity may not make the use or disclosure.

To illustrate how the presumption would apply, consider a hospital that has PHI about the provision of reproductive health care by a different facility. The hospital is not expected to conduct research or perform analysis into whether reproductive health care obtained at a different facility from another health care provider was lawful under the circumstances in which such health care was provided. Accordingly, the regulated entity, if they receive a request for PHI to which the prohibition at 45 CFR 164.502(a)(5)(iii) may apply, is not expected to review the individual's PHI to determine the lawfulness of the prior reproductive health care. In such situations, the regulated entity is also not expected to research other states' laws to determine whether the reproductive health care was lawful under the circumstances in which it was provided, nor are they expected to consult with an attorney to do the same. Rather, the presumption standard allows the regulated entity to limit their review to information supplied by the person making the request for the use or disclosure of PHI where the request addresses reproductive health care provided by someone other than the regulated entity receiving the request. Thus, a regulated entity that did not provide the reproductive health care must presume that the reproductive health care was lawful under the circumstances in which it was provided unless the conditions of rebutting the presumption are met.

Consider a different example in which a law enforcement official from State A issues a subpoena to a hospital in State A to request the PHI of an individual from State A who is suspected of obtaining reproductive health care in State B that would have been unlawful under the law of State A if provided there. The hospital did not provide the reproductive health care in question, nor did the individual provide information to the hospital about who may have provided such health care. At the time the law enforcement official issues the subpoena, the individual is no longer in the hospital, nor is the individual receiving treatment at the hospital. Additionally, the law enforcement official provided no information in the subpoena that would make it reasonable for the hospital to determine that the reproductive health care at issue was not lawful in the circumstances in which it was provided, that is, to determine that the reproductive health care was not lawful under the law of State B or was not protected, required, or authorized by Federal law. In this case, the hospital did not have actual knowledge that, nor did the information supplied to it by the law enforcement official making the request demonstrate to the hospital a substantial factual basis that, the individual had previously received unlawful reproductive health care; therefore, the reproductive health care is presumed to have been provided under circumstances in which it was lawful to provide such health care. Accordingly, this final rule would prohibit the hospital from disclosing the requested PHI unless the law enforcement official provides sufficient information to overcome the presumption and the use or disclosure is otherwise permitted by the Privacy Rule. This includes, as described elsewhere in this final rule, receipt of a valid attestation if the relevant permission requires one.

Conversely, if the hospital is provided with factual information that demonstrates a substantial factual basis that the reproductive health care at issue was not lawful under the specific circumstances in which such health care was provided, the presumption would be overcome. When a presumption is overcome or rebutted, the Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B) cannot be satisfied (i.e., the regulated entity has actual knowledge, or has received factual information from the person requesting the PHI to determine that there is substantial factual basis to believe, that the reproductive health care was not lawful under the circumstances in which it was provided), and thus, the use or disclosure would not be prohibited under the final rule. As such, the Privacy Rule would permit, but would not require, the hospital to disclose the PHI in response to the subpoena where the use or disclosure meets the requirements of an applicable permission, including the receipt of a valid attestation where required.

In another example, a law enforcement agency presents a covered entity's business associate, such as a cloud service provider, with a subpoena for the PHI of an individual who received reproductive health care as part of its investigation into the health care provider who provided such health care for the provision of that health care. The PHI is encrypted, and the business associate does not have the key to decrypt it or is not permitted under the terms of its business associate agreement with the covered entity to decrypt the PHI. Thus, the business associate lacks a complete view of the individual's PHI and did not provide ***33016** the underlying reproductive health care. Additionally, the business associate has no actual knowledge that the reproductive health

care was unlawful, nor did the person requesting the PHI supply it with information that demonstrates to the business associate a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. In such a case, the presumption that the reproductive health care at issue was lawful applies. If the law enforcement agency does not present more information to overcome the presumption, the Privacy Rule prohibits the business associate from disclosing the requested PHI in response to the subpoena, even if the law enforcement agency has provided an attestation; in this circumstance, the attestation would not be valid because the disclosure is for a purpose that is prohibited by 45 CFR 164.502(a)(5)(iii).

The presumption serves a different purpose than the attestation, which is required when there is a request for PHI potentially related to reproductive health care for certain permitted purposes under the Privacy Rule, as discussed further below. In contrast with the attestation, the presumption applies only where a request for PHI involves a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and the reproductive health care at issue was provided by someone other than the regulated entity that received the request for PHI, so the regulated entity does not have first-hand knowledge of the circumstances in which the reproductive health care was provided. Because the situations in which the presumption applies involve purposes prohibited under 45 CFR 164.502(a)(5)(iii), it is not reasonable for a regulated entity to rely, without additional information, on a statement from the person requesting the use or disclosure, including the statement required in the attestation by 45 CFR 164.509(b)(1)(ii), that the request is not made for a prohibited purpose or that the underlying reproductive health care was unlawful. Thus, such statement alone does not satisfy 45 CFR 164.502(a)(5)(iii)(C)(2). However, if a person requesting the use or disclosure of PHI provides the regulated entity with sufficient information, separate and distinct from the attestation itself, that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided, the presumption would be overcome; in this scenario, the Privacy Rule would permit, but would not require, the regulated entity to disclose the PHI in response to the subpoena. The presumption may also be overcome by, for example, a spontaneous statement from the individual about the circumstances under which they obtained reproductive health care.

As we explained above, this final rule, consistent with the Department's longstanding approach to the Privacy Rule, balances competing interests between the privacy expectations of individuals and society's interests in PHI for certain non-health care purposes. For example, since its inception, the Privacy Rule has permitted a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).[FN297] Elsewhere in the Privacy Rule, covered entities are required to make a determination of whether it is “reasonable under the circumstances” to rely on documentation, statements, or representations from a person requesting PHI to verify the identity of the person requesting PHI and the authority of the person to access the PHI.[FN298] In the case of public officials, we have previously explained that covered entities must verify the identity of the request by examination of reasonable evidence, such as written statement of identity on agency letterhead, an identification badge, or similar proof of official status. In addition, where explicit written evidence of legal process or other authority is required before disclosure may be made, a public official's proof of identity and oral statement that the request is authorized by law are not sufficient to constitute the required reasonable evidence of the legal process or authority.[FN299] In both instances, the Privacy Rule permits regulated entities to rely on representations made by public officials where it is reasonable to do so but makes clear that in some instances, documentary or other evidentiary proof is needed.[FN300]

In this final rule, the Department has enshrined the requirement that a regulated entity make a reasonable determination of whether PHI should be disclosed in response to a request from law enforcement, or other official, in regulatory text and determined that is not reasonable to rely solely on representations of law enforcement or other officials without a written attestation. This approach is due to the high potential for harm to the individual who is the subject of the PHI or to persons who are subject to liability for the mere act of seeking, obtaining, providing or facilitating reproductive health care.

Further, as we discussed above, even in the scenario where a state official seeks PHI to investigate whether the underlying reproductive health care was unlawful, a regulated entity's reasonable determination that the conditions of the prohibition set

forth in the Rule of Applicability are met means that the prohibition applies and the regulated entity is prohibited from using or disclosing the PHI. This does not foreclose the ability of state officials to investigate the circumstances surrounding the provision of the reproductive health care, including through the collection of information from sources that are not regulated under HIPAA, to determine whether a health care provider or other person may have acted unlawfully. Rather, this final rule prohibits the use or disclosure of PHI when it is being used to investigate or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care, or to identify any person to initiate such activities. Indeed, the individual's privacy interests are especially strong where individuals seek lawful reproductive health care and risk either avoiding such lawful health care or being less than truthful with their health care providers because they fear that their PHI will be disclosed.

The Department is re-designating proposed 45 CFR 164.502(a)(5)(iii)(B) as 45 CFR 164.502(a)(5)(iii)(D) and modifying it in response to the ***33017** commenters who provided examples of situations where they could reasonably expect to receive a request for PHI that might relate to "seeking, obtaining, providing, or facilitating reproductive health care." To address these concerns, the Department is revising the list of activities in 45 CFR 164.502(a)(5)(iii)(D) that explain the scope of actions taken by persons that the Department is protecting against impermissible requests for PHI. Specifically, the Department is adding the terms "administering," "authorizing," "providing coverage for," "approving," and "counseling about" to the current list of descriptive activities in the proposed rule and removing "inducing" from the list. We are removing "inducing" from the list in response to concerns from commenters that the prohibition might apply in circumstances where individuals are coerced to obtain reproductive health care. It was never the Department's intention for the prohibition on the use or disclosure of PHI to apply in such circumstances. Rather, we intended it to refer to situations in which a health care provider "induces" labor under circumstances in which such health care is lawful; however, we believe our intended meaning of "inducing" is encompassed in other terms in the list. The revised list better explains the type of activities in which a person may be engaged and about which the Department intends to prevent the use or disclosure of PHI.

The Department is not finalizing a separate Rule of Construction because the need is obviated by incorporating the key content into the prohibition itself at 45 CFR 164.502(a)(5)(iii). The Department proposed the Rule of Construction to clarify that 45 CFR 164.502(a)(5)(iii) should not be construed to prohibit a use or disclosure of PHI otherwise permitted by the Privacy Rule unless such use or disclosure is "primarily for the purpose of" investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care. By incorporating the Rule of Construction into the main standard and removing the proposed "primarily for the purpose of" language, the Department now more clearly conveys its intent to prohibit the use and disclosure of PHI for the specified purposes only when it relates to the "mere act of" seeking, obtaining, providing, or facilitating reproductive health care. As discussed in greater detail below in our responses to comments, this change is designed to reduce confusion for regulated entities about how to reconcile and apply the Rule of Construction with the main prohibition standard and does not change the scope of the prohibition as proposed. The revisions and restructuring of regulatory text formerly included in the Rule of Construction improve readability and reduce redundancy. Likewise, the final rule incorporates other minor wording changes to improve readability and updates regulatory text references to other paragraphs to accurately reflect the organization of this section.

Comment: Many commenters expressed support for the Department's proposal to create a new category of prohibited uses and disclosures about reproductive health care. A few of these commenters explained the rationale for their support as based on the proposed approach's balance of preventing harm to individuals from certain uses and disclosures and permitting beneficial uses and disclosures, while providing regulated entities with clarity with respect to when uses and disclosures of PHI would be permitted.

A few commenters agreed with the Department's view that a purpose-based prohibition is preferable to other approaches to protecting the privacy of individuals that would require labeling or segmenting of PHI. Other commenters focused on how the proposal would better facilitate HIPAA's goals of providing high-quality health care and encouraging the flow of information to covered entities.

Response: The approach we are taking in this final rule preserves the ability of regulated entities to use and disclose PHI for permitted purposes while also enhancing protections for PHI, to strike the appropriate balance between privacy interests and other societal interests, including law enforcement. As discussed above, the Department's approach will lead to numerous benefits associated with enhanced privacy protections.

Comment: A few commenters asserted that the Department's proposal would provide a consistent standard for all states to follow.

Response: The Department believes this final rule will provide clear standards for regulated entities, especially health care providers, by incorporating the prohibition into the Privacy Rule. However, we stress that the prohibition attaches to only requests for uses and disclosures that are for a prohibited purpose where the reproductive health care is lawful under the circumstances in which such health care is provided. Different states and localities have promulgated different standards for the lawfulness of reproductive health care.

Comment: A few commenters expressed their appreciation that the proposal encompassed a broad range of reproductive health care and explained the importance of ensuring that a final rule protects any health information about reproductive health care.

Response: As the Department acknowledged in the 2023 Privacy Rule NPRM, many routine medical examinations and treatments could involve PHI about an individual's reproductive health or reproductive organs and systems. This final rule is not limited to PHI about abortion. The Department recognized the impracticability of attempting to parse out the types of reproductive health care that should be subject to the prohibition and those that should not be. For this reason, and in keeping with the existing scheme of the Privacy Rule, the Department proposed and is finalizing a purpose-based approach to prohibiting the use and disclosure of any PHI for use against any person for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. A regulated entity that receives a request for PHI is charged with making a reasonable determination of whether the conditions of lawfulness set forth in the Rule of Applicability apply. To further assist regulated entities in understanding the broad scope of "reproductive health care," we provide in the preamble a non-exclusive list of examples that fit within the definition.

Comment: Some commenters expressed opposition to this proposal, asserting that the proposed new category would interfere with the enforcement of state laws that restrict or regulate abortion or that the proposal would make it more difficult for regulated entities to determine whether a requested use or disclosure of PHI is permitted under the Privacy Rule because it lacked sufficient specificity.

Response: The Department is finalizing a narrowly tailored prohibition that will only apply when an individual's privacy interest in lawfully obtained reproductive health care outweighs society's interest in obtaining PHI for non-health care purposes. As discussed above, the Department has adopted an approach that strikes the appropriate balance between privacy interests and other interests, including law enforcement interests in accessing PHI to investigate or impose liability on persons for seeking, obtaining, providing, or facilitating reproductive health care that ***33018** is unlawful under the circumstances in which such health care is provided. To help regulated entities operationalize the prohibition, the Department is finalizing an attestation requirement in 45 CFR 164.509 in which persons requesting PHI under a permission that is mostly likely to be used to request PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) must attest that the request is not subject to the prohibition. The Department acknowledges that requests for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) may be made pursuant to another applicable permission and reminds regulated entities that they must evaluate all requests made by a third party for the use or disclosure of PHI to ensure that they are not for a prohibited purpose. Requests not subject to the prohibition would still be subject to the conditions of the relevant permissions in the Privacy Rule. When requests for PHI meet the conditions for permissions in the Privacy Rule, including conditions specified in 45 CFR 164.512, regulated entities are permitted to use and disclose PHI in accordance with such permissions.

Moreover, as we describe above, the Department is modifying the final rule to clarify that the prohibition restricts the use and disclosure of PHI for the enumerated purposes when connected to the "mere act of" seeking, obtaining, providing, or facilitating

reproductive health care. Thus, the prohibition does not prevent the use or disclosure of the PHI about reproductive health care obtained by an individual in all circumstances. Rather, it prevents the use or disclosure of PHI when the purpose of the disclosure is to investigate or impose liability on a person because they sought, obtained, provided, or facilitated reproductive health care that was lawful under the circumstances in which such health care was provided, as determined by the regulated entity that received the request for PHI. For example, a regulated entity would not be prohibited from disclosing an individual's PHI when subpoenaed by law enforcement for the purpose of investigating allegations of sexual assault by or of the individual, assuming that law enforcement provided a valid attestation and met the other conditions of the permission under which the request was made.

Comment: A commenter expressed opposition to the proposal and asserted that it relied on the assumption that it would be readily apparent or ascertainable whether particular reproductive health care was lawfully provided. According to this commenter, persons who violate the law have an interest in concealing their activity, and the proposal would impede law enforcement investigations to determine whether lawbreaking has occurred. Additionally, the commenter expressed their concern that the proposal would represent a departure from the Privacy Rule's existing approach to law enforcement investigations and proceedings.

Response: The Department is finalizing a regulatory presumption to address the narrow circumstance of when lawfulness is not readily apparent to a regulated entity who is the recipient of a request for the use or disclosure PHI when the regulated entity did not provide the underlying reproductive health care. As we explained above, this final rule is intended to support and clarify the privacy interests of individuals availing themselves of lawful reproductive health care, and not to thwart the interests of states and the Federal government in conducting lawful investigations or imposing liability on the provision of unlawful reproductive health care. While this new regulatory presumption may make it more difficult for law enforcement officials to investigate whether reproductive health care was unlawful under the circumstances in which it was provided (e.g., when other sources of information that is not PHI are unavailable), the Department has considered those interests and determined that the effects are justified by countervailing privacy benefits. We also reiterate here that the presumption is not a blanket presumption. It only applies where the reproductive health care at issue is provided by someone other than the regulated entity that received the request for the use or disclosure of PHI, and it may be overcome in the circumstances identified above.

We note that the Privacy Rule has always and continues to permit regulated entities to disclose PHI for law enforcement purposes, subject to certain conditions or limitations. In this final rule, the Department has found that changes in the legal landscape now necessitate codifying a prohibition against uses and disclosures for the purposes specified in 45 CFR 164.502(a)(5)(iii)(A), subject to the Rule of Applicability in 45 CFR 164.502(a)(5)(iii)(B). The Department is not otherwise changing the existing permissions in the Privacy Rule that permit regulated entities to use or disclose PHI for law enforcement purposes and other important non-health care purposes, except as discussed elsewhere in this rule. These purposes include when PHI is required by law to be disclosed for purposes other than those prohibited by this final rule, for public health and health oversight activities, for other law enforcement purposes not in conflict with this rulemaking, for reports of child abuse, about decedents when not prohibited by this final rule, and other purposes specified in the Privacy Rule.

In particular, in the 2023 Privacy Rule NPRM, the Department discussed the interaction of this rule with HIPAA's statutory preemption provisions [FN301] and explained that it was necessary to preempt state laws that require the use and disclosure of PHI for the purposes prohibited by this rule to give effect to the prohibition consistent with HIPAA. As discussed above, to achieve the purpose for which HIPAA was enacted, to enable the electronic exchange of identifiable health information, we must protect the privacy of that information to further individuals' trust in the health care system. As finalized, the prohibition is limited only to circumstances in which the privacy interests of an individual and the interests of society in an effective health care system outweigh society's interest in obtaining PHI for non-health care purposes.

Comment: A commenter stated that, to the extent the ability of a state to determine whether to investigate or bring a proceeding is based on information in the possession of a regulated entity, the proposed rule did not adequately address a state's need to regulate the medical profession and health care facilities.

Response: As finalized, the prohibition prevents the use and disclosure of PHI for certain purposes where a person sought, obtained, provided, or facilitated reproductive health care that is lawful under the circumstances in which such health care is provided. As discussed above, the final rule strikes the appropriate balance between privacy interests and other interests. Public officials remain free to investigate the provision of health care by seeking information from non-covered entities. Moreover, the prohibition does not prevent a state from enforcing its laws. Instead, it protects the privacy of individuals' PHI in certain circumstances.

Comment: A few commenters expressed concern that the proposed prohibition may also affect the enforcement of Federal laws.

Response: The Department has consulted extensively with other Federal agencies and officials in the ***33019** development of this rule, including the Attorney General, and does not believe that this rule will impede the enforcement of Federal laws. As discussed above, this rule carefully balances privacy and other interests, applying only in certain narrowly tailored situations.

Comment: Numerous commenters recommended that the Department expand the scope of the proposed prohibition to include other or all types of stigmatized health care. A few commenters recommended expanding the proposed prohibition to all health care or to provide individuals the ability to prevent the disclosure of their PHI through HIEs.

Generally, commenters supporting expansion of the proposal's scope expressed the belief that it was necessary for HIPAA to promote trust between individuals and health care providers and to improve health care quality and outcomes.

Several commenters explained that persons seeking, obtaining, providing, or facilitating other types of health care are facing the same challenges as described in the proposal with respect to reproductive health care, including health care obtained outside of the health care system, and provided examples of such challenges. Many commenters also made recommendations for how the Department should address those challenges.

Response: The Department is issuing this final rule to protect the privacy of PHI when it is sought for activities to investigate or impose liability on persons for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care. Lawfulness is based on a reasonable determination made by a regulated entity that has received a request for PHI for one of the purposes specified at 45 CFR 164.502(a)(5)(iii)(A) that at least one of the conditions in the Rule of Applicability applies. We are finalizing a prohibition that is not specific to certain procedures, laws, or types of providers. Rather, the prohibition we finalize here requires regulated entities to consider the purpose of the requested use or disclosure. To the extent that the specific types of health care referenced by commenters above meet the definition of reproductive health care, this final rule will prevent the disclosure of PHI where it is sought for activities with the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided. In adopting a purpose-based prohibition, the Department has chosen an administrable standard that reflects the appropriate balance between protecting individuals' privacy interests and allowing the use or disclosure of PHI in support of other important societal interests. Additional privacy protections for information about SUD treatment may be afforded to PHI in Part 2 records under Part 2.[FN302]

Comment: In response to the Department's specific request about whether it should require a regulated entity to obtain an individual's authorization for any uses and disclosures of “highly sensitive PHI” or otherwise address such a defined category of PHI in the Privacy Rule, a few commenters urged the Department to expand the proposed prohibition to protect all people at risk of criminal or other investigation for use of essential health care or care, services, or supplies related to the health of the individual that could expose any person to civil or criminal liability. Several commenters recommended that the Department expand the scope of the proposed prohibition to, variously, all “highly sensitive health information,” “sensitive personal health care,” “highly sensitive PHI,” or “highly sensitive PHI and restricted health care service” because of the potential harms that could result if such health information were to be disclosed without stringent privacy safeguards.

Several commenters asserted that creating a category of or separate standard for "highly sensitive PHI" would cause significant confusion because it would be difficult to define in a commonly understood manner. According to these commenters, this would make compliance more challenging and costly and further decrease the individual's privacy. A few commenters expressed concern that creating a special category of highly sensitive PHI would further stigmatize certain types of health care.

Several commenters expressed concern that prohibiting or limiting uses or disclosures of highly sensitive PHI for certain purposes may negatively affect efforts to eliminate the need for data segmentation, such as efforts to align the Privacy Rule and Part 2; reduce or eliminate stigmatization of certain health conditions and diagnoses; and improve health care management and health care coordination.

Response: We appreciate these comments and generally agree with commenters who expressed concern that the Privacy Rule should address the shifting legal landscape to ensure that it continues to protect PHI, regardless of how the PHI is transmitted or maintained. We also agree that to the extent possible, the Privacy Rule should promote administrative efficiency and disincentivize adverse actions by health care providers grounded in fear of prosecution or legal risks borne from providing lawful health care to individuals, which may erode patients' trust and confidence in the health care system and deter them from seeking lawful health care. The Department's approach to promulgating a narrowly tailored prohibition focused on clarifying the use and disclosure of PHI for the purposes prohibited by this final rule accomplishes these goals. As we explained in the 2023 Privacy Rule NPRM and re-affirm in this final rule, recent developments in the legal environment have made information about lawful reproductive health care sought by or provided to an individual more likely to be of interest for punitive non-health care purposes, and thus more likely to be used or disclosed if sought for a purpose permitted under the Privacy Rule today. As explained, the Department has identified concerns that the use or disclosure of PHI for the prohibited purposes in this rule would erode individuals' trust in the privacy of legal reproductive health care. Such erosion would negatively affect relationships between individuals and their health care providers, result in individuals forgoing needed treatment, and make individuals less likely to share pertinent health concerns with their health care providers. Modifying the Privacy Rule to focus on and address this shifting landscape is the most efficient way to return to a regulatory landscape that is balanced and consistent with the goals of HIPAA.

We do not believe that it is necessary to modify the Privacy Rule to prohibit the use and disclosure of PHI for any criminal, civil, or administrative investigation or effort to impose criminal, civil, or administrative liability related to all health care, services, or supplies. Sections 164.512(e) and (f) already set forth the specified conditions under which regulated entities may disclose PHI for judicial and administrative proceedings and law enforcement purposes.

We decline to modify the prohibition to apply it to the use and disclosure of "highly sensitive PHI." We are persuaded by commenters who voiced concern about the feasibility of defining the phrase such that regulated entities would be able to understand and ***33020** operationalize it. We also find persuasive comments about the compliance burden that would result from implementing such a prohibition. While PHI about reproductive health care may be found throughout an individual's record and may be collected or maintained by multiple types of providers, the term "reproductive health care" is defined in a manner that is clearly connected to the reproductive system, its functions, and processes.[FN303]

In contrast, applying the prohibition to all "highly sensitive PHI" or any use or disclosure of PHI that results in harm, stigma, or adverse result for an individual would be unworkable because of lack of consensus about how to define such categories and would likely create the issues with segmentation and care coordination discussed above. As discussed above, the purpose of this final rule and narrowly crafted prohibition is to adopt the appropriate balance in the Privacy Rule between protecting individuals' privacy and permitting PHI to be used and disclosed for other societal benefits. The commenters' objectives reflect a desire to protect individuals, but their discussion does not properly account for other societal interests that are supported by certain disclosures of PHI, interests that the Privacy Rule has balanced since its inception.

Comment: A commenter requested that the Department clarify that state laws may protect the privacy of health information when the Privacy Rule does not apply, such as when individuals' health information is in the possession of a person that is not a regulated entity, such as a friend or family member, or is stored on a personal cellular phone or tablet.

Response: HIPAA provides the Department with the authority to protect the privacy and security of IIHI that is maintained or transmitted by covered entities, and in some cases, their business associates. Other laws may apply where the HIPAA Rules do not. Guidance on protecting the privacy and security of health information when using a personal cell phone or tablet is available on OCR's website.[FN304]

Comment: Many commenters cited potential operational challenges with the proposed prohibition and confirmed that current health IT generally does not provide regulated entities with the ability to segment PHI into specific categories afforded special protections. A few commenters recommended that the Department work with EHR vendors to modernize health care data management platforms to better address data segmentation, while others recommended that the Department ensure interagency coordination of data segmentation policies and provide individuals with granular level of control over their PHI.

A few commenters requested that the Department address concerns about the interaction between the minimum necessary standard and this final rule.

A commenter asserted that privacy protections that do not account for individual privacy preferences would result in individuals withholding information from their health care providers, and some health care providers electing not to generate or document certain information from or about individuals.

Response: The prohibition, as finalized, should not implicate additional data segmentation concerns beyond those that already exist. We acknowledge the low adoption rate of data segmentation standards and challenges related to the technical and administrative feasibility of data segmentation (e.g., costs), and as discussed above, are finalizing a purpose-based approach to address such concerns. The Department continues its active engagement, particularly through ONC, to identify robust data sharing standards that facilitate appropriate privacy controls.

With respect to concerns about the Privacy Rule minimum necessary standard, we do not anticipate that this final rule will affect the ability of regulated entities subject to the standard to comply. First, the prohibition is applicable only for the purposed uses and disclosures specified in 45 CFR 164.502(a)(5)(iii). Regulated entities must make reasonable efforts to limit the use or disclosure of PHI pursuant to 45 CFR 164.512, other than 45 CFR 164.512(a), to the minimum amount of PHI necessary to accomplish the intended purpose of the use, disclosure, or request.[FN305] Regulated entities are required to have in place policies and procedures that outline how the entity complies with the standard.[FN306]

Comment: A few commenters requested that the Department clarify the roles and responsibilities of covered entities and business associates with respect to compliance with the proposed prohibition and attestation requirements and whether business associate agreements would need to be amended to reflect the requirements of the final rule.

Response: The prohibition standard finalized in 45 CFR 164.502(a)(5)(iii)(A) applies directly to all regulated entities; meaning, all HIPAA covered entities and business associates. We also note that the finalized presumption of lawfulness for the underlying health care, when applicable, directly applies to business associates, as does the attestation requirement in 45 CFR 164.509. As such, business associates of covered entities that hold PHI by virtue of their business associate relationship with the covered entity are subject to the express prohibition on using or disclosing PHI for the specified purposes, regardless of whether the prohibition is specified in the business associate agreement. The attestation requirement and its application to business associates are discussed in greater detail below.

Comment: A commenter expressed support for the application of the proposal to health care providers, but also recognized states' interest in ensuring that health care providers render health care in accordance with the standard of care in that state. Another commenter questioned the Department's authority under HIPAA to implement this provision.

Response: The Department is modifying the proposed definition of "Reproductive health care" to explicitly clarify that the definition does not set a standard of care for or determine what constitutes clinically appropriate reproductive health care. Additionally, as discussed above, the application of this rule is limited to reproductive health care that is lawful under the circumstances in which such health care is provided as described at 45 CFR 164.502(a)(5)(iii)(B). Lawfulness is determined by the regulated entity that receives the request for PHI, after a reasonable determination that at least one of the conditions in the Rule of Applicability apply. As explained above, the prohibition is carefully tailored to protect the privacy of individuals' health information in circumstances where the reproductive health care at issue was lawful under the circumstances such care was provided, reflecting the appropriate balance between privacy interests and other societal interests.

Comment: Many commenters recommended alternative or additional ***33021** approaches to the purpose-based prohibition, such as eliminating or narrowing the permissions for use or disclosure of PHI without an individual's authorization or limiting disclosures to third parties subject to an individual's authorization.

A few commenters recommended that the Department revise specific Privacy Rule permissions to clarify the use and disclosure of PHI for certain administrative or law enforcement requests, instead of promulgating a new prohibition.

Response: The Department's approach to prohibit the uses and disclosures of PHI for the purposes described in this final rule is consistent with the Privacy Rule's longstanding balancing of individual privacy interests with society's interests in PHI for non-health care purposes. Adopting the correct balance is necessary to preserve and promote trust between individuals and health care providers. Instead of modifying specific permissions at 45 CFR 164.512, we are finalizing modifications that prohibit the use or disclosure of PHI to ensure the correct balance, instead of modifying specific permissions at 45 CFR 164.512. Recognizing that requests that fall under these permissions represent important public policy objectives (e.g., health oversight, law enforcement, protection of individuals subject to abuse), the Department is imposing a new attestation requirement, as described in greater detail below, to protect against harm that may arise from the use or disclosure of PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii), which is more likely to occur when a person requesting the use or disclosure of PHI relies on certain permissions. The new attestation condition will also provide a mechanism that will enable a regulated entity to better evaluate the request. The Department declines to make additional changes at this time and will consider these topics for future guidance. The Department also declines to finalize its proposal to prevent an individual from requesting that a regulated entity use or disclose PHI pursuant to a valid authorization.

Comment: A few commenters questioned the ability of regulated entities to use or disclose PHI in compliance with mandatory reporting laws, such as laws requiring the reporting of suspected child abuse or domestic violence.

A few of these commenters questioned whether mandatory reporting requirements would change a regulated entity's duty to apply the minimum necessary standard.

A few commenters asserted that mandatory reporting laws dissuade individuals from seeking health care, prevent the development of trust between individuals and health care providers, and generally are implemented in an inequitable fashion that disproportionately apply to individuals from marginalized or historically underserved communities or communities of color.

Response: The Department acknowledges that there may be some mandatory reporting laws that require a regulated entity to determine whether a request for PHI is for a purpose prohibited by this rule. However, whether in response to a mandatory reporting law or routine request, the final rule's operation remains the same, that is, it prohibits a regulated entity from using or disclosing PHI for a prohibited purpose when the reproductive health care under investigation or at the center of the activity to impose liability is lawful under the circumstances that it was provided.

To the extent mandatory reporting requirements apply to the reporting of PHI to public health authorities for public health purposes, including PHI about reproductive health care, this final rule does not prevent a regulated entity from complying with such mandate.

To aid stakeholders in understanding how the prohibition operates with respect to public health reporting, the Department is clarifying that the term "Public health," as used in public health surveillance, investigation, and intervention, includes identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of PHI. In so doing, we are clarifying that public health surveillance, investigation, and intervention are outside of the scope of activities prohibited by 45 CFR 164.502(a)(5)(iii). These changes will offer additional protection to individuals who would otherwise be subject to having their PHI disclosed for a prohibited purpose because the underlying mandatory reporting requirement did not clearly specify its relationship to public health. This final rule does not change the minimum necessary standard or the circumstances in which the Privacy Rule requires a regulated entity to apply the minimum necessary standard.

Comment: Many commenters expressed concern that the purposes for which the Department proposed to prohibit uses or disclosures would interfere with the ability of law enforcement to conduct investigations, including into coercion, child abuse, and sex trafficking and assault, would prevent states from verifying state licensure requirements, and would hamper the ability of health care professionals to report illegal behavior by other health care professionals.

Response: As discussed above, the prohibition applies only to activities conducted for the purpose of investigating or imposing liability on a person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is provided under circumstances in which such health care is lawful. A regulated entity is permitted to disclose PHI to a person who requests PHI for other purposes if a permission applies and the underlying conditions of the relevant permission are met, including the attestation condition, if applicable.

Comment: A few commenters recommended that the Department establish a safe harbor for the use or disclosure of PHI by regulated entities for TPO.

Response: We appreciate the comment but do not believe such a safe harbor is necessary. The Privacy Rule permits the disclosure of an individual's PHI for TPO when the conditions set forth in the TPO provisions of the rule are met.[FN307] The prohibited uses and disclosures codified in this rulemaking would rarely intersect with uses and disclosures that qualify as TPO activities. As explained above, to the extent a person requesting the use or disclosure of PHI reasonably articulates a basis for a request that is not related to the mere act of seeking, obtaining, providing, or facilitating reproductive health care, a regulated entity may use or disclose the PHI where otherwise permitted by the Privacy Rule.

Comment: A commenter recommended that the Department clarify that the prohibition applies to the activities of insurers and third-party administrators of self-funded plans by adding "administering, authorizing, covering, approving, or gathering or providing information about" to the explanation of "seeking, obtaining, providing, or facilitating."

Response: The prohibition applies to all activities that a person could reasonably be expected to engage in with a regulated entity that could result in a use or disclosure of PHI that might be sought for prohibited purposes, including activities conducted or performed by or on behalf of a health ***33022** plan, including a group health plan.[FN308] Accordingly, the Department has modified the scope of activities initially proposed in the 2023 Privacy Rule NPRM to better explain what it meant by seeking, obtaining, providing, or facilitating reproductive health care. The modified text is finalized at 45 CFR 164.502(a)(5)(iii)(D), [FN309] and adds administering, authorizing, providing coverage for, approving, counseling about to the non-exhaustive list of example activities.

Comment: Several commenters expressed support for the proposed Rule of Applicability. A few commenters expressed support for the proposed Rule of Applicability because it would reassure residents of the state in which the lawful health care is provided and individuals who travel to such states for lawful health care that their medical records will not be disclosed for prohibited purposes.

Response: We are finalizing a modified Rule of Applicability as described above.

Comment: Some comments expressed varying levels of support for the Department's references to "substantial interests" by states or superseding state laws. A few commenters disagreed with the Department's assertion that states lack a legitimate interest in conducting a criminal, civil, or administrative investigation or proceeding into lawful reproductive health care where the investigation is based on the mere fact that reproductive health care was or is being provided. Others asserted that the proposed rule would be unworkable and would assign health care providers and the Department the power to determine whether reproductive health care was provided lawfully, thereby affording them the authority to enforce certain state laws.

Response: As explained above, the Rule of Applicability reflects the Department's careful balancing of privacy interests and other societal interests. For the reasons explained above, the Department has determined that the privacy interest of an individual and the interest of society in an effective health care system outweigh the interests of society in seeking the use of PHI for non-health care purposes that could result in harm to the individual where a regulated entity that receives a request for PHI reasonably determines that at least one of the conditions in the Rule of Applicability applies. To help clarify this discussion further, the Department provides examples where the Rule of Applicability applies in this section of this final rule.

Comment: Several commenters recommended that the Department eliminate the distinction between health care that is lawful and health care that is not and that all forms of reproductive health care should be protected from criminalization and government investigation.

Several commenters stated that the term "lawful" would incorrectly suggest that receiving certain types of reproductive health care could be unlawful, even though most prohibitions on reproductive health care apply to providing or performing the health care, rather than receiving it. They also questioned whether the proposed Rule of Applicability would protect individuals who obtained reproductive health care in another state.

Response: We are finalizing a Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B) that ensures the privacy of PHI when it is sought to conduct an investigation into or impose liability on any person for the mere act of seeking, obtaining, providing or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided, consistent with applicable Federal or state law. A regulated entity that receives a request for PHI must make a reasonable determination that at least one of the conditions in the Rule of Applicability applies. As discussed above, this approach reflects a careful balance between privacy interests and other societal interests.

Comment: Some commenters asserted that medical records should not be used for purposes outside of the health care setting in ways that could harm the subject of the records, particularly for law enforcement or other governmental purposes. One commenter expressed concern that disclosures of PHI would not be limited for all purposes, and that the proposal would not prevent a state from pursuing actions where the health care is later found to be unlawful. Another commenter asserted that disclosing PHI to law enforcement in connection with an investigation into reproductive health care is a secondary use of PHI that would be directly at odds with the purpose for which the PHI was collected, while others stated that the proposal risks deterring individuals from seeking or obtaining necessary health care.

A few commenters expressed concerns that health care providers could be inhibited from providing necessary health care, fully educating individuals about their options, or documenting the health care provided.

Response: When the Department promulgated the 2000 Privacy Rule, we acknowledged that the rule balanced the privacy interests of individuals with the interests of the public in ensuring PHI was available for non-health purposes. As we explained in the 2023 Privacy Rule NPRM, "individuals' right to privacy in information about themselves is not absolute. It does not, for instance, prevent reporting of public health information on communicable diseases or stop law enforcement from getting information when due process has been observed." [FN310] At the same time, in the 2023 Privacy Rule NPRM, the Department acknowledged that adverse consequences do result when individuals question the privacy of their health information and explained that the purpose of HIPAA is to protect the privacy of information and promote trust in the health care system to ensure that individuals do not forgo lawful health care when needed or withhold important information that may affect the quality of their health care.[FN311]

Accordingly, the Privacy Rule provides a clear framework to operationalize these principles, and this final rule is intended to balance these interests. The Privacy Rule does not protect information received or maintained by entities other than those that are regulated under HIPAA, including information that is used for a purpose other than the purpose for which it was initially requested. This final rule provides heightened protection, as necessary, to the privacy of PHI where its use or disclosure may result in harm to a person in connection with seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which such health care is provided. With respect to other disclosures to law enforcement or to other governmental interests, the Privacy Rule includes other carefully crafted permissions that specify the conditions under which such disclosures must be made to ensure a reasonable balance between privacy and the public policies that disclosure would serve.

Comment: Several commenters asserted that the proposed Rule of Applicability would not protect all PHI pertaining to lawful health care. For example, commenters suggested that the proposed Rule of Applicability would be unlikely to protect individuals who ***33023** obtain care outside of the health care system and urged the Department to clarify the final rule to strengthen protections for individuals who receive care in this manner. As another example, a commenter expressed concern that the proposal would not protect PHI for individuals who obtain legal reproductive health care, but as a result of complications, subsequently access health care in a state where the same reproductive health care is illegal.

Response: The definition of "reproductive health care" is discussed in greater detail above. As noted above, this final rule does not establish a standard of care, nor does it regulate what constitutes clinically appropriate health care.

Commenters who point out that different results may arise in different states are correct, but this has been true since the inception of the Privacy Rule because it sets a national floor for privacy standards, rather than a universal rule. The prohibition applies, and therefore liability attaches, when the prohibition is violated, based on the "circumstances in which such health care is provided." Thus, a regulated entity is not permitted to disclose PHI about reproductive health care that was provided in another state where such health care was provided under circumstances in which it was lawful to provide such health care, even where the individual subsequently accesses related health care in a state where it would have been unlawful to provide the underlying health care under the circumstances in which such health care was provided. HIPAA liability attaches in cases where attempts to circumvent the Privacy Rule result in impermissible or wrongful uses or disclosures.[FN312]

We remind regulated entities that the Privacy Rule permits the use or disclosure of PHI, without an individual's signed authorization, only as expressly permitted or required by the Privacy Rule. For example, where state or other applicable law prohibits certain reproductive health care but does not expressly require a regulated entity to report that an individual obtained the prohibited health care, the Privacy Rule would not permit a disclosure to law enforcement or other investigative body pursuant to the "required by law" permission (but could potentially allow it pursuant to other provisions).[FN313]

Comment: One commenter recommended the Department add language to the proposed Rule of Applicability or elsewhere to ensure that there would be protections for PHI where a health care provider believes the health care is legal, even when the person requesting the use or disclosure of PHI disputes the legality. A few commenters asserted that the health care provider

making the decision could be a party to the reproductive health care at issue, making it a conflict of interest for the health care provider to make the determination regarding the lawfulness of the reproductive health care.

Response: We do not believe additional language is necessary because, under the prohibition, the regulated entity—and not the person making the request—is responsible for reasonably determining whether health care was lawful before making a disclosure. As explained above, this framework is consistent with how the Privacy Rule's permissions are administered, whereby regulated entities must determine whether a use or disclosure is permitted under the relevant permission. For example, when evaluating whether a use or disclosure of PHI is permitted because the use or disclosure is required by law, the regulated entity must look to the relevant law to determine whether the use or disclosure falls within that permission.[FN314] Furthermore, as with other use and disclosure provisions in the Privacy Rule, regulated entities remain subject to HIPAA liability for impermissible or wrongful disclosures. Neither the statute nor the Privacy Rule provides an exception to such liability for circumstances involving conflicts of interest.

Comment: Many commenters expressed concern regarding the burden imposed upon and resources that would be required for regulated entities to determine whether the reproductive health care at issue was lawful if they did not provide the health care at issue, particularly considering the evolving nature of state law in this area. Several commenters expressed concern that the proposal incorrectly assumes that regulated entities would know where the reproductive health care at issue occurred and inquired about specific scenarios, such as where requests for PHI are received by clinical laboratories that have no face-to-face interaction with individuals and that rely on information provided by other covered entities. A few commenters asserted that requiring regulated entities to make the required legal determinations would not be conducive to building a trusting relationship between individuals and health care providers.

Some commenters offered recommendations to the Department, such as providing guidance for health care providers regarding their rights and responsibilities under a final rule, revising the proposal to clarify that there would be a presumption that reproductive health care occurred under lawful circumstances, absent compelling evidence to the contrary, particularly when an individual travels for health care, and clarifying the Rule of Applicability by including examples in the regulatory text.

Some commenters asserted that regulated entities in different states or with different interpretations of certain state requirements could reach different determinations about whether the reproductive health care was provided lawfully, in part because of the lack of clarity or consistency in the interpretation in these laws. Yet another commenter recommended that the Department add an express directive that, in the event of any ambiguity or unsettled law, the scope of what is considered lawful should be interpreted consistently with the intent of the rule to protect the privacy of PHI to the maximum extent possible. A commenter recommended that where the regulated entity decides in good faith, it should not be subject to penalties or enforcement action if their determination is incorrect or if the Department disagrees with the determination. Another commenter recommended that the Department clarify that regulated entities may use a reasonableness standard when making the determination about whether state laws conflict with the Privacy Rule and are therefore preempted by HIPAA.

A few commenters expressed concern about the potential interpretation or application of the proposed Rule of Applicability, particularly when the laws at issue are ambiguous. Commenters recommended inclusion of language that PHI need not be disclosed to a government agency or law enforcement if the health care provider deems, in good faith, that the reproductive health care is lawful under the circumstances in which it is provided, and that the Department clarify the application of preemption or provide in preamble examples of each condition of the proposed Rule of Applicability.

Response: We appreciate the many comments the Department received in response to its inquiry asking whether the proposed Rule of Applicability would be sufficiently clear to individuals and covered entities, and ***33024** whether the provision should be made more specific or otherwise modified. Considering the many comments expressing concern about the burden associated with, the difficulty of, or the liability that could attach when someone other than the person who provided the health care must determine whether the underlying reproductive health care is lawful, the Department is adding a regulatory presumption in the final rule.

As discussed above, the regulatory presumption in 45 CFR 164.502(a)(5)(iii)(C) will permit a regulated entity receiving a PHI request that may be subject to the prohibition to presume the reproductive health care at issue was lawful under the circumstances in which such health care was provided when provided by a person other than the regulated entity receiving the request. The presumption includes a knowledge requirement such that the regulated entity must not have actual knowledge that the reproductive health care was unlawful under the circumstances in which such health care was provided or factual information supplied by the person requesting the use or disclosure of PHI that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

Comment: A commenter asserted that the proposed rule would unlawfully thwart enforcement of Federal criminal laws on reproductive health care because the proposed rule would be limited to circumstances where reproductive health care is permitted by state law, thereby prohibiting disclosures for the purpose of enforcing Federal laws pertaining to reproductive health care when they conflict with state law. A few commenters expressed their support for the Department's proposal that the prohibition against the use or disclosure of PHI apply where certain Federal laws apply. A few commenters requested greater specificity with respect to the application of Federal and state laws on abortion.

Response: Federal laws that involve reproductive health care form the underlying basis for examining whether reproductive health care was protected, required, or authorized by Federal law under the circumstances in which it was provided, pursuant to the 45 CFR 164.502(a)(5)(iii)(B)(2). Under this final rule, Federal and state authorities retain the ability to investigate or impose liability on persons where the investigation or imposition of liability is centered upon the provision of reproductive health care that is unlawful under the circumstances in which it is provided. As discussed above, this rule reflects a careful balance between privacy interests and other societal interests, and the prohibition is tailored to cover situations where the reproductive health care was lawfully provided, whether state or Federal law is at issue.

Comment: A few commenters provided examples of and expressed concerns about the electronic availability of PHI about health care lawfully provided in one state to health care providers in another state where such health care would not have been lawful.

A few commenters requested that the Department clarify that clinical laboratory testing involving a validated laboratory-developed test used within a single laboratory certified pursuant to the Clinical Laboratory Improvement Amendments of 1988 [FN315] (CLIA) and the implementing regulations, an in vitro diagnostic test cleared or approved by the Food and Drug Administration (FDA), or a validated laboratory-developed test that is an in vitro diagnostic test cleared or approved by the FDA and used within a single CLIA-certified laboratory would fall within the scope of reproductive health care that would be "authorized by Federal law" for the purposes of the Rule of Applicability. The commenters also recommended that a clinical laboratory test furnished under the authority of a state with legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements, and is therefore exempt from CLIA requirements, also be considered "authorized by Federal law" for the purposes of the Rule of Applicability.

Response: We interpret the language "authorized by Federal law" in the Rule of Applicability to include activities, including clinical laboratory activities, that are conducted as allowed under applicable Federal law, in circumstances where there is no conflicting state restriction on the Federally authorized activity or where applicable Federal law preempts a contrary state restriction. In such circumstances, these activities are lawfully conducted because there either is no relevant state restriction or Federal law preempts a contrary state restriction. This provision thus reflects the Department's careful balancing of privacy interests and other societal interests in disclosure. As explained above, in circumstances where reproductive health care is lawfully provided, privacy interests are heightened while other societal interests in disclosure are reduced. This final rule and the operation of HIPAA's general preemption authority do not supersede applicable state law pertaining to the lawfulness of reproductive health care.

Comment: One commenter expressed support for including the phrase "based primarily" to clarify that the proposed Rule of Construction would only address situations where the purpose of the disclosure is to investigate or impose liability because

reproductive health care was provided, rather than for an issue related to, but not focused on the provision of such health care, such as the quality of the health care provided or whether claims for certain health care were submitted appropriately.

All other commenters recommended removing "primarily" to ensure that there is consistent implementation. In the alternative, the commenters recommended that the Department provide additional examples of scenarios in which a situation would and would not be considered "primarily for the purposes of" or "primarily based on" the provision of reproductive health care. One commenter asserted that the definition is uncertain and could be interpreted as permitting secondary or additional uses or disclosures. Another commenter explained that permitting a use or disclosure where conducting the investigation or imposing liability is only for a secondary or incidental purpose would create too much risk for individuals and health care providers and would undermine the intent of the proposed prohibition. And another stated it is foreseeable that a requesting entity could still use the PHI for one of the purposes for which the Department proposed to prohibit uses or disclosures of PHI once they have it if it was not the primary purpose of their request. A commenter expressed concern that the language could be exploited to manufacture a "primary" purpose that would be permissible to permit PHI to be used or disclosed for a prohibited purpose, particularly because the PHI would lose the protections of the Privacy Rule once it is disclosed to another person, unless that person is also a regulated entity. Another commenter asserted that the proposed rule did not define "primarily" or "mere act," nor did it provide sufficient examples to provide regulated entities with sufficient information to understand the proposal.

A commenter explained that a request for PHI is often for multiple purposes ***33025** and recommended that the Department revise the proposed Rule of Construction to allow the proposed prohibition to apply where at least one of the purposes for which PHI is sought is to use or disclose the information for a prohibited purpose. Similarly, this commenter recommended the proposed attestation requirement in 45 CFR 164.509(b)(1) be revised to state that "one of the uses or disclosures" is not prohibited by 45 CFR 164.502(a)(5)(iii).

Response: We agree with the commenter that explained that a request for PHI may be multi-purposed. We also agree with commenters that pointed out that as proposed, the regulatory Rule of Construction appeared to create a secondary standard to consider whether a regulated entity should be prohibited from using or disclosing PHI. As discussed above, the Department is not finalizing a separate Rule of Construction and is not incorporating the phrase "primarily for the purpose of" originally proposed in 45 CFR 164.502(a)(5)(iii)(D) into the final prohibition standard. The modified prohibition standard more clearly conveys that it only prohibits the use and disclosure of PHI for the specified purposes when it relates to the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care in certain circumstances.

Comment: Commenters also recommended that the proposed Rule of Construction prohibit health care providers from reporting individuals for the sole reason of having received health care in a state where it was not lawful. They described concerns about the effect of interoperability and data sharing rules that give health care providers ready access to individuals' full medical records and urged the Department to expand the proposed Rule of Construction to mitigate the risks created by the electronic exchange of PHI.

Response: The prohibition, as finalized, is narrowly tailored to operate in a manner that protects the interests of individuals and society in protecting the privacy of PHI while still allowing the use or disclosure of PHI for certain non-health care purposes. We remind regulated entities that they are generally prohibited from disclosing PHI unless there is a specific provision of the Privacy Rule that permits (or, in limited instances, requires) such disclosure. For example, the Privacy Rule permits but does not require regulated entities to disclose PHI about an individual, without the individual's authorization, when such disclosure is required by another law and the disclosure complies with the requirements of the other law.[FN316] The permission to disclose PHI as "required by law" is limited to a "mandate contained in law that compels an entity to use or disclose PHI and that is enforceable in a court of law." [FN317] Further, where a disclosure is required by law, the disclosure is limited to the relevant requirements of such law.[FN318] Disclosures that do not meet the "required by law" definition of the HIPAA Rules,[FN319] or that exceed what is required by such law," [FN320] are not permissible disclosures under the required by law permission. Accordingly, regulated entities are prohibited from proactively disclosing PHI under the required by law permission at 45 CFR 164.512(a) absent a law requiring mandatory reporting of such PHI.

Comment: A few commenters asserted that the Department should modify the regulatory text of the proposed prohibition to eliminate the need for the proposed Rule of Construction because it is confusing and appears to set forth two different standards.

Response: For the reasons discussed above, we agree and have incorporated the Rule of Construction into the prohibition standard as described above.

Comment: A commenter expressed concerns that beneficial uses or disclosures, such as for conducting investigations into health care fraud, would be too limited and would not address criminal, civil and administrative proceedings, which are not related to receiving, obtaining, facilitating, or providing reproductive health services where the receipt or provision of these services could serve as evidence of another crime.

Response: We disagree with concerns that beneficial uses or disclosures would be too limited under the changes. If PHI is requested for a purpose that is not prohibited and the request complies with the conditions of an applicable permission, including the requirements of the attestation condition are met, where applicable, the regulated entity is permitted to comply with the request.

Comment: Another commenter cited studies to assert that the proposed Rule of Construction would continue to permit health care providers to proactively report on individuals. The commenter also stated that the proposed rule would not clarify how it would interact with mandatory reporting laws that could expose individuals and health care providers to investigations based on the provision of reproductive health care.

Response: The Privacy Rule does not permit a regulated entity to disclose PHI for law enforcement purposes, proactively or otherwise, without an individual's authorization when the disclosure is not made pursuant to process or as otherwise required by law.[FN321] This is true currently and remains true under this final rule.

As discussed above, HIPAA generally preempts state laws requiring the use or disclosure of PHI, except in limited circumstances. Where such mandatory reporting laws are not preempted by HIPAA, regulated entities are limited to disclosing the minimum amount of PHI necessary to comply with the mandatory reporting requirement or the relevant requirements of such law.[FN322]

Comment: Several commenters responded to the question about whether it would be beneficial for the Department to further clarify or provide examples of uses or disclosures of PHI that would be permitted under a final rule. All of these commenters agreed that it would be beneficial for the Department to do so. Of those, several commenters specified that the Department should provide such examples in the final regulatory text. A few commenters who requested examples be provided within the regulatory text also recommended that the language make clear that the examples are illustrative.

Response: The Department declines to include examples of uses or disclosures of PHI that would be permitted in this rule, in regulatory text. We have provided illustrative examples above.

3. Clarifying Personal Representative Status in the Context of Reproductive Health Care

Section 164.502(g) of the Privacy Rule contains the standard for personal ***33026** representatives and generally requires a regulated entity to treat an individual's personal representative as the individual if that person has authority under applicable law (e.g., state law, court order) to act on behalf of the individual in making decisions related to health care.[FN323] For example, the Privacy Rule would treat a legal guardian of an individual who has been declared incompetent by a court as the personal representative of that individual, if consistent with applicable law.[FN324] In this and certain other provisions, the Department seeks to maintain the longstanding balance HIPAA strikes between the interest of a state or other authorities to regulate health and safety and protect vulnerable individuals [FN325] with the goal of maintaining the privacy protections established in the Privacy Rule.[FN326]

In the 2023 Privacy Rule NPRM, the Department expressed concern that some regulated entities may interpret the Privacy Rule as providing them with the ability to refuse to recognize as an individual's personal representative a person who makes reproductive health care decisions, on behalf of the individual, with which the regulated entity disagrees.[FN327] Under these circumstances, current section 45 CFR 164.502(g)(5) of the Privacy Rule could be interpreted to permit a regulated entity to assert that, by virtue of the personal representative's involvement in the reproductive health care of the individual, the regulated entity believes that the personal representative is subjecting the individual to abuse. Further, this regulated entity might exercise its professional judgment and decide that it is in the best interest of the individual to not recognize the personal representative's authority to make health care decisions for that individual.

To protect the balance of interests struck by the Privacy Rule, the Department proposed to modify 45 CFR 164.502 by adding a new paragraph (g)(5)(iii). Proposed 45 CFR 164.502(g)(5)(iii) would ensure that a regulated entity could not deny personal representative status to a person where such status would otherwise be consistent with state and other applicable law primarily because that person provided or facilitated reproductive health care for an individual. The Department expressed its belief that this proposal was narrowly tailored and respected the interests of states and the Department by not unduly interfering with the ability of states to define the nature of the relationship between an individual and another person, including between a minor and a parent, upon whom the state deems it appropriate to bestow personal representative status. The proposal would, however, maintain the existing HIPAA standard by ensuring personal representative status, when otherwise consistent with state law, would not be affected by the type of underlying health care sought.

Several commenters supported the Department's proposal to clarify that the covered entity's reasonable basis for electing not to treat a person as a personal representative of an individual, despite state law or other requirements of the Privacy Rule, cannot be primarily because the person has provided or facilitated reproductive health care. Other commenters expressed concern about their ability to determine what constitutes reproductive health care, as would be required to ascertain whether the covered entity had a reasonable basis to elect not to treat a person as an individual's personal representative. These commenters requested that the Department provide additional clarity in regulatory text or through examples. Other commenters questioned how the Department's proposal would align with existing state law on parental rights.

As discussed throughout this final rule, reproductive health care is uniquely sensitive and must be treated accordingly. Thus, we are finalizing 45 CFR 164.502(g)(5) with additional modifications as follows. This final rule precludes the denial of personal representative status where the basis of the denial is that the person provided or facilitated reproductive health care instead of the proposed standard that would have precluded denial “primarily” based on these actions. This change clarifies that the covered entity does not have to determine whether the reproductive health care is the “primary” basis for denying a person personal representative status. Additionally, the final rule adds the term “reasonable” before “belief” to align with 45 CFR 164.502(g)(5)(i)(A), clarifying that the basis of the covered entity's belief must be reasonable in the circumstances. We are also renumbering paragraphs. Collectively, these changes clarify that it is not reasonable to elect not to treat a person as an individual's personal representative because the person provides or facilitates reproductive health care for and at the request of the individual. The Department is making these changes in response to comments received on the 2023 Privacy Rule NPRM, which are further discussed below.

Comment: Several commenters supported the Department's proposal to clarify that the covered entity's basis for electing not to treat a person as a personal representative of an individual, despite state law or other requirements of the Privacy Rule, cannot be primarily because the person has provided or facilitated reproductive health care.

Response: As explained throughout this final rule, reproductive health care is uniquely sensitive and must be treated as such. Accordingly, we are finalizing this proposal with modifications as described above.

Comment: A commenter expressed concerns that regulated entities would have difficulty determining whether the “primary” basis for the belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by such person, or

that treating such person as the personal representative could endanger the individual related to the provision or facilitation of the reproductive health care, in some circumstances. The commenter requested that the Department provide additional clarity in the regulatory text or through examples.

Response: As discussed above, we have removed the term "primary" before "basis" and reorganized the provision. We believe this change clarifies that the covered entity does not have to determine whether the provision or facilitation of reproductive health care is the "primary" basis for believing that a person who is an individual's personal representative under applicable law has abused, neglected, or endangered the individual, or may do so in the future, such that the covered entity would be permitted to deny the person personal representative status.

Comment: A few commenters requested that the Department clarify that other existing provisions pertaining to personal representatives continue to apply, including the provision that a covered entity should not treat a parent or guardian as a personal representative where state law does not require a minor to obtain parental consent to lawfully obtain health care.

Response: As discussed above, the Privacy Rule generally requires a covered entity to treat a person who, under applicable law, has the authority to act on behalf of an individual in making decisions related to health care ***33027** as the individual's personal representative with respect to PHI relevant to such personal representation, with limited exception.[FN328] In this final rule, we are clarifying those limited exceptions apply to this general rule.[FN329] We did not propose, nor are we making any additional changes to the Privacy Rule's provisions on personal representatives. Nothing in this final rule is intended to alter any other use or disclosure permissions for personal representatives, nor does it interfere with the ability of states to define the nature of the relationship between a minor and a parent or guardian.

Comment: A commenter asserted that the proposal could lead to situations in which someone pretending to be a personal representative of the individual would consent to reproductive health care for the individual. According to a few commenters, the proposal would make it easier for a person abusing an individual to obtain access to an individual's PHI because of the limits imposed on the reasonable belief provisions by the proposal. Another commenter asserted that the proposal would hinder state investigations into crimes that affect an individual's reproductive health where such crimes are committed by a person meeting a state's definition of a personal representative.

Response: The Department has no reason to believe, and commenters provided no evidence to suggest, that the final rule will lead to abuse or undermine parental consent. Rather, the final rule will protect sensitive PHI by clarifying that a regulated entity must treat a person as a personal representative of an individual with respect to PHI relevant to such personal representation if such person is, under applicable law, authorized to act on behalf of the individual in making decisions related to health care. This includes a court-appointed guardian, a person with a power of attorney, or other persons with legal authority to make health care decisions. Further, under 45 CFR 164.514(h), a covered entity must verify the identity of a person requesting PHI and the authority of any such person to have access to PHI, if the identity is not already known to the covered entity.

Additionally, the final rule allows a covered entity to elect not to treat a person as a personal representative of an individual if the covered entity, in the exercise of professional judgment, has a reasonable belief that the individual has been or may be subjected to domestic violence, abuse, or neglect by such person, or that treating such person as the personal representative could endanger the individual. The final rule only clarifies that the reasonable basis cannot be the provision or facilitation of reproductive health care by the person authorized by applicable law.

Comment: A few commenters recommended that the Department define and interpret personal representative status in the context of reproductive health care consistent with its current interpretation.

Response: We appreciate the comments but decline to specifically define "personal representative" in the context of reproductive health care. We are reducing compliance burdens by eliminating the need for covered entities to determine whether the provision or facilitation of reproductive health care was the "primary" basis for their belief that an individual has been or may be

subjected to domestic violence, abuse, or neglect, or may be endangered by a person authorized by applicable law to act as an individual's personal representative if the covered entity treats the person as such, with respect to PHI relevant to such personal representation.

Comment: A covered entity recommended that the Department set reasonable threshold standards that covered entities would be required to meet if they deny personal representative status to a person because of any legal, social, or professional liability that could attach based on such denials. The commenter further recommended that the Department set objective universal thresholds for denials that are clear, concise, and easily defined.

Response: We appreciate the comment but decline to set a reasonable threshold standard that covered entities would be required to meet if they deny personal representative status to a person. As discussed above, the Department gives covered entities discretion to elect not to treat a person as a personal representative of an individual if the covered entity has a reasonable belief that the individual has been subjected to domestic violence, abuse, or neglect by or would be in danger from a person seeking to act as the personal representative, except where the basis of the denial is that the person provided or facilitated reproductive health care.

Response: As discussed above, a personal representative, with authority under applicable law, stands in the shoes of the individual and has the ability to act for the individual and exercise the individual's rights. Thus, with very limited exceptions, covered entities must provide the personal representative access to the individual's PHI in accordance with 45 CFR 164.524 to the extent such information is relevant to such representation.

4. Request for Comments

The Department requested comment on whether to eliminate or narrow any existing permissions to use or disclose "highly sensitive PHI." [FN330] Most of the comments on this question are discussed in the context of the prohibition.

C. Section 164.509—Uses and Disclosures for Which an Attestation Is Required

1. Current Provision

The Privacy Rule currently separates uses and disclosures into three categories: required, permitted, and prohibited. Permitted uses and disclosures are further subdivided into those to carry out TPO; [FN331] those for which an individual's authorization is required; [FN332] those requiring an opportunity for the individual to agree or object; [FN333] and those for which an authorization or opportunity to agree or object is not required.[FN334] For an individual's authorization to be valid, the Privacy Rule requires that it contain certain specific information to ensure that an individual authorizing a regulated entity to use or disclose their PHI to another person knows and understands to what it is they are agreeing.[FN335]

2. Proposed Rule

As we described in the 2023 Privacy Rule NPRM, a regulated entity presented with a request for PHI would need to discern whether using or disclosing PHI in response to the request would be prohibited. To facilitate compliance with the proposed prohibition at 45 CFR 164.502(a)(5)(iii) while also providing a pathway for regulated entities to disclose PHI for certain permitted purposes, the Department proposed to require that a covered entity obtain an attestation from a person requesting the use or disclosure of PHI in certain circumstances.[FN336]

***33028** Specifically, the Department proposed to add a new section 45 CFR 164.509, "Uses and disclosures for which an attestation is required." This proposed condition would require a regulated entity to obtain certain assurances from the person requesting PHI potentially related to reproductive health care before the PHI is used or disclosed, in the form of a signed and dated written statement attesting that the use or disclosure would not be for a purpose prohibited under 45 CFR 164.502(a)(5)(iii), where the person is making the request under the Privacy Rule permissions at 45 CFR 164.512(d) (disclosures for

health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for law enforcement purposes), or (g)(1) (disclosures about decedents to coroners and medical examiners).

The proposed new section included a description of the proposed attestation contents, including a statement that the use or disclosure is not for a purpose the Department proposed to prohibit as described at 45 CFR 164.502(a)(5)(iii). The 2023 Privacy Rule NPRM also included a discussion about how the Department anticipated the proposed attestation requirement would work in concert with Privacy Rule permissions. Additionally, the proposed attestation provision would also include the general requirements for a valid attestation, and defects of an invalid attestation.[FN337] The Department also proposed to require that an attestation be written in plain language [FN338] and to prohibit it from being "combined with" any other document. Further, the Department's proposal would explicitly permit the attestation to be in an electronic format, as well as electronically signed by the person requesting the disclosure.[FN339] Under the proposal, the attestation would be facially valid when the document meets the required elements of the attestation proposal and includes an electronic signature that is valid under applicable Federal and state law.[FN340]

Additionally, the proposal specified that each use or disclosure request would require a new attestation.

The Department proposed that a regulated entity would be able to rely on the attestation provided that it is objectively reasonable under the circumstances for the regulated entity to believe the statement required by 45 CFR 164.509(c)(1)(iv) that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), rather than requiring a regulated entity to investigate the validity of an attestation.[FN341] We explained that it would not be objectively reasonable for a regulated entity to rely on the representation of the person requesting PHI about whether the reproductive health care was provided under circumstances in which it was lawful to provide such health care. This is because we believed that the regulated entity, not the person requesting the disclosure of PHI, has the information about the provision of such health care that is necessary to make this determination. Therefore, we explained that this determination would need to be made by the regulated entity prior to using or disclosing PHI in response to a request for a use or disclosure of PHI that would require an attestation under the proposal.

The attestation proposal also would require a regulated entity to cease use or disclosure of PHI if the regulated entity develops reason to believe, during the course of the use or disclosure, that the representations contained within the attestation were materially incorrect, leading to uses or disclosures for a prohibited purpose.[FN342] Relatedly, the 2023 Privacy Rule NPRM included a discussion of the consequences of material misrepresentations that cause the impermissible use or disclosure of IIHI relating to another individual under HIPAA.

To reduce the burden on regulated entities implementing this proposed attestation, the Department requested comment on whether it should develop a model attestation that a regulated entity may use when developing its own attestation templates. The Department did not propose to require that regulated entities use the model attestation.

3. Overview of Public Comments

Most commenters expressed support for the proposal to require an attestation for certain uses and disclosures. Some commenters questioned why the Department did not extend the attestation requirement directly to business associates, consistent with the general prohibition and recommended that the attestation requirements be applied to business associates.

Some of those commenters that supported the proposal to require an attestation expressed concern or made additional recommendations about its components, content, and scope, and the consequences for covered entities that make inadvertent disclosures of PHI without an attestation. A small number of opposing commenters also expressed concerns about the effectiveness and administrative burden of the proposed attestation requirement.

About half of the commenters concerned about the administrative burden of the attestation expressed support for limiting the applicability of the proposed attestation to certain types of uses and disclosures of information, while the other half recommended

expanding the scope of the proposed attestation requirement to mitigate burdens on covered entities or to increase privacy protections for individuals.

Many commenters expressed concern about the Department's statement in the 2023 Privacy Rule NPRM that it would not be objectively reasonable for a regulated entity to rely on the representation of a person requesting the use or disclosure of PHI about whether the PHI sought was related to lawful health care. Specifically, commenters asserted that regulated entities may have difficulties determining whether an attestation is "objectively reasonable" and were unlikely to possess the information necessary to determine the purpose of a person's request for the use or disclosure of PHI.

***33029** Most commenters urged the Department to expand the proposal beyond requests for PHI potentially related to reproductive health care to requests for any PHI because of the associated administrative burden of identifying and segmenting PHI about reproductive health care from other types of PHI. These commenters asserted that the burden would be significant because such PHI can be found throughout the medical record. Commenters also expressed concerns about the ability of EHRs to segment data.

Most commenters recommended that the Department add to or modify the content of the proposed attestation, including to add a statement that the recipient pledges not to redisclose PHI to another party for any of the prohibited purposes or that the request is for the minimum amount of information necessary. Many supported the inclusion of a signed declaration under penalty of perjury and a statement regarding the penalties for perjury to add a layer of accountability.

4. Final Rule

As we explained in the 2023 Privacy Rule NPRM, it may be difficult for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose, which could lead regulated entities to deny use or disclosure requests for permitted purposes. Additionally, absent an enforcement mechanism, it is likely that persons requesting the use or disclosure of PHI could seek to use Privacy Rule permissions for purposes that are prohibited under the new 45 CFR 164.502(a)(5)(iii). Accordingly, the Department is finalizing the proposed attestation requirement, with modification, as described below. We intend to publish a model attestation prior to the compliance date for this final rule.

First, the Department is renumbering the attestation provision such that the requirement is now 45 CFR 164.509(a)(1) and modifying that requirement to hold business associates directly liable for compliance with the attestation requirement. This change was made to address concerns raised by commenters who questioned why the Department did not extend the attestation requirement directly to business associates, consistent with the general prohibition and with revisions made to the HIPAA Rules in the 2013 Omnibus Rule, as required by the HITECH Act. The Department has authority to take enforcement action against business associates only for requirements for which the business associate is directly liable.[FN343] Thus, under the proposed attestation requirement, a business associate would only have been required to comply with the proposed 45 CFR 164.509 if such obligation was explicitly included within its business associate agreement.[FN344]

Both covered entities and business associates process requests for PHI. The Privacy Rule permits regulated entities to determine whether a business associate can respond to such requests or whether they are required to defer to the covered entity.[FN345] As noted by commenters, while many PHI requests processed by a business associate pursuant to 45 CFR 164.512(d)-(g)(1) are processed on behalf of the covered entity, persons may elect to request PHI directly from the business associate. Thus, the Department has determined that it is appropriate to hold both covered entities and business associates directly liable for compliance with the attestation requirement. Expanding the attestation requirement to apply to business associates will ensure that the business associate is directly liable for compliance with it, regardless of whether compliance with 45 CFR 164.509 is explicitly included in a BAA.

The Department is also adopting the proposed attestation requirement that a regulated entity obtain an attestation only for PHI "potentially related to reproductive health care." As discussed in the 2023 Privacy Rule NPRM, this will limit the number of requests that require an attestation, and therefore, the burden of the attestation requirement on regulated entities

and persons requesting PHI. The Department reminds regulated entities that they are permitted, but not required, to respond to law enforcement requests for PHI where the purpose of the request is not one for which regulated entities are prohibited from disclosing PHI. By narrowing the scope of the attestation to PHI "potentially related to reproductive health care," the attestation requirement will not unnecessarily interfere with or delay law enforcement investigations that do not involve PHI "potentially related to reproductive health care." While in practice this scope may be wide, we believe the privacy interests of individuals who have obtained reproductive health care necessitates the inclusion of "potentially related" PHI. We are concerned that extending the attestation requirement to all PHI could unnecessarily delay law enforcement investigations that are not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). We acknowledge commenters' concerns about the ability of regulated entities to operationalize the attestation condition and note that the requirement to obtain an attestation applies where the request is for PHI "potentially related to reproductive health care," as opposed to PHI "related to reproductive health care." Consistent with the Department's instructions to regulated entities since the Privacy Rule's inception, we have taken a flexible approach to allow scalability based on a regulated entity's activities and size. All regulated entities must take appropriate steps to address privacy concerns. Regulated entities should weigh the costs and benefits of alternative approaches when determining the scope and extent of their compliance activities, including when developing policies and procedures to comply with the Privacy Rule.[FN346] The Department will assess the progress of regulated entities' compliance with this requirement and promulgate guidance as appropriate. The Department also notes that with limited exceptions, the Privacy Rule generally permits but does not require the use or disclosure of PHI when the conditions set by the Privacy Rule for the specific use or disclosure of PHI are met.

The Department is adopting the proposed requirement that an attestation be obtained where a request is made under the Privacy Rule permissions at 45 CFR 164.512(d) (disclosures for health oversight activities), (e) (disclosures for judicial and administrative proceedings), (f) (disclosures for law enforcement purposes), or (g)(1) (disclosures about decedents to coroners and medical examiners). This requirement will help ensure that these Privacy Rule permissions cannot be used to circumvent the new prohibition at 45 ***33030** CFR 164.502(a)(5)(iii) and continue permitting essential disclosures, while also limiting the attestation's burden on regulated entities by providing a standard mechanism by which the regulated entity can ascertain whether a requested use or disclosure is prohibited under this final rule. The attestation requirement is intended to reduce the burden of determining whether the PHI request is for a purpose prohibited under 45 CFR 164.502(a)(5)(iii), but it does not absolve regulated entities of the responsibility of making this determination, nor does it absolve regulated entities of the responsibility for ensuring that such requests meet the other conditions of the relevant permission.

We are modifying the proposal by revising 45 CFR 164.509(a)(1) to clarify that a regulated entity may not use or disclose PHI where the use or disclosure does not meet all of the Privacy Rule's applicable conditions, including the attestation requirement. While this is consistent with the existing requirements of the Privacy Rule, we determined that it was necessary to reiterate this requirement here based on comments we received. Thus, when this final rule is read holistically, a regulated entity is not permitted to use or disclose PHI where such disclosure does not meet all of the Privacy Rule's applicable conditions, including the attestation requirement.

We are also modifying the proposal by adding 45 CFR 164.509(a)(2) to clarify that the use or disclosure of PHI based on a defective attestation does not meet the attestation requirement. For example, the attestation requirement would not be met if a regulated entity relies on an attestation where it is not reasonable to do so because the attestation would be defective under 45 CFR 164.509(b)(2)(v). Accordingly, it would be a violation of the Privacy Rule if the regulated entity makes a use or disclosure in response to a defective attestation.

The Department is modifying the proposal to prohibit inclusion in the attestation of any elements that are not specifically required by 45 CFR 164.509(c). This provision addresses concerns that regulated entities might require persons requesting PHI to provide information beyond that which is required under 45 CFR 164.509(c). Such additional requirements could make it burdensome for persons requesting PHI to submit a valid attestation when they make a request pursuant to 45 CFR 164.512(d), (e), (f), or (g)(1). Additionally, a person requesting PHI is not required to use the specific attestation form provided by a regulated entity, as long as the attestation provided by such person is compliant with the requirements of 45 CFR 164.509.

Additionally, the Department is modifying the proposed prohibition on compound attestations. Specifically, the final rule prohibits the attestation from being "combined with" any other document. The modification clarifies that while an attestation may not be combined with other "forms," additional documentation to support the information provided in the attestation may be submitted. This additional documentation may not replace or substitute for any of the attestation's required elements. The attestation itself must be clearly labeled, distinct from any surrounding text, and completed in its entirety, but documentation to support the statement at 45 CFR 164.509(c)(1)(iv) or to overcome the presumption at 45 CFR 164.502(a)(5)(iii)(C) may be appended to the attestation. Thus, a regulated entity must ensure that the required elements of the attestation are met, and should review any additional documents provided by the person making the request when making the required determinations.

A regulated entity may use this information—the information on the attestation combined with any additional documentation provided by the person making the request for PHI—to make a reasonable determination that the attestation is true, consistent with 45 CFR 164.509(b)(2)(v). For example, an attestation would not be impermissibly "combined with" a subpoena if it is attached to it, provided that the attestation is clearly labeled as such. As another example, an electronic attestation would not be impermissibly "combined with" another document where the attestation is on the same screen as the other document, provided that the attestation is clearly and distinctly labeled as such.

The Department is finalizing the proposed content requirements with modifications as follows. Specifically, the Department is finalizing the proposal that an attestation must include that the person requesting the disclosure confirm the types of PHI that they are requesting; clearly identify the name of the individual whose PHI is being requested, if practicable, or if not practicable, the class of individuals whose PHI is being requested; and confirm, in writing, that the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). For purposes of the "class of individuals" described in 45 CFR 164.509(c)(1)(i)(B), the Department clarifies that the requesting entity may describe such a class in general terms—for example, as all individuals who were treated by a certain health care provider or for whom a certain health care provider submitted claims, all individuals who received a certain procedure, or all individuals with given health insurance coverage.

As we proposed, we are finalizing a requirement that the attestation include a clear statement that the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). This requirement may be satisfied with a series of checkboxes that identifies why the use or disclosure is not prohibited under 45 CFR 164.502(a)(5)(iii) (i.e., the use or disclosure is not for a purpose specified in 45 CFR 164.502(a)(5)(iii)(A); or the use or disclosure is for a purpose that would be prohibited under 45 CFR 164.502(a)(5)(iii)(A), but the reproductive health care at issue was not lawful under the circumstances in which it was provided so the Rule of Applicability is not satisfied, and thus the prohibition does not apply).

The Department is adding another new required element, a statement that the attestation is signed with the understanding that a person who knowingly and in violation of HIPAA obtains or discloses IIHI relating to another individual, or discloses IIHI to another person, may be subject to criminal liability.[FN347] We believe that adding this language satisfies the intent that led us to consider including a penalty of perjury requirement and with applicable law. The statement does not impose new liability on persons who sign an attestation; instead, including the statement in the attestation ensures that persons who request the use or disclosure of PHI for which an attestation is required are on notice of and acknowledge the consequences of making such requests under false pretenses.

The Department is also finalizing the proposed requirement that the attestation must be written in plain language. Additionally, the Department is finalizing its proposal to permit the attestation to be in electronic format and for it to be electronically signed by the person requesting the disclosure where such electronic signature is valid under applicable law.[FN348] The Department declines to mandate a specific electronic format for the attestation.

As we proposed, an attestation will be limited to the specific use or disclosure. Accordingly, each use or disclosure ***33031** request for PHI will require a new attestation.

There is no exception to the minimum necessary standard for uses and disclosures made pursuant to an attestation under 45 CFR 164.509.[FN349] Thus, a regulated entity will have to limit a use or disclosure to the minimum necessary when provided in response to a request that would be subject to the proposed attestation requirement, unless one of the specified exceptions to the minimum necessary standard in 45 CFR 164.502(b)(2) applies. Where the person requesting the PHI is also a regulated entity, that person will also need to make reasonable efforts to limit their request to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.[FN350]

The Department is not requiring a regulated entity to investigate the validity of an attestation provided by a person requesting a use or disclosure of PHI. Rather, a regulated entity is generally permitted to rely on the attestation if, under the circumstances, a regulated entity reasonably determines that the request is not for investigating or imposing liability for the mere act of seeking, obtaining, providing, or facilitating allegedly unlawful reproductive health care. In addition, a regulated entity is generally permitted to rely on the attestation and any accompanying material if, under the circumstances, a regulated entity reasonably could conclude (e.g., upon examination of adequate supporting documentation provided by the person making the request) that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), consistent with the approach taken in the Privacy Rule [FN351] and elsewhere in this final rule. If such reliance is not reasonable, then the regulated entity may not rely on the attestation. This is a change from the proposed language, which permitted reliance based on an "objectively reasonable" standard. The proposed standard was modified because a reasonable person standard is inherently objective.[FN352] Thus, including "objectively" in the description of the standard was redundant.

For requests involving allegedly unlawful reproductive health care, the extent to which a regulated entity may reasonably rely on an attestation depends in part on whether the regulated entity provided the reproductive health care at issue. Under the final rule, it would not be reasonable for a regulated entity to rely on the representation made by a person requesting the use or disclosure of PHI that the reproductive health care was unlawful under the circumstances in which it was provided unless such representation meets the conditions set forth in the presumption at 45 CFR 164.502(a)(5)(iii)(C). As discussed above, under the presumption, reproductive health care is presumed to be lawful under the circumstances in which such health care is provided unless a regulated entity has actual knowledge, or information from the person making the request that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. Where the reproductive health care at issue was provided by a person other than the regulated entity receiving the request for the use or disclosure of PHI and the presumption is overcome, the regulated entity is permitted to use or disclose PHI in response to the request upon receipt of an attestation where it is reasonable to rely on the representations made in the attestation. It is not reasonable for the regulated entity to rely solely on a statement of the person requesting the use or disclosure of PHI that the reproductive health care was unlawful under the circumstances in which such health care was provided. Instead, the person requesting the use or disclosure of PHI must provide the regulated entity with information such that it would constitute actual knowledge or that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. A regulated entity that receives a request for PHI involving reproductive health care provided by that regulated entity should review the relevant PHI in its possession and other related information (e.g., license of health care provider that provided the health care, operating license for the facility in which such health care was provided) to determine whether the reproductive health care was lawful under the circumstances in which it was provided prior to using or disclosing PHI in response to a request for PHI that requires an attestation. Where the request is about reproductive health care that is provided by the regulated entity receiving the request, it would not be reasonable for a regulated entity to automatically rely on a representation made by a person requesting the use or disclosure of PHI about whether the reproductive health care was provided under the circumstances in which it was lawful to provide such health care. Rather, the regulated entity must review the individual's PHI to consider the circumstances under which it provided the reproductive health care to determine whether such reliance is reasonable. Therefore, where the request involves the use or disclosure of PHI potentially related to reproductive health care that was provided by the recipient of the request, the regulated entity must make the determination about whether it provided the health care lawfully prior to using or disclosing PHI in response to a request that requires an attestation.

For example, if a law enforcement official requested PHI potentially related to reproductive health care to investigate a person for the mere act of seeking, obtaining, providing or facilitating allegedly unlawful reproductive health care, it would not be reasonable for a regulated entity that receives such a request to rely solely on a signed attestation that states that the reproductive health care was not lawful under the circumstances in which it was provided, as set forth in 45 CFR 164.502(a)(5)(iii)(B), and therefore, that the requested disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii)(A). This is regardless of whether the regulated entity receiving the request for PHI provided the reproductive health care at issue. Assuming that the attestation is not facially deficient, a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances. To determine whether it is reasonable to rely on the attestation, a regulated entity should consider, among other things: who is requesting the use or disclosure of PHI; the permission upon which the person making the request is relying; the ***33032** information provided to satisfy other conditions of the relevant permission; the PHI requested and its relationship to the stated purpose of the request; and, where the reproductive health care was supplied by another person, whether the regulated entity has: (1) actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided; or (2) factual information supplied by the person requesting the use or disclosure of PHI that would demonstrate to a reasonable regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

For example, a regulated entity receives an attestation from a Federal law enforcement official, along with a court ordered warrant demanding PHI potentially related to reproductive health care. The law enforcement official represents that the request is about reproductive health care that was not lawful under the circumstances in which such health care was provided, but the official will not divulge more information because they allege that doing so would jeopardize an ongoing criminal investigation. In this example, if the regulated entity itself provided the reproductive health care and, based on the information in its possession, reasonably determines that such health care was lawful under the circumstances in which it was provided, the regulated entity may not disclose the requested PHI.

If the regulated entity did not provide the reproductive health care, it may not disclose the requested PHI absent additional factual information because the official requesting the PHI has not provided sufficient information to overcome the presumption at 45 CFR 164.502(a)(5)(iii)(C). Further, it also would not be reasonable under the circumstances for the regulated entity to rely on the attestation that the information would not be used for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) because of the presumption that the reproductive health care was lawfully provided.

However, in cases where the presumption of lawfulness applies, the regulated entity would be permitted to make the disclosure, for example, where the law enforcement official provides additional factual information for the regulated entity to determine that there is a substantial factual basis that the reproductive health care was not lawful under the circumstances in which such health care was provided. As another example, a regulated entity could rebut the presumption of lawfulness by relying on a sworn statement by a law enforcement official that the PHI is necessary for an investigation into violations of specific criminal codes unrelated to the provision of reproductive health care (e.g., billing fraud) or an affidavit from an individual that the individual obtained unlawful reproductive health care from a different health care provider and the requested PHI is relevant to that investigation. Similarly, if a regulated entity receives an attestation from a Federal law enforcement official, along with a court-ordered warrant demanding PHI potentially related to reproductive health care, that both specify that the purpose of the request is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), the regulated entity may rely on the attestation and warrant, subject to the requirements of 45 CFR 164.512(f)(1)(ii)(A).

Lastly, this final rule requires a regulated entity to cease use or disclosure of PHI if the regulated entity, during the course of the use or disclosure, discovers information reasonably showing that the representations contained within the attestation are materially incorrect, leading to uses or disclosures for a prohibited purpose.[FN353] As we explained in the 2023 Privacy Rule NPRM, pursuant to HIPAA, a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability. [FN354] Thus, a person who knowingly and in violation of HIPAA [FN355] falsifies an attestation (e.g., makes material misrepresentations about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could

be subject to criminal penalties as outlined in the statute.[FN356] Additionally, a disclosure made based on an attestation that contains material misrepresentations after the regulated entity becomes aware of such misrepresentations constitutes an impermissible disclosure, which requires notifications of a breach to the individual, the Secretary, and in some cases, the media. [FN357]

The attestation requirement does not replace the conditions of the Privacy Rule's permissions for a regulated entity to disclose PHI, including in response to a subpoena, discovery request, or other lawful process, or administrative request. Instead, the attestation is designed to work with the permissions and their requirements. If PHI is disclosed pursuant to 45 CFR 164.512(e)(1)(ii) or (f)(1)(ii)(C), a regulated entity will need to verify that the requirements of each provision are met, in addition to satisfying the requirements of the new attestation provision under 45 CFR 164.509. Furthermore, the requirements of 45 CFR 164.528, the right to an accounting of disclosures of PHI made by a covered entity, are not affected by the attestation requirement. Thus, disclosures made pursuant to a permission under 45 CFR 164.512(d), (e), (f), or (g) must be included in the accounting, including when they are made pursuant to an attestation.

5. Responses to Public Comments

Comment: Most commenters supported the proposal to require an attestation for certain uses and disclosures. A few commenters recognized the benefits of the attestation requirement, despite the potential increase in administrative burden for regulated entities.

Many commenters opposed the proposal for what they described as administrative burden, questionable effectiveness, and lack of clarity. A few commenters stated that the requirements imposed an inappropriate compliance burden on covered entities that would need to determine whether a PHI request was "potentially related" to sensitive personal health care, and, along with a health care provider who otherwise supported the attestation, they recommended instead that the Department impose requirements on the person requesting the use or disclosure of PHI. Many commenters expressed concerns about the ability of covered entities to operationalize the proposed requirement with the limitation to PHI potentially related to reproductive health care because it would require the ability to segment PHI, which the Department previously acknowledged is generally unavailable. A few commenters questioned the effectiveness of the proposed attestation ***33033** requirement, as compared to its potential burden, enforceability, and effects on access to maternal and specialty health care.

Response: We agree with commenters that the attestation requirement will bolster the privacy of PHI and acknowledge that implementation of this important safeguard requires additional administrative activities by regulated entities. The Department considered removing the limitation on the application of the attestation condition to PHI "potentially related to reproductive health care," but we are concerned that expanding it to apply to all requests for PHI made for specified purposes would impose even more burden on regulated entities. The requirement is to determine whether the requested PHI is "potentially related to reproductive health care," not whether it is "related to reproductive health care." Thus, regulated entities are not required to make an affirmative determination that the requested PHI is in fact related to reproductive health care before requiring a person requesting PHI to provide an attestation. We note that the focus of the attestation requirement has been limited to PHI potentially related to reproductive health care because the changes to the legal landscape have heighted privacy concerns about reproductive health care that is lawful under the circumstances in which such health care is provided. We also note that the provision of an attestation itself is not determinant of whether the request is for a prohibited purpose. Rather, regulated entities must consider whether a request for PHI is for a prohibited purpose, regardless of whether the request is made for a purpose for which the Privacy Rule requires an attestation.

The Department is limited to applying the HIPAA Rules to those entities covered by HIPAA (i.e., health plans, health care clearinghouses, and health care providers that conduct covered transactions) and to business associates, as provided under the HITECH Act. Accordingly, the Department is limited to imposing obligations on persons requesting the use or disclosure of PHI to those who are also regulated entities.

The attestation condition has been drafted to promote the privacy of information about lawful reproductive health care, including maternal and specialty health care, while still permitting certain uses of PHI. Regulated entities, including covered entities that specialize in providing reproductive health care may determine, based on their assessment of what PHI is potentially related to reproductive health care, that an attestation must accompany all requests they receive for the use or disclosure of any PHI made pursuant to and in compliance with 45 CFR 164.512(d)-(g)(1). Further, the attestation requirement only applies to the specified requests for PHI and should not affect any intake of new patients or provision of maternal health care.

The Department is not requiring a regulated entity to investigate the veracity of the information provided in support of an attestation because doing so would impose a significant administrative burden on regulated entities and persons requesting the use or disclosure of PHI without proportional benefit. Additionally, requiring such an investigation by the regulated entity may cause unnecessary delays to law enforcement activities. Rather, the Department is finalizing a regulated entity's ability to rely on the attestation provided that it is reasonable under the circumstances for the regulated entity to believe the statement required by 45 CFR 164.509(c)(1)(iv) that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii). If such reliance is not reasonable, then the regulated entity may not rely on the attestation.

A regulated entity that receives a request for PHI potentially related to reproductive health care for purposes specified in 45 CFR 164.512(d), (e), (f), or (g)(1) may accept information, in addition to the attestation, from the person requesting the PHI to support its ability to make the determinations required by 45 CFR 164.502(a)(5)(iii) and 45 CFR 164.509(b)(v).

For example, it likely would not be reasonable for a regulated entity to rely on an attestation from a public official who represents that their request is for a purpose that is not prohibited, if the request for PHI is overly broad for its purported purpose and the public official has publicly stated that they will be investigating health care providers for providing reproductive health care. In such cases, regulated entities should consider the circumstances surrounding an attestation to determine whether they can reasonably rely on the attestation. Although we have modified the regulatory text by removing “objectively,” the standard remains unchanged in practice because a reasonableness standard is an objective standard. As we also discussed above, it is not reasonable for a regulated entity that provided the reproductive health care at issue to rely on a representation made by a person requesting the use or disclosure of PHI that the reproductive health care at issue was unlawful under the circumstance in which such health care was provided. A regulated entity that makes a disclosure where it was not reasonable to rely on the representation made by the person requesting the use or disclosure may be subject to enforcement action by OCR.

Additionally, as discussed in greater detail above, a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability.[FN358] We believe that this provision serves as a deterrent for those who otherwise might request PHI in violation of this final rule. It also will continue to permit essential disclosures while ensuring that Privacy Rule permissions cannot be used to circumvent the new prohibition, thereby enhancing the privacy of individuals' PHI and protecting other important interests.

Comment: Several commenters opposed the attestation proposal because they believed that the proposal would make it more difficult for law enforcement to request PHI and for entities to respond to such requests, potentially putting them in situations where they need to choose between complying with a court order and impermissibly disclosing PHI. A few individuals stated that the proposal would have a chilling effect on the ability of a state to conduct investigations or proceedings for which the use or disclosure of PHI could be beneficial, particularly in cases involving rape, incest, sex trafficking, domestic violence, abuse, and neglect.

Response: We acknowledge that the attestation provision may require regulated entities to obtain additional information from persons requesting PHI in certain circumstances. As discussed above, this condition is consistent with the operation of the Privacy Rule since its inception, which has always required regulated entities to obtain additional information from persons requesting PHI in certain circumstances, such as where the use or disclosure is one for which an authorization or opportunity to agree or object is not required.[FN359] However, as also discussed above, any burden the attestation may impose on persons requesting PHI is outweighed by the privacy interests that this final rule is designed to protect.

A person requesting PHI pursuant to 45 CFR 164.512(d)-(g)(1) may elect to provide an attestation with their request, even if a determination has not ***33034** yet been made concerning whether such request is for PHI potentially related to reproductive health care. Similarly, the Privacy Rule does not require a regulated entity to respond to requests for PHI.

Comment: Some commenters were concerned about the effect of the attestation requirement on the electronic exchange of PHI and recommended approaches for incorporating attestations into a HIE environment. A commenter expressed concern that the requirement for an attestation would delay or prevent automated data exchange using Fast Healthcare Interoperability Resources® (FHIR®) APIs and might impede innovation. They requested guidance on how to implement the attestation condition in an HIE environment without impeding regulated exchanges or industry innovations using extensive data exchange via FHIR APIs. Commenters also recommended that the Department issue guidance on implementing attestation policies in circumstances not required by this rule that would not constitute information blocking. A commenter encouraged the Department to implement processes that limit the liability of health care providers for the actions of third parties. For example, the commenter requested that the Department clarify that a refusal to disclose PHI absent an attestation is protected from a finding of information blocking.

Response: We do not believe that this final rule prevents the disclosure of PHI via a HIE. We disagree that this requirement prevents the exchange of data using FHIR APIs under these permissions or for automated health data exchange more broadly. PHI can be disclosed as requested if the regulated entity obtains a valid attestation and the request meets the conditions of an applicable permission. The attestation requirement does not affect any requests via FHIR API that fall outside of the 45 CFR 164.512(d)-(g)(1) permissions. For example, a disclosure of PHI from a covered health care provider to another health care provider for care coordination purposes would not require an attestation because the disclosure would not be for a purpose addressed by 45 CFR 164.512(d)-(g)(1). The importance of ensuring the protection of an individual's interests in the privacy of their PHI and society in improving the effectiveness of the health care system far outweigh any potential administrative burdens or delays in the electronic exchange of PHI for non-health care purposes. Further, compliance with applicable law does not constitute information blocking.[FN360] Thus, we do not believe additional regulatory language is necessary at this time. OCR regularly collaborates with other Federal agencies, including ONC, to develop guidance on compliance with Federal standards and to address questions that arise about the ability of regulated entities to comply with applicable laws.

The permissions for which the Department is requiring that a regulated entity obtain an attestation prior to using or disclosing PHI are already conditioned upon meeting certain requirements, which generally require manual review. The Department acknowledges that certain persons may need to adjust their workflows to account for the attestation requirement. While there may be some delays until new processes are implemented, any disruptions will decrease over time. Thus, we do not anticipate that this final rule will contribute to additional delays in the disclosure of PHI.

The Department is finalizing a new regulatory presumption that permits a regulated entity to presume reproductive health care provided by another person was lawful unless the regulated entity has actual knowledge or factual information supplied by the person requesting the use or disclosure of PHI that demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided. This presumption will facilitate the determination by the regulated entity about whether a request for the use or disclosure of PHI would be subject to the prohibition, and thus will reduce the risk of an impermissible use or disclosure of the requested PHI, thereby reducing the liability of regulated entities that receive requests for PHI to which the prohibition may apply, but where they did not provide the reproductive health care at issue.

Comment: Many commenters questioned the Department's rationale for not extending the attestation requirement directly to business associates, consistent with the general prohibition. Some commenters recommended that the attestation requirement be applied to business associates because persons requesting the use or disclosure of PHI may directly approach a business associate for this PHI (and the business associate agreement may permit such disclosures or be silent regarding whether the business

associate may respond to them). Commenters also requested clarification of the responsibilities of business associates with respect to attestations and questioned whether the proposal would require amendment of their business associate agreements.

Response: As discussed above, we agree with the commenters that the attestation requirement should apply directly to business associates because they receive direct requests for PHI and are subject to the general prohibition in the same manner as covered entities. Therefore, we are modifying 45 CFR 164.509 to ensure that it expressly applies to both covered entities and their business associates.

Comment: Although a few commenters expressed support for limiting the attestation condition to requests regarding "PHI potentially related to reproductive health care," many commenters recommended that the proposed requirement to obtain an attestation be broadly applied to requests for any PHI. Many stated that it would be easier and more efficient for regulated entities if all requests related to a prohibited purpose required the attestation, regardless of the PHI being requested. According to these commenters, this would allow the regulated entity to avoid making any determinations regarding the PHI. A few explained that expanding the requirement to all PHI would appropriately place the burden of demonstrating that the requested disclosure was permissible on the person making request.

Several commenters asserted that information related to reproductive health care is potentially found in every department, record, and system, including those that may not have a readily apparent relationship to reproductive health care. As a result, according to these commenters, it would be onerous and costly to separate different types of health information in a medical record. According to other commenters, the volume of records requests received by health systems would render any requirement on a health care provider to redact PHI from an individual's medical record in the absence of an attestation overly burdensome and increase the risk of unauthorized disclosure. Some ***33035** commenters explained that staff managing health information generally do not have the legal or medical training to determine whether a PHI request may be for PHI potentially related to reproductive health care, particularly given the breadth of most requests (e.g., for all medical records of an entity, of a particular health care provider or a particular individual). These commenters also raised concerns that the lack of legal or medical training could lead to inconsistent application of the rule, the inadvertent disclosure of PHI potentially related to reproductive health care, or delay the use or disclosure of PHI, even when the individual has not sought or obtained reproductive health care. Many commenters asserted that determining whether a request for the use or disclosure of PHI includes PHI potentially related to reproductive health care is difficult and a significant burden on health information professionals, particularly where the covered entity did not provide or facilitate the health care. According to some commenters, some business associates, such as cloud services providers, may not have the ability to determine whether the PHI that they maintain includes PHI potentially related to reproductive health care.

Some commenters posited that the result of this requirement would be that health care providers would refuse to provide any PHI in response to a request for the use or disclosure PHI on any matter that could possibly be construed as potentially related to reproductive health care. They and others stated that limiting the proposed prohibition to one category of PHI would require regulated entities to label or segment certain PHI within medical records, which would be impractical and costly because EHRs are unable to reliably segregate or flag PHI retrospectively.

Response: We acknowledge the comments from regulated entities that expressed concerns about the effects of the limitation of the attestation requirement to PHI potentially related to reproductive health care. However, the Department is concerned that extending the attestation requirement to all PHI could result in unintended consequences, such as the potential delay of law enforcement investigations that do not require PHI potentially related to reproductive health care. By contrast, an attestation requirement is necessary for PHI potentially related to reproductive health care because of recent changes to the legal landscape that make it more likely that PHI will be sought for punitive non-health care purposes, and thus more likely to be subject to disclosure by regulated entities if the requested disclosure is permissible under the Privacy Rule, thereby harming the interests that HIPAA seeks to protect. Accordingly, the Department is not modifying the attestation requirement that a regulated entity obtain an attestation only for PHI potentially related to reproductive health care.

The Department acknowledges that the attestation requirement may increase the burden on regulated entities, but we disagree that regulated entities are unable to make the required assessments of attestations. Regulated entities currently conduct similar assessments when determining whether PHI may be disclosed to a personal representative, when making disclosures that are required by law or for public health purposes, and for various other permitted purposes. Regulated entities also regularly review medical records to comply with minimum necessary requirements. The Department is cognizant that an expanded attestation requirement could significantly increase burden if it were to expand this requirement to all disclosures in the absence of the sensitivities described in this final rule.

Comment: Many commenters supported the proposal to limit the requirement to obtain an attestation with a request for uses and disclosures for certain permissions, namely that have the greatest potential to be connected with a purpose for which the Department proposed to prohibit the use and disclosure of PHI. Some commenters expressed their belief that the Department had identified the appropriate permissions for which the attestation would provide additional safeguards.

Many commenters suggested modifications, primarily expansions or clarifications of the types of permitted uses and disclosures that would be subject to the attestation. Generally, commenters explained their belief that their recommended modifications would either mitigate the burden of the requirement to ascertain the purposes of the requested disclosure or increase privacy protections for individuals.

Commenters recommended multiple ways to expand the attestation requirement, such as extending it to all permissions in 45 CFR 164.512; disclosures required by law, for public health activities, and to avert a serious threat to health or safety; disclosures for treatment purposes to a person not regulated by HIPAA or disclosures to any person who might use the PHI for a prohibited purpose; and any disclosure at the discretion of the covered entity.

Response: The Department declines to expand the permissions for which an attestation is required at this time. The Department specifically chose to limit the attestation condition to the permissions at 45 CFR 164.512(d)-(g)(1) because these permissions have the greatest potential to result in the use or disclosure of an individual's PHI for a purpose prohibited at 45 CFR 164.502(a)(5)(iii). In the context of other permissions, where the risk of improper use or disclosure is less, the benefits of an attestation condition would be outweighed by the administrative burden of compliance. Accordingly, any disclosures made pursuant to 45 CFR 164.512(b), which includes disclosures for public health surveillance, investigations, or interventions, do not require an attestation. However, we note that requests made pursuant to other permissions of the rule remain subject to and must be evaluated for compliance with the prohibition at 45 CFR 164.502(a)(5)(iii).

Comment: A commenter stated that no attestation should be needed for judicial and administrative proceedings because current requirements are adequate. Instead, the commenter requested that the Department consider expanding procedural protections.

Response: We are finalizing the requirement that regulated entities obtain an attestation as a condition of a use or disclosure of PHI for judicial and administrative proceedings. As previously discussed, the attestation requirement ensures that certain Privacy Rule permissions are not used to circumvent the prohibition. The attestation requirement also reduces the burden on regulated entities because it is specifically designed to facilitate compliance with the prohibition under 45 CFR 164.502(a)(5)(iii) by helping regulated entities determine whether the use or disclosure of the requested PHI is permitted. Although a court order, qualified protective order, satisfactory assurance, or subpoena may have a restriction that prevents information requested from being further disclosed, it protects PHI only after it has been used or disclosed. Thus, the regulated entity's use or disclosure of PHI could still violate the prohibition at 45 CFR 164.502(a)(5)(iii), even if that disclosure is made in response to a court order, qualified protective order, satisfactory assurance, or subpoena. The attestation requirement helps to mitigate the risk of violations in these circumstances.

Comment: A few commenters expressed concerns about their ability to implement the attestation requirement ***33036** in circumstances where the use or disclosure is triggered by a mandatory reporting law or verbal request and recommended that no attestation should be required in any case where disclosure of PHI is required by law. According to the commenters, an

attestation requirement could require a significant change to operational workflows for permitted disclosures and significantly impede operations for state and local agencies that conduct death investigations and perform public health studies and initiatives.

Response: The Privacy Rule at 45 CFR 164.512(a) permits certain uses and disclosures of PHI that are required by law, including notification of certain deaths by a covered health care provider to a medical examiner, when those uses and disclosures are limited to the requirements of such law. The attestation condition does not apply to the mandatory disclosures made pursuant to 45 CFR 164.512(a). Other mandatory reporting that is subject to 45 CFR 164.512(a)(2) has always been subject to the additional requirements of 45 CFR 164.512(c), (e), or (f). Further, mandatory reporting for public health activities pursuant to 45 CFR 164.512(b) do not require an attestation.

The attestation condition applies if the regulated entity is making a use or disclosure to a coroner or medical examiner pursuant to 45 CFR 164.512(g)(1). We understand that this may require regulated entities to adjust their workflows to comply with this requirement. For example, regulated entities could consider having an electronic attestation form readily available for persons that request the use or disclosure of PHI potentially related to reproductive health care because doing so may reduce delays in the regulated entity's response time related to the attestation condition. Thus, this condition will not significantly impede operations for persons who request information because the interruptions will decrease as they adjust their workflows to accommodate the new condition.

We remind regulated entities that the prohibition in 45 CFR 164.502(a)(5)(iii) applies, regardless of whether the request for PHI is made pursuant to a permission for which an attestation is required or another permission.

Comment: Many commenters urged the Department to implement a reasonable, good faith standard or a safe harbor for situations in which a regulated entity discloses PHI and the person requesting the PHI either uses or rediscloses it for a purpose that would be prohibited under the proposed rule. Some commenters were concerned that a covered entity will be liable for inadvertent disclosures of PHI and sought the benefit of the affirmative defense afforded at 45 CFR 160.410(b)(2).

Response: The Department declines to add a “good faith” standard or safe harbor to this final rule. As discussed above, the Department is not finalizing a separate Rule of Construction and is not incorporating the phrase “primarily for the purpose of” into the final prohibition standard.

As we explained in the 2023 Privacy Rule NPRM, 45 CFR 164.509 requires a new attestation for each use or disclosure request; a single attestation would not be sufficient to permit multiple uses or disclosures. This requirement is unlike the authorization, where generally, when a regulated entity receives a valid authorization, they may continue to use or disclose PHI to the person requesting the use or disclosure of PHI pursuant to that authorization after the initial disclosure, provided that such subsequent uses and disclosures are valid and related to that authorization. We understand that this may constitute an additional administrative burden for both the regulated entity and the person or entity requesting the information; however, requiring an attestation for each use or disclosure is necessary to ensure that certain Privacy Rule permissions are not used to circumvent the new prohibition at 45 CFR 164.502(a)(5)(iii), and to permit essential disclosures.

Comment: Some commenters expressed support for permitting a regulated entity to rely on an attestation if “it appears objectively reasonable” or “when objectively reasonable” and not requiring covered entities to investigate the accuracy of an attestation, thereby mitigating liability to the regulated entity, if not fully protecting an individual. Many commenters expressed concern that it would not be objectively reasonable for a regulated entity to rely on a representation made by the person requesting the use or disclosure of PHI that the PHI sought was related to unlawful health care. The commenters requested a guarantee that a health care provider's reliance on a “facially valid” attestation would be objectively reasonable without requiring the entity to investigate the intentions of the person requesting the use or disclosure of PHI and the validity of their attestation. A commenter recommended that the final rule direct regulated entities to take attestations at face value and hold harmless regulated entities in the event of a false attestation.

Commenters offered several reasons for these recommendations, including the burden on covered entities where they are required to determine: (1) the veracity of every attestation; (2) whether an attestation is required; and (3) whether the statement that the request for the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) is objectively reasonable.

Response: To assist in effectuating the prohibition, this Final Rule requires an attestation in some circumstances. We recognize the potential burden on regulated entities to investigate the validity of every attestation and do not require that they conduct a full investigation in each instance. However, as discussed above, if an attestation, on its face, meets the requirements at 45 CFR 164.509(c), a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances. To determine whether it is reasonable to rely on the attestation, a regulated entity should consider, among other things: who is requesting the use or disclosure of PHI; the permission upon which the person making the request is relying; the information provided to satisfy other conditions of the relevant permission; the PHI requested and its relationship to the purpose of the request (i.e., does the request meet the minimum necessary standard in relation to the purpose of the request); and, where the presumption at 45 CFR 164.502(a)(5)(iii)(C) applies, information provided by the person requesting the use or disclosure of PHI to overcome that presumption.

For example, as discussed above, it may not be reasonable for a regulated entity to rely on an attestation filed by a public official that a request for PHI potentially related to reproductive health care is not for a prohibited purpose when that public official has publicly stated their interest in investigating or imposing liability on those who seek, obtain, provide, or facilitate certain types of lawful reproductive health care. If a regulated entity concludes that it would not reasonable to rely on the attestation in this instance, the regulated entity would be prohibited from disclosing the requested PHI unless and until the public official provided additional information that enables the regulated entity to assess the veracity of its attestation. In contrast, it may be reasonable to rely on the representation of a public official that a request for PHI potentially related to reproductive ***33037** health care is not for a prohibited purpose if the stated purpose for the request is to investigate insurance fraud and the public official making the request is expressly authorized by law to conduct insurance fraud investigations as part of their legal mandate. Therefore, as discussed above, the Department is balancing these considerations by finalizing language that generally permits a regulated entity to rely on the attestation if it is reasonable for the regulated entity to believe the statement that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii).[FN361] To further assist regulated entities in determining whether it is reasonable to rely on the attestation, the requirement that the attestation include a clear statement that the use or disclosure is not for a prohibited purpose under 45 CFR 164.502(a)(5)(iii) may be satisfied with a statement that identifies why the use or disclosure is not prohibited, which could be checkboxes that indicate that the use or disclosure is not for a purpose described in 45 CFR 164.502(a)(5)(iii)(A), or that the reproductive health care does not satisfy the Rule of Applicability at 45 CFR 164.502(a)(5)(iii)(B).

Where the request for the use or disclosure of PHI is made of the regulated entity that provided the reproductive health care at issue, the regulated entity should ensure that the reproductive health care was not lawful under the circumstances in which such health care was provided before using or disclosing the requested PHI. If the reproductive health care at issue was provided under circumstances in which such health care was lawful, the regulated entity must obtain an attestation and determine whether it is reasonable to rely on the attestation that the use or disclosure is not being requested to conduct an investigation into or impose liability on any person for the mere act of seeking, obtaining, providing, or facilitating such reproductive health care. If the reproductive health care at issue was provided under circumstances in which such health care was unlawful, the regulated entity is permitted, but not required, to disclose the PHI if the disclosure is meets the conditions of an applicable Privacy Rule permission, which may include an attestation.

Regulated entities will not generally be held liable for disclosing PHI to a person who signed the attestation under false pretenses, provided that the requirements of 45 CFR 164.509 are met, and it is reasonable under the circumstances for the regulated entity to believe the statement that the requested disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii).

Comment: A commenter recommended that the rule clarify the relationship between the attestation and 45 CFR 164.514(h) regarding verification requirements. They requested that the Department consider making explicit in the Final Rule that reliance on legal process would not be appropriate in the absence of an attestation.

Response: The verification requirement under 45 CFR 164.514(h) [FN362] is separate from the attestation requirement, and a regulated entity must still comply with 45 CFR 164.514(h) when processing an attestation. The final rule makes clear that the attestation requirement will apply if the request for PHI potentially related to reproductive health care is made pursuant to permissions under 45 CFR 164.512(d)-(g)(1), which may include disclosing PHI pursuant to a legal process.

Comment: Some commenters stated that it is difficult to determine the purpose of a request for the use or disclosure of PHI because many requests include only a general purpose. A commenter asserted that staff would need to screen all incoming requests, a task that may require legal or clinical expertise. Further, some commenters stated that regulated entities may experience conflict with persons requesting the use or disclosure of PHI about signing the form.

Response: This final rule prohibits the use and disclosure of PHI for certain purposes and conditions disclosures for certain purposes upon the receipt of an attestation. Thus, it is incumbent upon the regulated entity receiving the request to determine whether disclosure is in compliance with the Privacy Rule. To help the regulated entity make such a determination, the Department is adding to the required elements of the attestation a description of the purpose of the request that is sufficient for the regulated entity to determine whether the prohibition at 45 CFR164.502(a)(5)(iii) may apply to the request. Requests for the use or disclosure of PHI for the specified purposes are likely subject to heightened scrutiny by the regulated entity currently because of other conditions imposed upon such disclosures by the Privacy Rule, so additional expertise will not always be required when processing a request for the use or disclosure of PHI and the accompanying attestation. For example, under the Privacy Rule, a regulated entity must determine whether a request for the use or disclosure of PHI for a judicial or administrative proceeding made using a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal contains "satisfactory assurances" that reasonable efforts have been made by the person making the request either: (1) to ensure that the individual who is the subject of the PHI that has been requested has been given notice of the request; [FN363] or (2) to secure a qualified protective order that meets certain requirements specified in the Privacy Rule.[FN364] The Privacy Rule further details how regulated entities are to determine whether they have received "satisfactory assurances" for both options described above.[FN365] Such requirements ensure that a regulated entity must already carefully review requests for such purposes, such that the attestation condition likely poses minimal additional burden for such requests. In any event, the Department believes that these administrative burdens are outweighed by the privacy interests that this final rule seeks to protect.

Comment: Many commenters asserted that it would be reasonable to require affirmative verification under penalty of perjury that the request for the use or disclosure of PHI is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) because it would signal an intent to penalize requests ***33038** made to contravene the prohibition; would incentivize persons requesting the use or disclosure of PHI to consider whether their request is for a purpose prohibited under 45 CFR 164.502(a)(5)(iii); deter unlawful "fishing expeditions" or conceal improper intent; and add a layer of accountability. Another commenter stated this heightened standard would enable the covered entity to reasonably rely in good faith on the substance of the attestation without further investigation, delay, cost, burden, or dispute. According to the commenter, a person making a request for the use or disclosure of PHI in good faith should have minimal to no concern when providing a statement signed under penalty of perjury. Another commenter supported a requirement that a person requesting the use or disclosure of PHI provide an affirmative verification made under penalty of perjury that the use or disclosure is not for purpose prohibited under 45 CFR 164.502(a)(5)(iii) because it would suggest that evidence obtained falsely would not be admissible in a legal proceeding. A commenter asserted that it is important to ensure that the proposed attestations would be as effective as possible, and including a signed declaration made under penalty of perjury is critical to ensuring their effectiveness in the current legal environment. A commenter endorsed adding a statement regarding perjury to the proposed attestation because it would place the person requesting the use or disclosure of PHI on notice of the criminal penalties if the person were to violate the proposed requirement.

A commenter asserted that the penalty of perjury requirement is a common signature standard for legal and administrative proceedings and expressed support for expanding it to other proceedings. The commenter also expressed support for considering other options because of concerns that the application and consequences of making a statement under a penalty of perjury may lack clarity outside of certain proceedings.

Response: We appreciate commenters' suggestions; however, the Department ultimately decided that the addition of a penalty of perjury would be unnecessary in light of the statutory criminal and civil penalties under HIPAA. 42 U.S.C. 1320d-6 provides that any person who knowingly and in violation of the Administrative Simplification provisions obtains IIHI relating to another individual or discloses IIHI to another person is subject to criminal liability.[FN366] A regulated entity is also subject to civil penalties for violations of requirements of the HIPAA Rules.[FN367] Thus, a person that requests PHI who knowingly falsifies an attestation (e.g., makes material misrepresentations as to the intended uses of the PHI requested) to obtain PHI or cause PHI to be disclosed would be in violation of HIPAA and could be subject to criminal penalties.[FN368]

Comment: Some commenters expressed support for requiring that the attestation include a statement that a person signing an attestation is doing so under penalty of perjury, but they also questioned its ability to prevent a person from requesting the use or disclosure of PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and recommended additional requirements or alternatives. One commenter expressed concern that there would be no disincentive for the recipient to submit an attestation signed under false pretenses in the absence of enforceable penalties. A different commenter questioned the efficacy of a penalty of perjury requirement because the person requesting the use or disclosure may not be the person that uses the PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii); it might be another person who uses the information for a purpose prohibited under that provision. According to the commenter, no criminal or other penalty would attach because that other person did not sign the attestation. The commenter also expressed concern that an attestation signed on behalf of an entity may not be enforceable because the person who signed the attestation did not have authority to bind the entity.

Commenters variously recommended that the Department include language that the person requesting the use or disclosure of PHI would not further use or disclose the PHI for a purpose prohibited under 45 CFR 164.502(a)(5)(iii) and that the requested information is the minimum necessary, or require a search warrant or data use agreement instead of an attestation. A commenter recommended that the Department provide individuals with an actionable remedy, such as the right to receive a portion of any civil money penalty assessed to the regulated entity or the right to “claw back” the disclosure from the receiving entity if the party that signed the attestation later violates its terms.

Response: The Department understands and shares commenters' concerns about redisclosures that would be prohibited by this rule if the disclosure was made by a regulated entity. However, HIPAA limits the Department's authority to regulating PHI maintained or transmitted by a regulated entity, that is a covered entity or their business associate. Accordingly, a person that is not a regulated entity generally may use or disclose such information without further limitation by the HIPAA Rules.

Requiring search warrants or data use agreements as a condition of the use or disclosure of PHI is beyond the scope of this final rule.

With respect to the commenter's concern about situations in which a person who does not have the appropriate authority requests PHI on behalf of a public official, the Privacy Rule generally requires that a regulated entity verify the identity and legal authority of persons requesting PHI prior to making the disclosure.[FN369] Where a disclosure of PHI is to a public official or person acting on behalf of a public official who has the authority to request the information, a regulated entity may verify the authority of that public official by relying on, if reliance is reasonable under the circumstances, either a written statement of legal authority under which the information is requested (or an oral statement, if the written statement is impracticable).[FN370] Alternatively, a regulated entity may presume the public official's legal authority if a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or judicial administrative tribunal.[FN371] We remind regulated entities that a determination that a public official has the authority to make a request for the use or disclosure does not mean that the Privacy Rule permits them to obtain any and all information that the official requests. In such circumstances,

the regulated entity should carefully review the conditions of the applicable permission to ensure that they are met. Where the condition involves a warrant, subpoena, or similar instrument, the regulated entity must also review the scope of the authority granted by the warrant, subpoena, or order to determine the extent of the PHI that it is permitted to disclose.[FN372] Further, a regulated entity may rely, if such reliance is reasonable under the ***33039** circumstances, on a requested disclosure by a public official as the minimum necessary if the public official represents that the requested PHI is the minimum necessary for the stated purpose.[FN373]

HIPAA specifies the remedies available to the Federal Government where persons violate the statute's Administrative Simplification provisions: civil monetary penalties [FN374] and criminal fines and imprisonment.[FN375] HIPAA does not include a private right of action.

Comment: One commenter asked the Department to clarify that anyone providing a false attestation would be held accountable for false statements with appropriate or significant civil fines or criminal penalties for the material misrepresentation. Another commenter specifically recommended that the Department consider it a material misrepresentation for a person to sign an attestation without an objectively reasonable basis to suspect that the reproductive health care of interest was unlawful under the circumstances in which such health care was provided. The commenter asserted that the attestation should include specific language that any person who is requesting the use or disclosure of PHI because they believe the reproductive health care was not lawful under the circumstances in which such health care was provided must have a reasonable basis for that belief (e.g., a statement from a witness) and that the absence of an articulable, fact-based reasonable suspicion would constitute a material misrepresentation. According to the commenter, such a requirement would prevent fishing expeditions because persons requesting the use or disclosure of PHI would be required to have an actual, objective reason for believing that a person provided health care in violation of state or Federal law.

Response: The Department agrees that it would be a material misrepresentation if a person who signs an attestation does not have an objectively reasonable basis to suspect that the reproductive health care was provided under circumstances in which it was unlawful, and that an objectively reasonable basis of suspicion requires specific and articulable facts associated with the individual whose PHI is requested and the health care they received. We decline to include a statement of this position on the attestation because it is encompassed in the language that requires persons making a request for PHI to attest that they are not making the request for a prohibited purpose and the language ensuring that persons making such requests are aware of the potential liability for knowingly and in violation of HIPAA obtaining IIHI relating to an individual or disclosing IIHI to another person.

Comment: Some commenters urged the Department to include additional provisions to monitor and enforce the attestation condition, including requiring that a court order, written attestation, or valid authorization accompany requests for the use or disclosure of PHI for legal or administrative proceedings or law enforcement investigations.

Response: The attestation condition does not replace the conditions of the Privacy Rule's permissions for a regulated entity to disclose PHI in response to a subpoena, discovery request, or other lawful process,[FN376] or administrative request.[FN377] Instead, it is designed to work with these permissions and associated condition. For PHI to be disclosed pursuant to 45 CFR 164.512(e)(1)(ii) and (f)(1)(ii)(C), a regulated entity must verify that the relevant conditions are met and also satisfy the attestation condition at 45 CFR 164.509. We do not believe it is necessary to include additional requirements to monitor and enforce implementation of the attestation condition because a person who knowingly and in violation of the Administrative Simplification provisions obtains or discloses IIHI relating to another individual or discloses IIHI to another person would be subject to criminal liability.[FN378]

Comment: Almost all commenters responding to the Department's request for comment expressed support for a Department-developed model attestation or sample language that could be used by regulated entities to reduce the implementation burden of the attestation condition. A large health care provider expressed appreciation for options that would simplify the process for reviewing requests for the use or disclosure of PHI made pursuant to 45 CFR 164.512(d)-(g)(1). Other commenters asserted

that a standard form would reduce unnecessary variation, support a consistent approach, decrease implementation costs, and make it easier for a regulated entity to identify requests for the use or disclosure of PHI for purposes prohibited under 45 CFR 164.502(a)(5)(iii).

Several commenters suggested that a universal or standardized attestation form would reduce the burden of the attestation requirement, especially for smaller health care providers, and reduce delays in the disclosure of PHI resulting from the need for legal review or unfamiliarity with the format of an attestation provided by a person requesting the use or disclosure of PHI. One of these commenters stated this would also support electronic data exchange by standardizing attestation fields and the format. Most commenters expressed opposition to a Department-required format and recommended that the Department permit covered entities to modify the language of the attestation.

Some commenters requested that the model attestation include a plain language explanation and a tip sheet or guidance for completion. They also requested that the model be an electronic, fillable form with a clear heading and that the editing capabilities be limited to the specific required fields. Some commenters recommended that the model attestation contain an outline of penalties for misuse of PHI.

A commenter requested that the Department guarantee that a health care provider's good faith reliance on a model attestation form would be objectively reasonable.

Response: We appreciate these recommendations and intend to publish model attestation language before the compliance date of this final rule. As discussed above, if an attestation, on its face, meets the requirements at 45 CFR 164.509(c), a regulated entity must consider the totality of the circumstances surrounding the attestation and whether it is reasonable to rely on the attestation in those circumstances.

Comment: In response to the Department's request for comment on how the proposed attestation would affect a regulated entity's process for responding to regular or routine requests from certain persons, a few commenters explained their current workflows and the resource requirements for managing these requests.

Some commenters suggested that an attestation requirement might require changes to workflows and discussed the changes that might be made.

Response: The Department appreciates these insights into how regulated entities currently respond to certain requests for the use or disclosure of PHI. We confirm that a person requesting the use or disclosure of PHI ***33040** pursuant to 45 CFR 164.512(d), (e), (f), or (g)(1) must provide the regulated entity a signed and truthful attestation where the request is for PHI potentially related to reproductive health care before the regulated entity is permitted to use or disclose the requested PHI. The Department will consider developing guidance and technical assistance as needed on these topics in the future as necessary to ensure compliance with the Privacy Rule, including both the prohibition at 45 CFR 164.502(a)(5)(iii) and 164.509. It may benefit a regulated entity to require such documentation where the requested use or disclosure is for TPO or in response to a valid authorization or individual right of access request.

Comment: A few commenters recommended imposing obligations to limit redisclosures of PHI for certain purposes.

A few commenters stated that a person requesting the use or disclosure of PHI could seek a court order or provide a written attestation to permit the regulated entity to make the disclosure in question in the event they were unable to obtain an authorization.

Response: While we understand commenters' concerns regarding the uses and disclosures of health information by entities not covered by the Privacy Rule, the Department is limited to applying the HIPAA Rules to those entities covered by HIPAA (i.e.,

health plans, health care clearinghouses, and health care providers that conduct covered transactions) and to business associates, as provided under the HITECH Act.

In the 2023 Privacy Rule NPRM, the Department considered permitting regulated entities to make uses or disclosures of PHI only after obtaining a valid authorization. However, the Department rejected the approach because requiring an authorization in all circumstances would not reflect the appropriate balance between individual privacy interests and other societal interests in disclosure. In particular, individuals may decline to authorize disclosure of PHI even in circumstances where their privacy interests are reduced and societal interests in disclosure are heightened, such as where the reproductive health care was unlawful under the circumstances in which it was provided.

Comment: Some commenters requested that the Department provide educational resources for regulated entities to implement the attestation. A commenter encouraged the Department to strongly enforce the attestation provision.

Response: We appreciate these recommendations and commit to providing additional resources to assist regulated entities with implementation of this rule.

Comment: In response to the Department's request for comment on alternative documentation that could assist regulated entities in complying with the proposed limitations on the use and disclosure of PHI, some commenters recommended that an attestation always be required, even if additional documentation is mandated, because the attestation would place the person requesting the use or disclosure of PHI on notice of the prohibition and to hold them accountable if they use the PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii), in addition to helping a covered entity to determine whether the PHI is being requested for a legitimate or prohibited purpose. Others agreed because of the risk of coercion when authorizations are sought from individuals for certain purposes.

Some commenters suggested that the Department require that a court order, written attestation, or valid authorization accompany a request for the use or disclosure of any PHI for legal or administrative proceedings or law enforcement investigations because there are circumstances under which it would be unlikely for a person to obtain an authorization. Some commenters recommended that the Department not require an attestation when the disclosure of PHI is required by law, or when so ordered by a court of competent jurisdiction. A commenter proposed that the Department permit regulated entities to make the specified uses and disclosures with a written attestation, a HIPAA authorization, or alternative documentation described by the Department, including a court order, to minimize the administrative burden.

Response: The Department appreciates the approaches recommended by commenters to ensure that PHI requested is not for a prohibited purpose. We also believe that the attestation will place the person requesting the use or disclosure of PHI on notice of the prohibition and serve to hold them accountable if they use the PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii). However, we have limited the attestation requirement to requests for PHI that is potentially related to reproductive health care. In addition, as discussed above, because the Privacy Rule's authorization requirements empower individuals to make decisions about who has access to their PHI, we are not adopting the proposed exception to the permission to use or disclose PHI pursuant to a valid authorization, nor are we adopting the other recommendations made by commenters. The Department is not finalizing its proposal to prohibit the disclosure of PHI for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) pursuant to an authorization. Accordingly, the final rule permits the disclosure of an individual's PHI to another person pursuant to a valid authorization, even if the disclosure would otherwise be prohibited under this rule. Therefore, a regulated entity may disclose PHI for a purpose that otherwise would be prohibited under 45 CFR 164.502(a)(5)(iii) by obtaining a valid authorization or pursuant to the individual right of access. We reiterate that in all cases, the conditions of the underlying permission must be met before a regulated entity is permitted to use or disclose the requested PHI.

D. Section 164.512—Uses and Disclosures for Which an Authorization or Opportunity To Agree or Object Is Not Required

1. Applying the Prohibition and Attestation Condition to Certain Permitted Uses and Disclosures

Section 164.512 of the Privacy Rule contains the standards for uses and disclosures for which an authorization or opportunity to agree or object is not required. Many of the uses and disclosures addressed by 45 CFR 164.512 relate to government or administrative functions and are described in the 2000 Privacy Rule preamble as "national priority purposes." [FN379] These permissions for uses and disclosures were not required by HIPAA; instead they represented the Secretary's previous balancing of the privacy interests and expectations of individuals and the interests of communities in making certain information available for community purposes, such as for certain public health, health care oversight, and research purposes.[FN380] As discussed previously, the Department, in its implementation of HIPAA, has sought to ensure that individuals do not forgo health care when needed—or withhold important information from their health care providers that may affect the quality of health care they receive—out of a fear that their sensitive information would be revealed outside of their relationships with their health care providers.

To clarify that the proposal at 45 CFR 164.502(a)(5)(iii) would prohibit the use and disclosure of PHI in some ***33041** circumstances where such uses or disclosures are currently permitted, the Department proposed to cite the proposed prohibition at the beginning of the introductory text of 45 CFR 164.512 and condition certain disclosures on the receipt of the attestation proposed at 45 CFR 164.509.[FN381] The proposed modification would add the clause, "Except as provided by 45 CFR 164.502(a)(5)(iii), [. . .]" and add "and 45 CFR 164.509" to "subject to the applicable requirements of this section." This would create a new requirement to obtain an attestation from the person requesting the use and disclosure of PHI as a condition of making certain types of permitted uses and disclosures of PHI. Thus, under the proposal and subject to the Department finalizing the prohibition at paragraph (a)(5)(iii) of 45 CFR 164.502, uses and disclosures of PHI for certain purposes would be prohibited unless a regulated entity first obtained an attestation from the person requesting the use and disclosure under proposed 45 CFR 164.509.

The Department also proposed to replace "orally" with "verbally" at the end of the introductory paragraph for clarity.

Overview of Public Comments

While many commenters addressed the proposals to add a prohibition on the use and disclosure of PHI and to require an attestation in certain circumstances, few commenters addressed the proposal to modify the introductory paragraph to 45 CFR 164.512. Such commenters either expressed support for it or requested additional guidance on the Department's intention or the proposal's operation.

The Department is adopting its proposal without modification. As discussed above, this change creates a new requirement for a regulated entity to obtain an attestation from a person requesting the use or disclosure of PHI as a condition of making certain types of permitted uses and disclosures of PHI. For example, the Privacy Rule currently permits uses and disclosures for health care oversight,[FN382] judicial and administrative proceedings,[FN383] law enforcement purposes,[FN384] and about decedents to coroners and medical examiners,[FN385] provided specified conditions are met. When read in conjunction with the new prohibition at 45 CFR 164.502(a)(5)(iii), uses and disclosures of PHI for these purposes will be subject to an additional condition that the regulated entity first obtain an attestation from the person requesting the use and disclosure under the new attestation requirement at 45 CFR 164.509.

The Department assumes that there will be instances in which state or other law requires a regulated entity to use or disclose PHI for health care oversight, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners and medical examiners for a purpose not related to one of the prohibited purposes in 45 CFR 164.502(a)(5)(iii). The Department believes that a regulated entity will be able to comply with such laws and the attestation requirement. For example, a regulated entity may continue to disclose PHI without an individual's authorization to a state medical board, a prosecutor, or a coroner, in accordance with the Privacy Rule, when the request is accompanied by the required attestation. As a result, a regulated entity generally may continue to assist the state in carrying out its health care oversight, judicial and administrative functions, law enforcement, and coroner duties with the use or disclosure of PHI once a facially valid attestation has been provided to the regulated entity from whom PHI is sought. However, where an attestation is required but not obtained, a state seeking information about an individual's reproductive health or reproductive health care would need to obtain such information from

an entity not regulated under the Privacy Rule [FN386] or demonstrate that the regulated entity has actual knowledge that the reproductive health care was not lawful under the circumstances in which such health care was provided, thereby reversing the presumption described at 45 CFR 164.502(a)(5)(iii)(C).

Additionally, we are replacing "orally" with "verbally" for clarity. No substantive change is intended.

Comment: One commenter expressed support for the Department's proposed revision to 45 CFR 164.512, while another commenter requested additional examples or detail in preamble about what the Department intends by this revision.

Response: The Department intends that the uses and disclosures of PHI made in accordance with 45 CFR 164.512 would be subject to both the 45 CFR 164.502(a)(5)(iii) prohibition and the 45 CFR 164.509 attestation, when applicable, specifically uses or disclosures made for health oversight activities,[FN387] judicial and administrative proceedings,[FN388] law enforcement purposes,[FN389] and about decedents to coroners and medical examiners.[FN390] For example, a regulated entity may disclose PHI for law enforcement purposes, subject to the conditions of the permission at 45 CFR 164.512(f), where the purpose of the request for the use or disclosure is to investigate a sexual assault and the person requesting the PHI provides the regulated entity with a valid attestation signifying that the purpose of the request is not for a prohibited purpose. Similarly, where a request meets the requirements of 45 CFR 164.502(a)(5)(iii), a regulated entity may disclose PHI for law enforcement purposes, subject to the conditions of the permission at 45 CFR 164.512(f), where the purpose of the request for the use or disclosure is to investigate the unlawful provision of reproductive health care with a valid attestation signifying that the purpose of the request is not one that is prohibited (i.e., that the purpose of the use or disclosure is not to investigate or impose liability on any person for the lawful provision of reproductive health care). As another example, a regulated entity may disclose PHI to a state Medicaid agency in accordance with 45 CFR 164.512(d) where the purpose of the request is to ensure that the regulated entity is providing the reproductive health care for which the regulated entity has submitted claims for payment to Medicaid after obtaining an attestation that meets the requirements of 45 CFR 164.509 from the state Medicaid agency.

Comment: One commenter requested clarification regarding the intersection between the Department's proposed Rule of Construction at 45 CFR 164.502(a)(5)(iii)(D) and its proposal at 45 CFR 164.512.

Response: The Department is not adopting the proposed Rule of Construction. Rather, the language of the proposal has been integrated into the prohibition standard at 45 CFR 164.502(a)(5)(iii)(A). The finalized prohibition standard requires a ***33042** regulated entity to ensure that they obtain a valid attestation from a person requesting the use or disclosure of PHI for health oversight activities, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners or medical examiners, assuring the regulated entity that the purpose of the request is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii).

2. Making a Technical Correction to the Heading of 45 CFR 164.512(c) and Clarifying That Providing or Facilitating Reproductive Health Care Is Not Abuse, Neglect, or Domestic Violence

Paragraph (c) of 45 CFR 164.512 permits a regulated entity to disclose PHI, under specified conditions, to an authorized government agency where the regulated entity reasonably believes the individual is a victim of abuse, neglect, or domestic violence. The regulatory text includes a serial comma, which clearly indicates that the provision addresses victims of three different types of crimes, but the heading of this standard does not include the serial comma.

For grammatical clarity, the Department proposed to add the serial comma after the word "neglect" in the heading of the standard contained at 45 CFR 164.512(c).[FN391]

The Department also proposed to add a new paragraph (c)(3) to 45 CFR 164.512(c), with the heading "Rule of construction," to clarify that the permission to use or disclose PHI in reports of abuse, neglect, or domestic violence does not permit uses or disclosures based primarily on the provision or facilitation of reproductive health care to the individual.[FN392] The Department intended the proposed provision to safeguard the privacy of individuals' PHI against claims that uses and disclosures of that PHI

are warranted because the provision or facilitation of reproductive health care, in and of itself, may constitute abuse, neglect, or domestic violence.

A few commenters supported the proposal because it would clarify that providing or facilitating access to health care is not itself abuse, neglect, or violence, while others expressed opposition to the proposal because they believed it would prevent health care providers from reporting abuse based on the provision of reproductive health care, including potentially coerced reproductive health care. Commenters both supported and opposed the inclusion of the phrase "based primarily."

The Department is finalizing the proposal to add the serial comma after the word "neglect" in the heading of the standard contained at 45 CFR 164.512(c).

As we explained in the 2023 Privacy Rule NPRM, the Department is concerned that recent state actions may lead regulated entities to believe that they are permitted to make disclosures of PHI when they believe that persons who provide or facilitate access to reproductive health care are perpetrators of a crime simply because they provide or facilitate access to reproductive health care. Thus, the Department is clarifying that providing or facilitating access to lawful reproductive health care itself is not abuse, neglect, or domestic violence for purposes of the Privacy Rule. This is consistent with the Department's understanding that the provision or facilitation of lawful health care is not itself abuse, neglect, or domestic violence. Such clarification has not previously been required, but recent developments in the legal landscape have made it necessary for us to codify this interpretation in the context of reproductive health care.

Accordingly, the Department is finalizing the proposed Rule of Construction at 45 CFR 164.512(c)(3), with modification as follows. The modification clarifies the circumstances under which regulated entities that are mandatory reporters of abuse, neglect, or domestic violence are permitted to make such reports. Specifically, we are replacing "based primarily on" with language specifying that the prohibition at 45 CFR 164.502(a)(5)(iii) cannot be circumvented by the permission to use or disclose PHI to report abuse, neglect, or domestic violence where the "sole basis of" the report is the provision or facilitation of reproductive health care. Thus, the Department makes clear that it may be reasonable for a covered entity that is a mandatory reporter to believe that an individual is the victim of abuse, neglect, or domestic violence and to make such report to the government authority authorized by law to receive such reports in circumstances where the provision of reproductive health care to the individual is but one factor prompting the suspicion. For example, it would not be reasonable for a covered entity to believe that an individual is the victim of domestic violence solely because the individual's spouse facilitated the covered entity's provision of reproductive health care to the individual.

Comment: A few commenters supported the Department's proposal. One commenter asserted that providing or facilitating access to any type of health care is not in and of itself abuse, neglect, or domestic violence and urged the Department to expand the scope of this language, particularly if the prohibition is similarly expanded in the final rule.

Response: The Department appreciates the comments about the modifications to 45 CFR 164.512(c). As discussed above, the scope of the prohibition is limited to reproductive health care. The proposed and final regulations are narrowly tailored and limited in scope to not increase regulatory burden beyond appropriate public policy objectives. Thus, we decline to expand the scope of this provision, as well.

Comment: A large coalition expressed concerns about mandatory domestic violence and sexual assault reporting laws. According to the coalition, mandatory reporting laws reduce the willingness of domestic violence survivors to seek help, including health care, and that the reports themselves worsen the situation for most survivors. The coalition asserted that permitting the disclosure of PHI to law enforcement and other agencies for reports of abuse, neglect, or domestic violence isolates survivors of such abuse and puts them at risk of losing their children. These commenters recommended that the Department prevent such disclosures.

Some commenters expressed opposition to the proposal because they believe it would put victims of domestic abuse at risk because it would prevent health care providers from reporting abuse, including child abuse, based on the provision or facilitation of reproductive health care. A commenter asserted that the proposal would circumvent the exception prohibiting disclosures to abusive persons at 45 CFR 164.512(b)(1)(ii). According to another commenter, the change would chill the willingness of covered entities to cooperate with investigations and judicial proceedings concerning individuals who may have used reproductive health care, regardless of the matter being adjudicated.

According to another commenter, the proposal is aimed at undermining state laws and shielding persons who provide or facilitate reproductive health care. Commenters expressed concern that the proposal would prohibit reports of abuse, neglect, or domestic violence because such reports are made for the purpose of investigating or prosecuting a person for providing or facilitating ***33043** unlawful reproductive health care, and for committing sexual assault.

Response: The Department appreciates the concerns raised by the commenters. Since publication of the final Privacy Rule in 2000, the Department has acknowledged that covered entities, including covered health care providers, may have legal obligations to report PHI in certain circumstances, including about suspected victims of abuse, neglect, or domestic violence. The Department did not propose to modify the Privacy Rule's permission to disclose PHI at 45 CFR 164.512(c). The Department declines to expand its proposal to eliminate the permission for covered entities to disclose PHI to public health authorities, law enforcement, and other government authority authorized by law to receive reports of abuse, neglect, or domestic violence.

Additionally, the Department does not agree that covered entities will be prevented from reporting PHI about victims of abuse, neglect, or domestic violence. The new language at 45 CFR 164.512(c)(3) is narrowly tailored to reduce the conflation between lawfully provided reproductive health care and the view that such lawful health care, on its own, is abuse. Readers are referred to the preamble discussion of 45 CFR 164.502(a)(5)(iii) that describes the scope of disclosure changes which are being made applicable to 45 CFR 164.512(c).

The Department does not agree that the modifications circumvent the exception prohibiting disclosures to abusive persons at 45 CFR 164.512(b)(1)(ii). The new language at 45 CFR 164.512(c)(3) does not modify or change the current Privacy Rule provision for disclosures to a public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect. We believe the commenter is referring to 45 CFR 164.512(c)(2), which requires a covered entity to inform an individual that a report has been or will be made, and 45 CFR 164.512(c)(2)(ii), which removes the requirement to inform the individual when the covered entity would be informing a personal representative and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment. Because the new language at 45 CFR 164.512(c)(3) operates as a limitation on disclosure, it is not possible for the new provision to permit disclosures in more circumstances than previously permitted, and therefore does not circumvent the existing provision.

Comment: A commenter recommended that the Department clarify that the proposed Rule of Applicability would not prohibit disclosure and use of such records when they are sought for a defensive purpose by revising the proposed Rule of Construction at 45 CFR 164.512(c)(3) to more explicitly state that it permits such use or disclosure.

Response: The adopted Rule of Construction at 45 CFR 164.512(c)(3) applies to disclosures permitted by 45 CFR 164.512(c), which are explicitly to a government authority, including a social service or protective services agency, authorized by law to receive reports of abuse, neglect, or domestic violence. The Department is not aware of a disclosure that otherwise meets the requirements specified at 45 CFR 164.512(c)(1) that would constitute a disclosure for defensive purposes. Rather, disclosures of PHI for defensive purposes, such as a disclosure to defend against a prosecution for criminal prosecution for allegations of providing unlawful health care, are permitted by 45 CFR 164.512(f), as well as for health care operations when obtaining legal services. To the extent that a disclosure for a defensive purpose meets the applicable requirements and is permitted, the Department confirms that the final rule language generally would not prohibit a disclosure.

Comment: A few commenters requested clarification of the standard for determining what would constitute a report of abuse, neglect, or domestic violence that is based primarily on the provision of reproductive health care. Commenters also requested clarification about the interaction between the proposed prohibition and the permission at 45 CFR 164.512(c).

Response: The Privacy Rule permits but does not require the reporting of abuse, neglect, or domestic violence under certain conditions.[FN393] Under the final rule, the Department is clarifying that this permission does not apply where the sole basis of the report is the provision or facilitation of reproductive health care. With this modification, the Department makes clear that it may be reasonable for a covered entity that is a mandatory reporter to believe that an individual is the victim of abuse, neglect, or domestic violence and to make such report to the government authority authorized by law to receive such reports in circumstances where the provision or facilitation of reproductive health care is but one factor prompting the suspicion. We also note, as discussed above with respect to 45 CFR 164.512(b)(1)(i), this permission allows a covered entity to report known or suspected abuse, neglect, or domestic violence only for the purpose of making a report. The PHI disclosed must be limited to the minimum necessary information for the purpose of making a report.[FN394] These provisions do not permit the covered entity to disclose PHI in response to a request for the use or disclosure of PHI to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on a person based on suspected abuse, neglect, or domestic violence. Thus, any disclosure of PHI in response to a request from an investigator, whether in follow up to the report made by the covered entity (other than to clarify the PHI provided on the report) or as part of an investigation initiated based on an allegation or report made by a person other than the covered entity, must meet the conditions of disclosures for law enforcement purposes or judicial and administrative proceedings.[FN395]

3. Clarifying the Permission for Disclosures Based on Administrative Processes

Under 45 CFR 164.512(f)(1), a regulated entity may disclose PHI pursuant to an administrative request, provided that: (1) the information sought is relevant and material to a legitimate law enforcement inquiry; (2) the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and (3) de-identified information could not reasonably be used. Examples of administrative requests include administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law. The examples of administrative requests provided in the regulatory text include only requests that are enforceable in a court of law, and the catchall "or similar process authorized by law" similarly is intended to include only requests that, by law, require a response. This interpretation is consistent with the Privacy Rule's definition of "required by law," which enumerates these and other examples of administrative requests that constitute "a mandate contained in law that compels an entity to make a use or disclosure of protected health ***33044** information and that is enforceable in a court of law."

As we explained in the 2023 Privacy Rule NPRM, the Department has become aware that some regulated entities may be interpreting 45 CFR 164.512(f)(1) in a manner that is inconsistent with the Department's intent. Therefore, the Department proposed to clarify the types of administrative processes that this provision was intended to address.[FN396]

Specifically, the Department proposed to insert language to clarify that the administrative processes that give rise to a permitted disclosure include only requests that, by law, require a regulated entity to respond. Accordingly, the proposal would specify that PHI may be disclosed pursuant to an administrative request "for which a response is required by law." The Department does not consider this to be a substantive change because the proposal was consistent with express language of the preamble discussion on this topic in the 2000 Privacy Rule.[FN397] The Department intends that the express inclusion of this language will ensure that regulated entities more fully appreciate the permitted uses and disclosures pursuant to 45 CFR 164.512(f)(1)(ii)(C).

The Department received few comments on the proposal to clarify the permission at 45 CFR 164.512(f)(1)(ii)(C). Comments were mixed, with some support, some opposition, and some requesting additional modifications or additional examples or guidance.

While the Department received few comments on this clarification, the Department is aware of reports that covered entities are misinterpreting the intention of the requirements of 45 CFR 164.512(f)(1)(ii)(C) that disclosures of PHI to law enforcement be

necessary and limited in scope. For example, a congressional inquiry recently highlighted concerns about disclosures of PHI to law enforcement from retail pharmacy chains. The inquiry found that some pharmacy staff are providing PHI directly to law enforcement without advice from their legal departments in part because their staff "face extreme pressure to immediately respond to law enforcement demands." [FN398] Based on this inquiry, these disclosures often are made without a warrant or subpoena issued by a court.[FN399]

The Department is adopting the clarification as proposed because regulated entities are misinterpreting the requirements of 45 CFR 164.512(f)(1)(ii)(C) that ensure that disclosures of PHI to law enforcement are necessary and limited in scope. Accordingly, the Department is adding to 45 CFR 164.512(f)(1)(ii)(C) language that specifies that PHI may be disclosed pursuant to an administrative request "for which a response is required by law." Thus, the regulatory text now clearly states that the administrative processes for which a disclosure is permitted are limited to only requests that, by law, require a regulated entity to respond, consistent with preamble discussion on this topic in the 2000 Privacy Rule.[FN400]

Comment: A few commenters supported the Department's proposed clarification of 45 CFR 164.512(f)(1)(ii)(C). A commenter recommended that the Department revise the language to refer to an administrative subpoena or summons, a civil or other "expressly" authorized demand, or other similar process. The commenter recommended that, at a minimum, the Department prohibit disclosures in response to oral requests, require all informal administrative requests be in writing, and require qualifying administrative requests to obtain express supervisory approval.

A commenter asserted, without providing examples, that there are many disclosures currently made under Federal agencies' interpretations of the Privacy Act of 1974 [FN401] that would not be permitted under the NPRM proposal.

Response: The Department appreciates the comments on this clarification. The Department understands the commenter's request to add language identifying specific processes but declines to make the suggested modification at this time. The Department is concerned that references to specific items or actions could be understood to not apply to similarly situated administrative requests understood by different names. In guidance for law enforcement, the Department has provided its interpretation that administrative requests must be accompanied by a written statement.[FN402]

In addition, the Department does not control whether a verbal or other non-written request is sufficient to meet the standards of various jurisdictions for an administrative process that would require a responding covered entity to be legally required to respond. The Department understands that valid, justiciable reasons for responding to a verbal or other non-written request may exist, such as an emergent situation that requires an immediate response to avoid an adverse outcome. The Department believes the additional text sufficiently clarifies the misunderstandings of some regulated entities about what constitutes administrative process for the purposes of this permission.

4. Request for Information on Current Processes for Receiving and Addressing Requests Pursuant to 164.512(d) Through (g)(1)

The Department requested information and comments on certain considerations to help inform development of the final rule.[FN403] In particular, the Department asked how regulated entities currently receive and address requests for PHI when requested pursuant to the Privacy Rule permissions at 45 CFR 164.512(d), (e), (f), or (g)(1), and what effect expanding the scope of the proposed prohibition to include any health care would have on the proposed attestation requirement and the ability of regulated entities to implement it. Comments submitted in response to the question about the effects of expanding the scope of the proposed prohibition have been included in prior discussions of the specific policy issues elsewhere, as applicable.

Comment: Several commenters responded to this request for information concerning current processes for receiving certain requests pursuant to 45 CFR 164.512 by providing specific information about how they receive such requests. Some requests for PHI are received in hard copy, either by mail or hand delivery, while others are received via email. Still ***33045** others are received through the regulated entities online portal or facsimile. In emergency circumstances, such requests may be received verbally. Commenters generally receive assurances through hard copy, email, their patient portal, and fax. A few commenters

seek assurances for every subsequent related request, while another commenter stated that it does not require or obtain assurances for every subsequent related request if the subsequent request is related to the initial request for which the initial assurance was received.

A commenter asserted that the privacy interests at stake outweigh potential administrative burdens and provided examples of state laws that are more privacy protective than the Privacy Rule. The commenter explained that the privacy landscape is constantly evolving, as do the HIPAA Rules, and as such, regulated entities must adapt in response.

Response: The Department appreciates the information provided by commenters explaining the processes by which regulated entities currently receive requests for the use or disclosure of PHI for certain purposes and the workflows of regulated entities to ensure that such requests comply with the conditions of the applicable Privacy Rule permissions. We reviewed and considered this information when evaluating the burden of the proposed modifications to the Privacy Rule during the development of this final rule.

E. Section 164.520—Notice of Privacy Practices for Protected Health Information

1. Current Provision

The Privacy Rule generally requires that a covered entity provide individuals with an NPP to ensure that they understand how a covered entity may use and disclose their PHI, as well as their rights and the covered entity's legal duties with respect to PHI. [FN404] Section 164.520(b)(1)(ii) of the Privacy Rule describes the required contents of the NPP, including descriptions of the types of permitted uses and disclosures of their PHI. More specifically, the NPP must describe the ways in which the covered entity may use and disclose PHI for TPO, as well as each of the other purposes for which the covered entity is permitted or required to use or disclose PHI without the individual's written authorization. Additionally, the NPP must state the covered entity's duties to protect privacy, provide a copy of the NPP, and abide by the terms of the current notice. The NPP must also describe individuals' rights, including the right to complain to HHS and to the covered entity if they believe their privacy rights have been violated, as well as other statements if the covered entity uses PHI for certain activities, such as fundraising. The Privacy Rule does not, however, currently require a covered entity to provide information about specific prohibited uses and disclosures of PHI.

2. CARES Act

Section 3221(i) of the CARES Act directs the Secretary to modify the NPP provisions at 45 CFR 164.520 to include new requirements for covered entities that create or maintain PHI that is also a record of SUD treatment provided by a Part 2 program (i.e., covered entities that are Part 2 programs and covered entities that receive Part 2 records from a Part 2 program). The CARES Act amended 42 U.S.C. 290dd-2 to require the Department to revise Part 2 to more closely align with the Privacy Rule.

3. Proposals in 2022 Part 2 NPRM and 2023 Privacy Rule NPRM

The Department proposed in December 2022 to modify both the Patient Notice requirements at 42 CFR 2.22 and the NPP requirements at 45 CFR 164.520 to provide consistent notice requirements for all Part 2 records. Revisions to the Patient Notice requirements were addressed and finalized in the 2024 Part 2 Rule, while modifications to the NPP provisions proposed in the 2022 Part 2 NPRM were deferred to a future rulemaking. The Department also separately proposed to modify the NPP provisions to support reproductive health care privacy as part of the 2023 Privacy Rule NPRM.

As part of the 2022 Part 2 NPRM, the Department proposed several changes to the NPP provisions. We proposed in a new paragraph (2) to 45 CFR 164.520(a) that individuals with Part 2 records that are created or maintained by covered entities would have a right to adequate notice of uses and disclosures, their rights, and the responsibilities of covered entities with respect to such records. The Department also proposed to remove 45 CFR 164.520(a)(3), the exception for providing inmates a copy of the NPP, which would require covered entities that serve correctional facilities to provide inmates with a copy of the NPP.

Additionally, the Department proposed revising 45 CFR 164.520(b)(1) to specifically clarify that covered entities that maintain or receive Part 2 records would need to provide an NPP that is written in plain language and contains the notice's required elements. We also proposed to modify 45 CFR 164.520(b)(1)(i) to replace “medical” with “health” information.

The Department also proposed in the 2022 Part 2 NPRM to incorporate changes proposed to the NPP requirements in the 2021 Privacy Rule NPRM,[FN405] such as adding a requirement to include the email address for a designated person who would be available to answer questions about the covered entity's privacy practices; adding a permission for a covered entity to provide information in its NPP concerning the individual access right to direct copies of PHI to third parties when the PHI is not in an EHR and the ability to request the transmission using an authorization; and removing the requirement for a covered entity to obtain a written acknowledgment of receipt of the NPP. The Department is finalizing certain changes proposed in the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM that directly support the two final rules.

In both the 2022 Part 2 NPRM and 2023 Privacy Rule NPRM, the Department proposed to modify 45 CFR 164.520(b)(1)(ii), which requires covered entities to describe for individuals the purposes for which a covered entity is permitted to use and disclose PHI. Consistent with the CARES Act, we proposed in the 2022 Part 2 NPRM to modify paragraph (C) to clarify that where uses and disclosures are prohibited or materially limited by other applicable law, “other applicable law” would include Part 2, while the Department proposed to clarify at paragraph (D) that the requirement for a covered entity to include in the NPP sufficient detail to place an individual on notice of the uses and disclosures that are permitted or required by the Privacy Rule and other applicable laws, including Part 2.

The Department further proposed to require in 45 CFR 164.520(b)(1)(iii), which requires covered entities to include descriptions of certain activities in which the covered entity intends to engage, in a new paragraph (D) the inclusion of a statement that Part 2 records created or maintained by the covered entity will not be used in certain proceedings against the individual without the individual's written consent or a court order consistent with 42 CFR part 2. Additionally, we proposed to require in a new paragraph (E) that covered entities that intend to use Part 2 records for fundraising include a statement that ***33046** such records may be used or disclosed for fundraising purposes only if the individual grants written consent as provided in 42 CFR 2.31.

In 45 CFR 164.520(b)(1)(v)(C), which addresses a covered entity's right to change the terms of its notice, we also proposed to simplify and modify the regulatory text to clarify that this right is limited to circumstances where such changes are not material or contrary to law. The Department also proposed to add a new paragraph (4) to 45 CFR 164.520(d) to prohibit construing permissions for covered entities participating in organized health care arrangements [FN406] (OHCAs) to disclose PHI between participants as negating obligations relating to Part 2 records.

The 2023 Privacy Rule NPRM also proposed modifications to the NPP requirements.[FN407] Specifically, the Department proposed to modify 45 CFR 164.520(b)(1)(ii) by adding a new paragraph (F) to require a covered entity to describe and provide an example of the types of uses or disclosures prohibited by 45 CFR 164.502(a)(5)(iii), and to do so in sufficient detail for an individual to understand the prohibition. We also proposed adding a new paragraph (G) to 45 CFR 164.502(b)(1)(ii) to describe each type of use and disclosure for which an attestation is required under 45 CFR 164.509, with an example. Additionally, the Department requested comment on whether it would benefit individuals for the Department to require that covered entities include a statement in the NPP that would explain that the recipient of the PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply after PHI is disclosed for a permitted purpose to an entity other than a regulated entity (e.g., disclosed to a non-covered health care provider for treatment purposes).

4. Overview of Public Comments

We received many comments on the proposed NPP changes in both the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM. Some of the comments on the 2022 Part 2 NPRM addressed both the NPP and the Patient Notice. Comments concerning the Patient Notice are discussed in the 2024 Part 2 Rule.[FN408] Commenters on the NPP proposals in the 2022 Part 2 NPRM urged the Department to coordinate revisions to the NPP provisions across its proposed and final rules. Commenters also requested guidance about their ability to use a single form to satisfy both the NPP and Patient Notice requirements. Commenters

generally expressed support for the Department's proposals to modify 45 CFR 164.520(a) and 164.520(b)(1) to apply the NPP requirements to certain entities, in coordination with changes required by the CARES Act and consistent with Part 2.

Commenters to the 2022 Part 2 NPRM generally did not express opposition to the Department's proposed changes to paragraph (b)(iii) of 45 CFR 164.520, although some did request additional guidance. We received no comments on our proposed modifications to add a new paragraph concerning OHCAs to 45 CFR 164.520(d).

Most commenters expressed support for the Department's 2023 Privacy Rule NPRM proposals to revise the NPP requirements. Many also recommended additional modifications to the NPP requirements or clarifications to the requirements. Most also recommended that the Department add a requirement that NPPs include a statement that would explain that the recipient of PHI would not be bound by the proposed prohibition because the Privacy Rule would no longer apply after PHI is disclosed for a permitted purpose to an entity other than a regulated entity (e.g., disclosed to a non-covered health care provider for treatment purposes).

5. Final Rule

The Department published the 2024 Part 2 Rule on February 16, 2024. It included modifications to the Patient Notice in 42 CFR 2.22 and reserved modifications to the HIPAA NPP for a forthcoming HIPAA rule. We address the modifications proposed in the 2022 Part 2 NPRM here, in concert with the modifications proposed in the 2023 Privacy Rule NPRM.

As required by the CARES Act and in alignment with the Privacy Rule, we are modifying the NPP provisions in multiple ways. First, we are requiring in 45 CFR 164.520(a)(2) that covered entities that create or maintain Part 2 records provide notice to individuals of the ways in which those covered entities may use and disclose such records, and of the individual's rights and the covered entities' responsibilities with respect to such records. Second, we are revising 45 CFR 164.520(b)(1) to clarify that a covered entity that receives or maintains records subject to Part 2 must provide an NPP that is written in plain language and that contains the elements required. For clarity, we have reordered wording within this paragraph to refer to “receiving or maintaining” records, rather than “maintaining or receiving” records as initially proposed.

Third, the Department is modifying 45 CFR 164.520(b)(1)(ii) to revise paragraphs (C) and (D), and to add paragraphs (F), (G), and (H) to clarify certain statements and add new statements that must be included in an NPP. Consistent with the CARES Act, we are modifying paragraph (C) to clarify that where NPP's descriptions of uses or disclosures that are permitted for TPO or without an authorization must reflect “other applicable law” that is more stringent than the Privacy Rule, other applicable law includes Part 2. Likewise, we are modifying paragraph (D) to clarify that Part 2 is specifically included in the “other applicable law” referenced in the requirement to describe uses and disclosures that are permitted for TPO or without an authorization sufficiently to place an individual on notice of the uses and disclosures that are permitted or required by the Privacy Rule and other applicable law.

New paragraphs (F) and (G) provide individuals with additional information about how their PHI may or may not be disclosed for purposes addressed in this rule, furthering trust in the relationship between regulated entities and individuals by ensuring that individuals are aware that certain uses and disclosures of PHI are prohibited. Specifically, paragraph (F) requires that the NPP contain a description, including at least one example, of the types of uses and disclosures prohibited under 45 CFR 164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition, while paragraph (G) requires that the NPP contain a description, including at least one example, of the types of uses and disclosures for which an attestation is required under new 45 CFR 164.509.

Additionally, based on feedback from commenters, we are requiring in a new paragraph (H) that covered entities include a statement explaining to individuals that PHI disclosed pursuant to the Privacy Rule may be subject to redisclosure and no longer protected by the Privacy Rule.This will help individuals to make informed decisions about to whom they provide access to or authorize the disclosure of their PHI.

Under new paragraph (D) of 45 CFR 164.520(b)(1)(iii), the Department is requiring that covered entities provide notice to individuals that a Part 2 record, or testimony relaying the content of such record, may not be used or disclosed in a civil, criminal, administrative, or legislative proceeding against the individual absent written ***33047** consent from the individual or a court order, consistent with the requirements of 42 CFR part 2.

The Department is also finalizing a requirement at 45 CFR 164.520(b)(1)(iii)(E) that a covered entity must provide individuals with a clear and conspicuous opportunity to elect not to receive any fundraising communications before using Part 2 records for fundraising purposes for the benefit of the covered entity.

Lastly, we are finalizing our proposal to add a new paragraph (4) in 45 CFR 164.520(d) regarding joint notice by separate covered entities. This modification clarifies that Part 2 requirements continue to apply to Part 2 records maintained by covered entities that are part of OHCAs.

We are not finalizing in this rule the proposal to remove the exception to the NPP requirements for inmates of correctional facilities in this rule because it would be better addressed within the context of care coordination.

6. Responses to Public Comments

Comment: Commenters on both the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM urged the Department to coordinate any changes made to the NPP provisions based on proposals made in the separate rulemakings. According to the commenters, coordinating the changes to the NPP requirements would help to ensure consistency, reduce the administrative burden on covered entities, and ensure individual understanding of the permitted uses and disclosures of their PHI, including PHI that is also a Part 2 record. A few commenters on the 2022 Part 2 NPRM explained the different concerns that updates to the NPP pose to covered entities of differing sizes, based on resource constraints directly related to their size. Several commenters on the 2023 Privacy Rule NPRM requested that the Department provide sample language and examples or provide an updated model NPP.

Response: As part of this rulemaking, the Department is finalizing modifications to certain NPP requirements that were proposed in the 2022 Part 2 NPRM and the 2023 Privacy Rule NPRM. Thus, these changes serve to implement certain requirements of the CARES Act and to support reproductive health care privacy. The Department appreciates the recommendations and will consider them for future guidance.

Comment: A few commenters on the 2022 Part 2 NPRM requested that the Department clarify whether they would be permitted to use a single document or form when providing notice statements to individuals to ensure compliance by regulated entities and understanding of the notices by individuals. A few commenters agreed that a single NPP would reduce the administrative burden on regulated entities or be the most effective way to convey privacy information to individuals and asked for confirmation that this was permitted. A commenter requested that the Department update the Patient Notice in a manner such that the NPP header may be used in the combined notice if they are permitted to use a combined NPP/Patient Notice.

Response: As we have provided previously in guidance on the Privacy Rule and Part 2, notices issued by covered entities for different purposes may be separate or combined, as long as all of the required elements for both are included.[FN409] Thus, it is acceptable under both the Privacy Rule and Part 2 to meet the notice requirements of the Privacy Rule, Part 2, and state law by either providing separate notices or combining the required notices into a single notice, as long as all of the required elements are included.

Comment: A few commenters on the 2022 Part 2 NPRM and most of the commenters on the 2023 Privacy Rule NPRM suggested the proposed approach to modifying both the Patient Notice and NPP would bolster transparency and the public's understanding of how their health information is used or disclosed and collected. Many commenters on the 2023 Privacy Rule NPRM provided recommendations for ways in which the Department could improve the NPP, including requiring that the NPP be in plain language.

Response: The Department appreciates the comments on its proposal to modify the NPP to align with changes made in the Patient Notice and in support of reproductive health care privacy. The modifications will bolster transparency and public understanding of how information is used, disclosed, and protected. Covered entities have long been required under 45 CFR 164.520(b)(1) to provide an NPP that is written in plain language. Discussion of this requirement can be found in the preamble to the 2000 Privacy Rule.[FN410] The Department's model NPP forms, available in both English and Spanish, provide one example of how the plain language requirement may be met.[FN411]As discussed above, we are modifying 45 CFR 164.520 to clarify that this requirement applies to covered entities that use and disclose Part 2 records. Additional resources on writing in plain language can be found at https://plainlanguage.gov. Additionally, covered entities are required to comply with all Federal nondiscrimination laws, including laws that address language access requirements. Information about such requirements is available at www.hhs.gov/hipaa.

Comment: Commenters expressed concerns about the interplay of the Part 2 Patient Notice requirements with the NPP, the burden on covered entities to modify the NPP, and including the attestation requirement in the NPP.

Response: We have sought to align the requirements for the Patient Notice as closely as possible with the NPP requirements and to modify the NPP requirements to allow for a combined Patient Notice and NPP. The changes the Department is making to the NPP empower the individual and improve health outcomes by improving the likelihood that health care providers will make accurate diagnoses and informed treatment recommendations to individuals. These changes to the NPP provide the individual with clear information and reassurance about their privacy rights and their ability to discuss their reproductive health and related health care because they inform an individual that their PHI may not be used or disclosed for certain purposes prohibited by new 45 CFR 164.502(a)(5)(iii). As such, the qualitative benefits of providing individuals with information about how their PHI may be used and disclosed under the Privacy Rule outweigh the quantitative burdens for covered entities to revise their NPPs. Accordingly, we are finalizing the modifications proposed to the NPP as part of the 2023 Privacy Rule NPRM.

Comment: A majority of the commenters on the 2023 Privacy Rule NPRM who expressed support for revising the NPP also recommended that the Department require that the NPP include an explanation that the prohibition or Privacy Rule generally would no longer apply to PHI that has been disclosed for a permitted purpose to a person that is not a regulated entity. A few commenters opposed the addition as unnecessary or expressed concern about the potential length of the NPP. A ***33048** few of the commenters opposed adding such a statement because they believed it could deter individuals from seeking reproductive health care, increase individuals' mistrust of health care providers, or not add to individuals' understanding of their rights and protections under the Privacy Rule.

Response: In response to comments and in support of transparency for individuals, the Department is finalizing a new requirement to include in the NPP a statement adequate to put the individual on notice of the potential for information disclosed pursuant to the Privacy Rule to be subject to redisclosure by the recipient and no longer protected by the Privacy Rule. This change will provide additional clarity to individuals directly and assist covered entities in explaining the limitations of the Privacy Rule to individuals. We believe that any concerns about the negative effects of these modifications on length are outweighed by their benefits to the individual.

Comment: Several commenters to the 2023 Privacy Rule NPRM requested the Department provide additional time for compliance with the new NPP requirements and exercise enforcement discretion for a period of time after the compliance date.

Response: As noted above, we are finalizing certain modifications to the NPP provisions that were proposed in the 2022 Part 2 NPRM rule and other modifications to the same provisions that were proposed in the 2023 Privacy Rule NPRM. To ease the burden on covered entities and in compliance with 45 CFR 160.104, the Department is finalizing a compliance date of February 16, 2026, for the NPP provisions. The rationale for this compliance date is discussed in greater detail in the discussion of Effective and Compliance Dates.

F. Section 164.535—Severability

In the NPRM, the Department included a discussion of severability that explained how we believed the proposed rule should be interpreted if any provision was held to be invalid or facially unenforceable. We are finalizing a new 45 CFR 164.535 to codify this interpretation. The Department intends that, if a specific regulatory provision in this rule is found to be invalid or unenforceable, the remaining provisions of the rule will remain in effect because they would still function sensibly.

For example, the changes this final rule makes to the NPP requirements in 45 CFR 164.520 (including the changes finalizing proposals from the 2022 Part 2 NPRM) shall remain in full force and effect to the extent that they are not directly related to a provision in this rulemaking that is held to be invalid or unenforceable such that notice of that provision is no longer necessary. Conversely, if the NPP requirements are held to be invalid or unenforceable, the other modifications shall remain in full force and effect to the extent that they are not directly related to the NPP requirements.

As another example, we also intend that the revision in 45 CFR 160.103 to the definition of "person" shall remain in full force and effect if any other provision is held to be invalid or unenforceable because the new modified definition is not solely related to supporting reproductive health care privacy and is consistent with the Department's longstanding interpretation of the term and with regulated entities' current understanding and practices.

Similarly, we are finalizing technical corrections to the heading at 45 CFR 164.512(c) and a clarifying revision at 45 CFR 164.512(f) regarding the permission for disclosures based on administrative processes. Those changes are intended to remain in full force and effect even if other parts of this final rule are held to be invalid or unenforceable.

As another example, we also intend, if the addition in 45 CFR 160.103 of the definition of "public health," as used in the terms "public health surveillance," "public health investigation," and "public health intervention" is held to be invalid and unenforceable, the other modifications to the rules shall remain in full force and effect to the extent that they are not directly related to the definition of public health.

We further intend that if the rule is held to be invalid and unenforceable with respect to its application to some types of health care, it should be upheld with respect to other types (e.g., pregnancy or abortion-related care).

We also intend that any provisions of the Privacy Rule that are unchanged by this final rule shall remain in full force and effect if any provision of this final rule is held to be invalid or unenforceable.

These examples are illustrative and not exhaustive.

We received no comments on the language addressing severability in the 2023 Privacy Rule NPRM.

G. Comments on Other Provisions of the HIPAA Rules

Comment: A few commenters expressed concerns that the Department may grant exceptions to preemption and recommended that the Department clarify the standards for which exceptions to preemption would be made and consider strengthening these standards wherever possible or remove the potential for exceptions entirely.

One commenter expressed concern that the proposed rule could dissuade regulated entities from providing de-identified data for research, while another commenter recommended that the Department prohibit the sharing of de-identified reproductive health care data except in limited circumstances to prevent the re-identification of reproductive health data by third parties, such as law enforcement or data brokers

Response: The process for requesting exceptions to preemption and the standards for granting such requests are at 45 CFR 160.201 et seq. We did not propose any modifications to these provisions as part of the 2023 Privacy Rule NPRM, and as such, do not finalize modifications in this final rule.

The Department does not believe that this final rule will dissuade regulated entities from providing de-identified data for research or other purposes. Under the Privacy Rule, health information that meets the standard and implementation specifications for de-identification under 45 CFR 164.514 is considered not to be IIHI.[FN412] HIPAA confers on the Department the authority to set standards for the privacy of IIHI, including for de-identification. We did not propose to modify the de-identification standard as part of the 2023 Privacy Rule NPRM, and as such, do not finalize modifications in this final rule.

Comment: A commenter posited that the proposed rule's preemption of contrary state laws was not sufficiently clear and recommended that the Department reinforce the preemption provision in the final rule.

Response: The Department did not propose changes to the preemption provisions of the HIPAA Rules, which are based in statute, [FN413] and believes that the provisions, in combination with our discussion of preemption in the preamble, are sufficient.

VI. Regulatory Impact Analysis

A. Executive Order 12866 and Related Executive Orders on Regulatory Review

The Department of Health and Human Services (HHS or "Department") has examined the effects of this final rule under Executive Order (E.O.) 12866, Regulatory Planning and Review,[FN414] as ***33049** amended by E.O. 14094,[FN415] E.O. 13563, Improving Regulation and Regulatory Review,[FN416] the Regulatory Flexibility Act [FN417] (RFA), and the Unfunded Mandates Reform Act of 1995 [FN418] (UMRA). E.O.s 12866 and 13563 direct the Department to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive effects; and equity). This final rule is significant under section 3(f)(1) of E.O. 12866, as amended.

The RFA requires us to analyze regulatory options that would minimize any significant effect of a rule on small entities. As discussed in greater detail below, this analysis concludes, and the Secretary certifies, that the rule will not result in a significant economic effect on a substantial number of small entities.

The UMRA (section 202(a)) generally requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." [FN419] The current threshold after adjustment for inflation is $177 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly Federal mandate costs resulting from imposing enforceable duties on state, local, or Tribal governments or the private sector; or increasing the stringency of conditions in, or decreasing the funding of, state, local, or Tribal governments under entitlement programs. This final rule imposes mandates that would result in the expenditure by state, local, and Tribal governments, in the aggregate, or by the private sector, of more than $177 million in any one year. The impact analysis in this final rule addresses such effects both qualitatively and quantitatively. In general, each regulated entity, including government entities that meet the definition of covered entity (e.g., state Medicaid agencies), is required to adopt new policies and procedures for responding to requests for the use or disclosure of protected health information (PHI) for which an attestation is required and to train its workforce members on the new requirements. Additionally, although the Department has not quantified the costs, state, local, and Tribal law enforcement agencies must analyze requests that they initiate for the use or disclosure of PHI and provide regulated entities with an attestation that the request is not for a prohibited purpose in instances where the request is made for health oversight activities, judicial and administrative proceedings, law enforcement purposes, or about decedents to coroners and medical examiners, and is for PHI potentially related to reproductive health care. One-time costs for all regulated entities to change their policies will increase costs above the UMRA threshold in one year. The Department initially estimated that ongoing expenses for the new attestation condition would not increase significantly, but we sought additional data to inform our estimates. Although Medicaid makes Federal matching funds available for states for certain administrative costs, these are limited to costs specific to operating the Medicaid program. There are no Federal funds directed at Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance activities.

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996,[FN420] the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs has determined that this final rule meets the criteria set forth in 5 U.S.C. 804(2) because it is projected to have an annualized effect on the economy of more than $100,000,000. Because of the large number of covered entities that are subject to this final rule and the large number of individuals with health plan coverage, any rule modifying the HIPAA Privacy Rule that requires updating policies and procedures and the Notice of Privacy Practices (NPP) and distributing the NPP to a percentage of individuals is likely to meet the threshold in 5 U.S.C. 804(2).

The Justification for this Rulemaking and Summary of Final Rule Provisions section at the beginning of this preamble contain a summary of this rule and describe the reasons it is needed. The Department presents a detailed analysis below.

1. Summary of Costs and Benefits

The Department identified six general categories of quantifiable costs arising from these proposals: (1) responding to requests for the use or disclosure of PHI for which an attestation is required; (2) revising business associate agreements; (3) updating the NPP and posting it online; (4) developing new or modified policies and procedures; (5) revising training programs for workforce members; and (6) requesting an exception from HIPAA's general preemption authority. The first five categories apply primarily to covered entities, while the sixth category applies to states and other interested persons.

The Department estimates that the first-year costs attributable to this final rule total approximately $595.0 million. These costs are associated with covered entities responding to requests for the use or disclosure of PHI that are conditioned upon an attestation; revising business associate agreements; revising policies and procedures; updating, posting, and mailing the NPP; and revising training programs for workforce members, and with states or other persons requesting exceptions from preemption. These costs also include increased estimates for wages, postage, and the number of NPPs distributed by health plans as compared to the baseline of existing annual cost and burden estimates for these activities in the approved HIPAA information collection. For years two through five, estimated annual costs of approximately $20.9 million are attributable to ongoing costs related to the attestation requirement. Table 1 reports the present value and annualized estimates of the costs of this final rule covering a 5-year time horizon. Using a 7% discount rate, the Department estimates this final rule will result in annualized costs of $151.8 million; and using a 3% discount rate, these annualized costs are $142.6 million.

Table 1—Accounting Table, Costs of the Rule

[$ Millions]

Costs	Primary estimate	Year dollars	Discount rate (%)	Period covered
Present Value	$678.6	2022	Undiscounted	2024-2028
Present Value	622.3	2022	7	2024-2028
Present Value	653.1	2022	3	2024-2028

Annualized	151.8	2022	7	2024-2028
Annualized	142.6	2022	3	2024-2028

***33050** The changes to the Privacy Rule will likely result in important benefits and some costs that the Department is unable to fully quantify at this time. As explained further below, unquantified benefits include improved trust and confidence between individuals and health care providers; enhanced privacy and improved access to reproductive health care and information, which may prevent increases in maternal mortality and morbidity; increased accuracy and completeness in patient medical records, which may prevent poor health outcomes; enhanced support for survivors of rape, incest, and sex trafficking; and maintenance of family economic stability by allowing families to determine the timing and spacing of whether or when to be pregnant. Additionally, allowing regulated entities to accept an attestation for requests for the use or disclosure of PHI potentially related to reproductive health care, and to presume that reproductive health care provided by another person was lawful under the circumstances it was provided, will reduce potential liability for regulated entities by providing some assurance with respect to whether the requested disclosure is prohibited.

Table 2—Potential Non-Quantified Benefits for Covered Entities and Individuals

Benefits
Improve access to complete information about lawful reproductive health care options, including for individuals who are pregnant or considering a pregnancy (i.e., improve health literacy), by reducing concerns about disclosure of PHI.
Maintain or reduce levels of maternal mortality and morbidity by ensuring that individuals and their clinicians can freely communicate and have access to complete information needed for quality lawful health care, including coordination of care.
Decrease barriers to accessing prenatal health care by maintaining privacy for individuals who seek a complete range of lawful reproductive health care options.
Enhance mental health and emotional well-being of pregnant individuals by reducing fear of potential disclosures of their PHI to investigate or impose liability on a person for the mere act of seeking, obtaining, providing, or facilitating lawful health care.
Improve or maintain trust between individuals and health care providers by reducing the potential for health care providers to report PHI in a manner that could harm the individuals' interests.
Prevent or reduce re-victimization of pregnant individuals who have survived rape or incest by protecting their PHI from undue scrutiny.
Improve or maintain families' economic well-being by not exposing individuals or their family members to costly investigations or activities to impose liability for seeking, obtaining or facilitating lawful reproductive health care.
Maintain the economic well-being of regulated entities by not exposing regulated entities or workforce members to costly investigations or activities to impose liability on them for engaging in lawful activities.
Ensure individuals' ability to obtain full and complete information and make lawful decisions concerning fertility- or infertility-related health care that may include selection or disposal of embryos without risk of PHI disclosure for criminal, civil, or administrative investigations or activities to impose liability for engaging in lawful activities.

The Department also recognizes that there may be some costs that are not readily quantifiable, notably, the potential burden on persons requesting PHI to investigate or impose liability on persons for seeking, obtaining, providing, or facilitating reproductive health care that is not lawful under the circumstances in which such health care is provided. As discussed elsewhere in this final rule, we acknowledge that, in certain limited circumstances, the final rule may, prevent persons from obtaining an individual's PHI, such as where the request is directed to the health care provider that provided the reproductive health care and that

health care provider reasonably determines that such health care was provided lawfully. However, the existing permission for disclosures for law enforcement does not create a mandate for disclosure to law enforcement agencies. Rather, it establishes the conditions under which a regulated entity may disclose PHI if it so chooses. Accordingly, consistent with how the Privacy Rule has operated since its inception, persons whose requests for PHI are declined by regulated entities may incur additional costs if they choose to pursue their investigations through other methods and obtain evidence from non-covered entities. We have not previously quantified the costs to such persons for obtaining an individual's PHI, such as where a law enforcement official is required to prepare a formal administrative request or obtain a qualified protective order and we do not do so here. We do not view the attestation requirement as changing this calculus and have designed the attestation to impose a minimal burden on requests for PHI related to lawful conduct by health care providers by offering a model attestation form. Despite the minimal formality of providing a signed attestation, some state law enforcement agencies may experience the requirement as a burden, and we acknowledge that potential as a non-quantifiable cost.

2. Baseline Conditions

The Privacy Rule, in conjunction with the Security and Breach Notification Rules, protects the privacy and security of individuals' PHI, that is, individually identifiable health information (IIHI) transmitted by or maintained in electronic media or any other form or ***33051** medium, with certain exceptions. It limits the circumstances under which regulated entities are permitted or required to use or disclose PHI and requires covered entities to have safeguards in place to protect the privacy of PHI. The Privacy Rule also establishes certain rights for individuals with respect to their PHI and sets limits and conditions on the uses and disclosures that may be made of such information without an individual's authorization.

As explained in the preamble, the Department has the authority under HIPAA to modify the Privacy Rule to prohibit the use or disclosure of PHI for activities to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it was provided, as well as to identify any person for the purpose of initiating such activities. The Privacy Rule has been modified several times since it was first issued in 2000 to address statutory requirements, changed circumstances, and concerns and issues raised by stakeholders regarding the effects of the Privacy Rule on regulated entities, individuals, and others. Recently, as the preamble discusses, changed circumstances resulting from new inconsistencies in the regulation of reproductive health care nationwide and the negative effects on individuals' expectations for privacy and their relationships with their health care providers, as well as the additional burdens imposed on regulated entities, require the modifications made by this final rule.

For purposes of this Regulatory Impact Analysis (RIA), this final rule adopts the list of covered entities and cost assumptions identified in the Department's 2023 Information Collection Request (ICR).[FN421] The Department also relies on certain estimates and assumptions from the 1999 Privacy Rule NPRM [FN422] that remain relevant, and the 2013 Omnibus Rule, [FN423] as referenced in the analysis that follows.

The Department quantitatively analyzes and monetizes the effect that this final rule may have on regulated entities' actions to: revise business associate agreements between covered entities and their business associates, including release-of-information contractors; create new forms; respond to certain types of requests for PHI; update their NPPs; adopt policies and procedures to implement the requirements of this final rule; and train their employees on the updated policies and procedures. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of regulated entities might take in response to this rule.

Analytic Assumptions

The Department bases its assumptions for calculating estimated costs and benefits on several publicly available datasets, including data from the U.S. Census, the U.S. Department of Labor, Bureau of Labor Statistics, Centers for Medicare & Medicaid Services, and the Agency for Healthcare Research and Quality. For the purposes of this analysis, the Department assumes that benefits plus indirect costs equal approximately 100 percent of pre-tax wages and adjusts the hourly wage rates by multiplying

by two, for a fully loaded hourly wage rate. The Department adopts this as the estimate of the hourly value of time for changes in time use for on-the-job activities.

Implementing the regulatory changes likely will require covered entities to engage workforce members or consultants for certain activities. The Department assumes that a lawyer will draft or review the new attestation form, revisions to business associate agreements, revisions to the NPP, and required changes to HIPAA policies and procedures. The Department expects that a training specialist will revise the necessary HIPAA training and that a web designer will post the updated NPP. The Department further anticipates that a workforce member at the pay level of medical records specialist will confirm receipt of required attestations. To the extent that these assumptions affect the Department's estimate of costs, the Department solicited comment on its assumptions, particularly assumptions in which the Department identifies the level of workforce member (e.g., clerical staff, professional) that will be engaged in activities and the amount of time that particular types of workforce members spend conducting activities related to this RIA as further described below. Table 3 also lists pay rates for occupations referenced in the explanation of estimated information collection burdens in Section F of this RIA and related tables.

The Department received several comments about the occupations engaged in certain activities and the time burden associated with them. We reviewed these submissions and used the provided information to revise the estimate for the cost of processing requests for the use or disclosure of PHI that require an attestation. For more details, please see the sections discussing the costs of the rule below.

The Department received no comment on the hourly value of time; therefore, we retain all relevant assumptions laid out in the 2023 Privacy Rule NPRM, as described above (see Table 3 for a list of occupations and corresponding wages).[FN424]

Table 3—Occupational Pay Rates

Occupation code and title	Mean hourly wage	Fully loaded hourly wage
00-0000 All Occupations	$29.76	$59.52
43-3021 Billing and Posting Clerks	21.54	43.08
29-0000 Healthcare Practitioners and Technical Occupations	46.52	93.04
29-9021 Health Information Technologists and Medical Registrars	31.38	62.76
29-9099 Healthcare Practitioners and Technical Workers, All Other	32.78	65.56
15-1212 Information Security Analysts	57.63	115.26
23-1011 Lawyers	78.74	157.48
13-1111 Management Analysts	50.32	100.64
11-9111 Medical and Health Services Manager	61.53	123.06
29-2072 Medical Records Specialist	24.56	49.12
43-0000 Office and Administrative Support Occupations	21.90	43.80

11-2030 Public Relations and Fundraising Managers	68.56	137.12
13-1151 Training and Development Specialist	33.59	67.18
43-4171 Receptionists and Information Clerks	16.64	33.28
15-1255 Web and Digital Interface Designers	48.91	97.82

***33052** The Department assumes that most covered entities will be able to incorporate changes to their workforce training into existing HIPAA training programs rather than conduct a separate training because the total time frame for compliance from date of finalization would be 240 days.[FN425]

Covered Entities Affected

The Department received no substantive comments on the number or type of HIPAA covered entities affected by this rule; therefore, we retain the methodology and entity estimates as described in the 2023 Privacy Rule NPRM and the baseline conditions section above.

To the extent that covered entities engage business associates to perform activities under the rule, the Department assumes that any additional costs will be borne by the covered entities through their contractual agreements with business associates. The Department's estimate that each revised business associate agreement will require no more than 1 hour of a lawyer's labor assumes that the hourly burden could be split between the covered entity and the business associate. Thus, the Department calculated estimated costs based on the potential number of business associate agreements that will be revised rather than the number of covered entities or business associates with revised business associate agreements.

The Department requested data on the number of business associates (which may include health care clearinghouses acting in their role as business associates of other covered entities) that would be affected by the rule and the extent to which they may experience costs or other burdens not already accounted for in the estimates of burdens for revising business associate agreements. The Department also requested comment on the number of business associate agreements that would need to be revised, if any. We did not receive any actionable comments on the number of affected business associates, the number of business associate agreements, or any specific costs that business associates might bear. For more details, see the section on business associate agreements below.

The Department requested public comment on these estimates, including estimates for third party administrators and pharmacies where the Department has provided additional explanation. The Department additionally requested detailed comment on any situations, other than those identified here, in which covered entities would be affected by this rulemaking. We did not receive any substantive comments related to these issues.

Table 4—Estimated Number and Type of Covered Entities

Covered entities			
NAICS code	**Type of entity**	**Firms**	**Establishments**
524114	Health and Medical Insurance Carriers	880	5,379
524292	Third Party Administrators	456	783

622	Hospitals	3,293		7,012
44611	Pharmacies	19,540	[a] 67,753	
6211-6213	Office of Drs. & Other Professionals	433,267		505,863
6215	Medical Diagnostic & Imaging	7,863		17,265
6214	Outpatient Care	16,896		39,387
6219	Other Ambulatory Care	6,623		10,059
623	Skilled Nursing & Residential Facilities	38,455		86,653
6216	Home Health Agencies	21,829		30,980
532283	Home Health Equipment Rental	611		3,197
Total		549,713		774,331

***33053 Individuals Affected**

The Department believes that the population of individuals potentially affected by the rule is approximately 76 million overall, [FN426] representing nearly one-fourth of the U.S. population, including approximately 6 million pregnant individuals annually and an unknown number of individuals facing a potential pregnancy or pregnancy risk due to sexual activity, contraceptive avoidance or failure, rape (including statutory rape), and incest. According to Federal data, 78 percent of sexually active females received reproductive health care in 2015-2017.[FN427]

The Department received comments related to the number of individuals affected by the rule, some of which are summarized below. One commenter asserted that the Department had overestimated the number of affected individuals and urged reducing the estimate to 78 percent of sexually active females (52.72 million). The same commenter also argued that even this revised number might be an overestimate, and that the number of individuals directly affected by the rule would be closer to 50,400 a year. Another commenter suggested that the number of individuals potentially affected by the proposed rule is much larger than the estimate and that the estimate should include any individual who was ever capable of bearing children and their family members.

Another commenter asserted that the Department was underestimating the number of individuals that would be affected by the proposed rule but did not include an estimate of their own.

After reviewing the comments, the Department is finalizing the estimates of the number of individuals that will be affected by this final rule as described above, which includes updates for 2022 data. The Department considers a key category of individuals affected by this final rule those who have the potential to become pregnant because pregnancies may occur and result in a need for reproductive health care nationwide. Pregnancy, concern about potential pregnancy, and the need for reproductive health care do not recognize state boundaries or regulatory timelines.

Commenters recommended data points above and below the Department's proposed estimate of 74 million affected individuals. We believe that the number of affected individuals is far greater than the total who are survivors of sexual assault or sex trafficking (as recommended by a commenter), yet less than the number of all individuals who have ever been of childbearing age and their family members (as recommended by another commenter). We recognize that the age range for the proposed estimate of females, 10-44, imperfectly reflects the number of females of childbearing age; however, the number of females over age 44 who could become pregnant may be offset by the number of females aged 10-13 who are not yet capable of childbearing.

We use the number of females of potentially childbearing age as a proxy for the number of individuals affected by the final rule as shown in Table 5 below.

Table 5—Estimated Number of Individuals Affected

Females of potentially childbearing age [428]	Population estimate
10 to 14 years	10,327,799
15 to 19 years	10,618,136
20 to 24 years	10,957,463
25 to 29 years	10,762,368
30 to 34 years	11,440,546
35 to 39 years	11,013,337
40 to 44 years	10,771,942
Total	75,891,591

3. Costs of the Rule

Below, the Department provides the basis for its estimated quantifiable costs resulting from the changes to specific provisions of the Privacy Rule. Many of the estimates are based on assumptions formed through the Office for Civil Rights' (OCR's) experience with its compliance and enforcement program and accounts from stakeholders received at outreach events. The Department has quantified recurring burdens for this final rule for obtaining an attestation from a person requesting the use or disclosure of PHI potentially related to reproductive health care for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners or medical examiners.

The Department requested information or data points from commenters to further refine its estimates and assumptions. We examine the most substantive comments received in the cost section below. Additionally, we received comments that are also discussed below on topics that are not directly addressed in the cost section.

A commenter asserted that the Department did not account for the additional costs associated with major depressive disorders that would arise from the increase in abortions due to the rule. The Department does not believe that is a valid benchmark for the effects of this final rule, in part because we reject the premise, which is not backed by medical evidence or data, that this final rule will result in an increase in pregnancy terminations or depression.[FN429] Further, researchers have raised numerous concerns about the methodology of the 2011 study cited in ***33054** the comment.[FN430] Accordingly, we are not including the costs associated with treatment of depression in the cost section.

a. Costs Associated With Requests for Exception From Preemption

The Department anticipates that states with laws that restrict access to reproductive health care are likely to seek an exception to the requirements of this final rule that preempt state law. Given the pace at which state laws governing access to reproductive health care are changing, the Department is finalizing its proposed estimate that a potential increase of 26 states [FN431] will incur costs to develop a request to except a provision of state law from HIPAA's general preemption authority to submit to the Secretary.[FN432] Based on existing burden estimates for this activity,[FN433] the Department is finalizing its estimate that each exception request will require approximately 16 hours of labor at the rate of a general health care practitioner and that

approximately 26 states will make such requests. Thus, the Department estimates that states will spend a total of 416 hours requesting exception from preemption and monetize this as a one-time cost of $38,705 [= 16 x 26 x $93.04].

b. Estimated Costs From Adding a Requirement for an Attestation for Disclosures for Certain Purposes

Multiple commenters asserted that the projected attestation cost in the proposed rule was incorrect and underestimated the true cost of implementing the proposed requirement. One commenter asserted that the proposed rule underestimated the time to review medical records for PHI about reproductive health care and recommended that it be increased significantly. The same commenter also suggested that the Department adopt a requirement to obtain an individual's authorization, instead of an attestation, because it would reduce costs. Other commenters asserted that the proposed cost estimates for the attestation requirement did not account for associated administrative burdens, urged the Department to require an attestation for every request for PHI to decrease overall costs by establishing a procedural norm, or requested that the Department provide grants and trainings to regulated entities to offset the costs of the attestation provision. Finally, another commenter requested that the Department release a model attestation form to decrease the cost burden for covered entities.

A few commenters asserted that the Department mis-identified the types of staff that would performing specific components of the attestation requirement. One posited that both a lawyer and a medical professional would need to review medical records for the use or disclosure of PHI in response to the proposed revisions to the Privacy Rule. Another asserted that the person reviewing PHI in response to a request for the use or disclosure of PHI would be a medical records clerk.

The Department has modified the attestation requirement in response to public comments. As discussed above, this final rule requires regulated entities to obtain an attestation that the request for the use or disclosure of PHI is not for a purpose prohibited by 45 CFR 164.502(a)(5)(iii) when the request is for certain purposes (health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners) and is for PHI potentially related to reproductive health care. Where the request is for a purpose that implicates 45 CFR 164.502(a)(5)(iii) and the reproductive health care was provided by someone other than the regulated entity that received the request, such health care is presumed lawful under the circumstances in which it was provided unless the conditions of 45 CFR 164.502(a)(5)(iii)(C) are met. We expect the presumption of lawfulness to lower the burden for regulated entities to process requests for the use or disclosure of PHI for which an attestation is required; however, we also acknowledge that the proposed estimate did not fully represent the number of likely requests for the use or disclosure of PHI. The Department declines to require a valid authorization for these requests, as opposed to an attestation, and no grants to offset costs will be needed because of the lower estimated burden per request. The revised cost estimates include review of each request for the use or disclosure of PHI for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners, to determine if an attestation has been provided and administrative burdens associated with obtaining the attestation.

This final rule necessitates that regulated entities establish a process for responding to requests for the use or disclosure of PHI for which an attestation is required, such as reviewing and screening requests that are not accompanied by a valid authorization and are not a right of access request. We anticipate that across all regulated entities, this final rule will result in approximately 2,794,201 requests that regulated entities need to review in connection with the permissions under 45 CFR 164.512(d)-(g)(1). The Department estimates 5 minutes of average processing time per attestation based on the average wage of a mix of several occupations: medical and health services managers, medical records specialists, and health practitioners.[FN434] For example, a medical records specialist may forward certain requests for the use or disclosure of PHI (for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners and medical examiners) to a manager to review whether the request pertains to the lawfulness of reproductive health care. A health practitioner may review a number of records subject to a request for whether they contain PHI potentially related to reproductive health care. We calculate the annual cost for initial processing of the estimated 2,794,201 requests requiring attestations to total $20,585,500 [2,794,201 x (5/60) x $88.41]. For almost all of these requests, we believe that a brief review will be sufficient for a regulated entity to make a final disclosure determination.

For a small number of these requests, approximately 1,300, we assume that the brief review will not be sufficient; we assume that these requests will require legal review. This figure is an estimate of the number of requests that are generated to investigate or impose liability on a person for the mere act of seeking or obtaining lawful reproductive health care, including from a health care ***33055** provider in a state other than the state where the regulated entity is located. The Department's estimate assumes that approximately 26 states may seek to restrict access to out-of-state reproductive health care, including reproductive health care that is lawful under the circumstances in which it provided, and will initiate an average of 50 such requests annually. The Department estimates on average 1 hour of review for such requests based on the wage of a lawyer.[FN435] We calculate the annual legal review cost for the estimated 1,300 requests totals $204,724 [1,300 x 1 x $157.48]. This additional review increases the cost of processing attestations to $20,790,224.

We anticipate that approximately one-quarter of requests that result in legal reviews, approximately 325, will require additional managerial review by the regulated entity before making a disclosure decision. The Department estimates on average 3 hours of additional review for each of these requests based on the wage of medical and health insurance managers.[FN436] We calculate a total cost for additional actions for these requests of $119,984 [325 x 3 x $123.06]. The total annual estimated cost of processing attestations, including all additional legal and managerial reviews, is $20,910,207.

Upon consideration of the estimated cost for regulated entities to create a new attestation form, the Department is planning to develop a model form to be available prior to the compliance date of this final rule. This will save an estimated total of $60,970,823 [= 774,331 x (30/60) x $157.48], based on 30 minutes of labor by a lawyer.

c. Costs Arising From Revised Business Associate Agreements

The Department anticipates that a certain percentage of business associate agreements will likely need to be updated to reflect a determination made by parties about their respective responsibilities when either party receives requests for disclosures of PHI under 45 CFR 164.512(d), (e), (f), or (g)(1). For example, each of the parties to the business associate agreement may need to notify the other party when they have knowledge that a request is for an unlawful purpose and allocate their respective responsibilities for handling these less frequent requests. The Department is finalizing its proposed estimate that each new or significantly modified contract between a business associate and its subcontractors will require, on average, one hour of labor by a lawyer at the wage reported in Table 3. We believe that approximately 35 percent of 1 million business associates, or 350,000 entities, will decide to create or significantly modify subcontracts, resulting in total costs of $55,118,000 [= 350,000 x $157.48].

A few commenters asserted that the Department's estimates for business associates' costs were incorrect and that it should consider additional costs. A commenter recommended that the Department adopt a non-enforcement period to allow business associates to achieve compliance and limit legal costs. Another commenter stated that the Department did not adequately identify the costs that would be associated with increased legal scrutiny of business associates as a result of the proposed rule. And another commenter urged the Department to consider the additional costs for renegotiated contracts as a result of the proposed rule. Lastly, a commenter requested that the Department apply the attestation requirement to business associates because it would reduce the costs of the rule.

The Department has reviewed the comments and is adopting the 2023 Privacy Rule NPRM cost analysis in this final rule. Business associate costs are adequately captured by the estimate for revising agreements. Applying costs directly to business associates (as opposed to covered entities) is distributional and will not alter the total impact of the rule. The Department declines to create an additional non-enforcement period for this provision of the final rule beyond the 180 days from the date of publication for the final rule to the compliance date.[FN437] The estimated cost for responding to requests for PHI for which an attestation is required accounts for increased scrutiny of a small number of requests for PHI, and the estimated costs for updating business associate agreements accounts for renegotiation of an average of one release of information vendor contract for nearly half of all covered entities.

d. Costs Arising From Changes to the Notice of Privacy Practices

The final rule modifies the NPP to notify individuals that covered entities cannot use or disclose PHI for certain purposes and that in certain circumstances, covered entities must obtain an attestation from a person requesting the PHI that affirms that the use or disclosure is not for a purpose prohibited under 45 CFR 164.502(a)(5)(iii). The final rule also modifies the NPP to align with changes proposed in the 2022 Part 2 NPRM. This includes requiring covered entities that create or maintain Part 2 records to provide a notice that: addresses such records; references Part 2 as "other applicable law" that is more stringent than the Privacy Rule; explains that covered entities may not use or disclose a Part 2 record in a civil, criminal, administrative, or legislative proceeding against the individual absent written consent from the individual or a court order; and clarifies the applicability of Part 2 for organized health care arrangements that hold Part 2 records. Additionally, the final rule further modifies language for fundraising by covered entities that use or disclose Part 2 records to require a clear and conspicuous opt-out opportunity for patients. Finally, the modifications require the NPP to explain that PHI disclosed to a person other than a regulated entity is no longer subject to the requirements of the Privacy Rule.

The Department believes the burden associated with revising the NPP consists of costs related to developing and drafting the revised NPP for covered entities. The Department estimates that the updating and revising the language in the NPP will require 50 minutes of professional legal services at the wage reported in Table 3. Across all covered entities, the Department estimates a cost of $101,618,038 [= 774,331 x (50/60) x $157.48]. The Department does not anticipate any new costs for health care providers associated with distribution of the revised notice other than posting it on the entity's website (if it has one) because health care providers have an ongoing obligation to provide the notice to first-time patients that is already accounted for in cost estimates for the HIPAA Rules. Health plans that post their NPP online will incur minimal costs by posting the updated notice and then including the updated NPP in the next annual mailing to subscribers.[FN438] Health plans that do not provide an annual mailing will potentially incur an additional $12,743,700 in capital expenses for mailing the revised NPP to an estimated 10 percent of the 150,000,000 health plan subscribers who receive a mailed, paper copy of the notice, as well as the labor expense for an administrative support staff member at the rate shown in Table 3 to complete the mailing, for approximately $2,737,500 [= 62,500 hours x $43.80]. The Department further estimates the cost of posting the revised NPP on the ***33056** covered entity's website will be 15 minutes of a web designer's time at the wage reported in Table 3. Across all covered entities, the Department estimates a cost of online posting as $18,936,265 [= 774,331 x (15/60) x $97.82].

A commenter expressed concern that the Department was underestimating the cost of mailing updates associated with changes to NPP policies.

The Department is already accounting for the cost of mailing updated NPPs within the estimated capital costs, which include printing copies of NPPs that are provided in person and those that are mailed, and postage for health plans that will need to conduct a mailing that is off-cycle from its regular schedule. We estimate that half of NPPs will need to be mailed and that health plans may include the updated NPP with their next regular mailing to individuals.

e. Estimated Costs for Developing New or Modified Policies and Procedures

The Department anticipates that covered entities will need to develop new or modified policies and procedures for the new requirements for attestations, the new category of prohibited uses and disclosures, modifications to certain uses and disclosures permitted under 45 CFR 164.512, and clarification of personal representative qualifications. The Department is finalizing its proposed estimate that the costs associated with developing such policies and procedures will be the labor of a lawyer for 2.5 hours and that this expense represents the largest area of cost for compliance with this final rule, for a total of $304,854,115 [= 774,331 x 2.5 x $157.48].

A few commenters stated that the estimate for covered entities to draft new policies was incorrect and provided additional information or alternatives to reduce costs. A commenter stated that the time burden for drafting new policies was insufficient and did not accurately represent the amount of time it would take a covered entity to draft a policy that complied with the proposed rule. Another commenter urged the Department to include the costs for organizations to update their privacy policies because of the proposed rule. A few commenters requested that the Department provide organizations with additional time to develop new policies that comply with the final rule.

The Department considered the concerns raised by commenters about the burdens of the requirements to revise the Privacy Rule and made several additional modifications in this final rule to reduce burdens on regulated entities. For example, regulated entities are not required to develop policies to routinely evaluate whether reproductive health care that was provided by someone else was lawful. Instead, regulated entities will need to develop policies to ensure that regulated entities identify requests for health oversight activities, judicial and administrative proceedings, law enforcement purposes, and about decedents to coroners or medical examiners and procedures for obtaining the required attestation if it is not provided with the request for the use or disclosure of PHI. Additional policies will be required to address requests for the above purposes that could result in a prohibited use or disclosure, such as requests from law enforcement for the use or disclosure of PHI that assert, without any other information, that reproductive health care was provided unlawfully. The updating of privacy policies is included in the overall cost of updating policies and the estimate for updating the NPP. Because of changes in the final rule that simplify compliance with the new requirements, the Department is not adjusting the time burden for revising or creating new policies and procedures.

f. Costs Associated With Training Workforce Members

The Department anticipates that covered entities will be able to incorporate new content into existing HIPAA training requirements and that the costs associated with doing so will be attributed to the labor of a training specialist for an estimated 90 minutes for a total of $78,029,335 [= 774,331 x (90/60) x $67.18].

A few commenters addressed training costs within the proposed rule, including one who asserted that such costs could be reduced by ensuring that the effective date for all of the provisions of the rule is the same. Another commenter stated that covered entities would incur both a one time and yearly training cost, with the yearly training cost accounting for most of the total training cost in year 1.

The Department is finalizing the cost estimate for training workforce members as proposed, which includes the cost of a training a specialist to update the covered entity's HIPAA training program with new content to include in training for workforce members within the first year. Any further recurring component is likely to be implemented into regularly scheduled employee training and will thus not be directly attributable to this rule.

g. Total Quantifiable Costs

The Department summarizes in Table 6 the estimated nonrecurring costs that covered entities and states will experience in the first year of implementing the regulatory changes. The Department anticipates that these costs will be for requesting exceptions from preemption of contrary state law, implementing the attestation requirement, revising business associate agreements, revising the NPP, mailing and posting it online, revising policies and procedures, and updating HIPAA training programs.

Table 6—New Nonrecurring Costs of Compliance With the Final Rule

Nonrecurring costs	Burden hours/ action x hourly wage	Respondents	Total costs (millions)
Exception Requests	16 x $93.04	26 States	$0.04
BA Agreements, Revising	1 x $157.48	350,000 BAAs	55
NPP, Updating	50/60 x $157.48	774,331 Covered entities	102

NPP, Mailing	0.25/60 x $43.80	15,000,000 Subscribers	3
NPP, Posting Online	15/60 x $97.82	774,331 Covered entities	19
Policies & Procedures	150/60 x $157.48	774,331 Covered entities	305
Training	90/60 x $67.18	774,331 Covered entities	78
Capital Expenses, Mailing NPPs—Health Plans	$.85/NPP	15,000,000 Subscribers	13
Total Nonrecurring Burden		..... [a]	574

***33057** Table 7 summarizes the recurring costs that the Department anticipates covered entities will incur annually as a result of the regulatory changes. These new costs are based on responding to requests for uses and disclosures of PHI that are conditioned upon an attestation.

Table 7—Recurring Annual Costs of Compliance With the Final Rule [a]

Recurring costs	Burden hours x wage	Respondents	Total annual cost (millions)
Disclosures for which an attestation is required	232,850 x $88.41	2,794,201	$20,585,500
Attestation investigation review	1,300 x $157.48	1,300	204,724
Attestation additional actions	975 x 123.06	325	119,984
Total Recurring Annual Burden		.....	20,910,207

Costs Borne by the Department

The covered entities that are operated by the Department will be affected by the changes in a similar manner to other covered entities, and such costs have been factored into the estimates above.

The Department expects that it will incur costs related to drafting and disseminating a model attestation form and information about the regulatory changes to covered entities, including health care providers and health plans. In addition, the Department anticipates that it may incur a 26-fold increase in the number of requests for exceptions from preemption of contrary state law in the first year after a final rule becomes effective, at an estimated total cost of approximately $146,319 to analyze and develop responses for an average cost of $7,410 per request. This increase is based on the number of states that have enacted or are likely to enact laws restricting access to reproductive health care [FN439] and may seek to obtain individuals' PHI to enforce those laws. This estimate assumes that the Department receives and reviews exception requests from the 26 states, that half require a more complex analysis, and that all requests result in a written response within one year of the final rule's publication.

Benefits of the Final Rule

The benefits of this final rule to individuals and families are likely substantial, and yet are not fully quantifiable because the area of health care this final rule addresses is among the most sensitive and life-altering if privacy is violated. Additionally, the value of privacy, which cannot be recovered once lost, and trust that privacy will be protected by others, is difficult to quantify fully. Health privacy has many significant benefits, such as promoting effective communication between individuals and health care

providers, preventing discrimination, enhancing autonomy, supporting medical research, and protecting the individual from unwanted exposure of sensitive health information.[FN440]

Notably, reproductive health care may include circumstances resulting in a pregnancy, considerations concerning maternal and fetal health, family genetic conditions, information concerning sexually transmitted infections, and the relationship between prospective parents (including victimization due to rape, incest, or sex trafficking). Involuntary or poorly-timed disclosures can irreparably harm relationships and reputations, and even result in job loss or other negative consequences in the workplace, [FN441] as well as investigation, civil litigation or proceedings, and prosecution for lawful activities.[FN442] Additionally, fear of potential penalties or liability that may result from disclosing information to a health care provider about accessing reproductive health care may cast a long shadow, decreasing trust between individuals and health care providers, discouraging and deterring access to other valuable and necessary health care, or compromising ongoing or subsequent care if an individual's medical records are not accurate or complete.[FN443] This final rule will prevent or reduce the harms discussed here, resulting in non-quantifiable benefits to individuals and their families, friends, and health care providers. In particular, the role of trust in the health care system and its importance to the provision of high-quality health care is discussed extensively in Section III of this preamble.

The Department anticipates that this final rule will increase health literacy by improving access to complete information about health care options for individuals.[FN444] For example, the prohibition on the use and disclosure of PHI for purposes of investigating or imposing liability on an individual, a person assisting them, or their health care provider for lawful health care will increase individuals' access to complete information about their health care options because they will have increased confidence to share information about their life, including their health, with health care providers. In turn, the receipt of more complete information from patients will enable ***33058** health care providers to provide more accurate and relevant medical information about lawful reproductive health care, and the new prohibition will enable them to do so without fear of serious and costly professional repercussions.

This final rule will also contribute to increased access to prenatal health care at the critical early stages of pregnancy by affording individuals the assurance that they may obtain lawful reproductive health care without fearing that records related to that care would be subject to disclosure. For example, if a sexually active individual fears they or their health care providers could be subject to prosecution as a result of disclosure of their PHI, the individual may avoid informing health care providers about symptoms or asking questions of medical experts and may consequently fail to receive necessary support and health care for a pregnancy diagnosis.[FN445] Similarly, this final rule will likely contribute to a decreased rate of maternal mortality and morbidity by improving access to information about health services.[FN446]

Additionally, this final rule will enhance the mental health and emotional well-being of individuals seeking or obtaining lawful reproductive health care by reducing fear that their PHI will be disclosed to investigate or impose liability on the individual, their health care provider, or any persons facilitating the individual's access to lawful reproductive health care. This is especially important for individuals who need access to reproductive health care because they are survivors of rape, incest, or sex trafficking. For at least some such individuals, certain types of reproductive health care, including abortion, often remain legal even if pregnancy termination is not available to the broader population under state law. The Department expects that this final rule will help to prevent or reduce re-victimization of pregnant individuals who have been subject to rape, incest, or sex trafficking by protecting their PHI from disclosure.

Activities conducted to investigate and impose liability that rely on that information may be costly to defend against and thus are financially draining for the target of those activities and for persons who are not the target of the activity but whose information may be used as evidence against others. Witnesses or targets of such activities may lose time from work and incur steep legal bills that create unmanageable debt or otherwise harm the economic stability of the individual, their family, and their health care provider. In the absence of this final rule, much of the costs may be for defending against the unwanted use or disclosure of PHI. Thus, the Department expects that this final rule will contribute to families' economic well-being by reducing the risk of exposure to costly activities to investigate or impose liability on persons for lawful activities as a result of disclosures of PHI.

This final rule will also contribute to improved continuity of care and ongoing and subsequent health care for individuals, thereby improving health outcomes. If a health care provider believes that PHI is likely to be disclosed without the individual's or the health care provider's knowledge or consent, possibly to initiate or be used in criminal or civil proceedings against the individual, their health care provider, or others, the health care provider is more likely to omit information about an individual's medical history or condition, leave gaps, or include inaccuracies when preparing the individual's medical records. And if an individual's medical records lack complete information about the individual's health history, a subsequent health care provider may not be able to conduct an appropriate health assessment to reach a sound diagnosis and recommend the best course of action for the individual. Alternatively, health care providers may withhold from the individual full and complete information about their treatment options because of liability concerns stemming from fears about the privacy of an individual's PHI.[FN447] Heightened confidentiality and privacy protections enable a health care provider to feel confident maintaining full and complete patient records. Without complete patient records, an individual is less likely to receive appropriate ongoing or future health care, including correct diagnoses, and will be impeded in making informed treatment decisions.

Comparison of Benefits and Costs

A few commenters stated that the 2023 Privacy Rule NPRM reflected the staffing costs of covered entities in full. One posited that covered entities will receive more requests for PHI because of changes in the legal environment after Dobbs, which will require some regulated entities that may not typically get such requests to adjust according to the changes in the law and how it is enforced. Another commenter stated that the proposed rule did not account for higher staffing costs from more highly qualified employees. The commenters did not provide any relevant data or discussion of methodology for how these costs should be quantified. Therefore, the Department did not include any additional labor costs in the economic analysis based on this comment.

A few additional commenters expressed general concerns related to electronic health record (EHR) systems and data storage. One urged the Department to include costs associated with updating EHR systems to ensure compliance and to allow for data segmentation. Another asserted that the current classifications for different types of PHI are not clear enough for effective data segmentation, contributing to increased costs. As a result, they recommended that the Department provide clearer guidelines on the different types of PHI. The Department did not attempt to estimate additional data maintenance or EHR-related costs because any adjustments will be part of the regular cost of business for regulated entities.

A commenter stated that the Department did not quantify the costs associated with violations of the rule by regulated entities, such as incurring a monetary penalty after impermissibly responding to a court order. The Department does not quantify the costs of noncompliance as part of its analysis. Whether a violation will result in a monetary penalty is dependent on numerous factors and the aim of the Department's enforcement is to bring regulated entities into compliance.

A few commenters asserted that the proposed rule would make it more difficult for law enforcement to investigate criminals for crimes related to sex and recommended that the Department quantify this cost. The Department acknowledges that the final rule may result in some changes to procedures for handling law enforcement requests for PHI; however, the burden on regulated entities is calculated in its cost estimates. The Department is unable to quantify the burdens to law enforcement resulting from this final rule. However, to address concerns about victims' ability to disclose their PHI related to reproductive health care, the final rule ***33059** permits individuals to authorize disclosures for any purpose, including law enforcement investigations. Therefore, the Department is not including costs to law enforcement in the quantified costs and benefits analysis. The Department expects the totality of the benefits of this final rule to outweigh the costs, particularly in light of the privacy benefits for individuals who could become pregnant (nearly one-fourth of the U.S. population in any given year) and seek access to lawful health care without the risk of their PHI being used or disclosed in furtherance of activities to conduct criminal, civil, or administrative investigations or impose liability without their authorization. The Department expects covered entities and individuals to benefit from covered entities' increased confidence to be able to provide lawful health care according to professional standards.

The Department's qualitative benefit-cost analysis asserts that the regulatory changes in this final rule will support an individual's privacy with respect to lawful health care, enhance the relationship between health care providers and individuals, strengthen maternal well-being and family stability, and support victims of rape, incest, and sex trafficking. The regulatory changes will also aid health care providers in developing and maintaining a high level of trust with individuals and maintaining complete and accurate medical records to aid ongoing and subsequent health care. Greater levels of trust will further enable individuals to develop and maintain relationships with health care providers, which would enhance continuity of health care for all individuals receiving care from the health care provider, not only individuals in need of reproductive health care.

The financial costs of this final rule will accrue primarily to covered entities, particularly health care providers and health plans in the first year after implementation of a final rule, with recurring costs accruing annually at a lower rate.

B. Regulatory Alternatives to the Final Rule

In addition to regulatory proposals in the 2023 Privacy Rule NPRM that are not adopted here, the Department considered several alternatives to the policies finalized in this rule.

Define Public Health in the Context of Public Health Surveillance, Intervention, or Investigation

The Department considered alternatives to the proposed definition of "public health" in the context of public health surveillance, investigation, and intervention, particularly the reference to population-level activities. Specifically, the Department considered whether to add "individual-level" to further distinguish public health surveillance, investigation, and intervention from other activities but did not adopt this approach because it would add a new undefined term that would generate more complexity without adding clarity. The Department also considered removing "population-level" from the definition in this final rule, but we are not adopting that approach because it might lead people to believe that the focus of public health is not on activities benefiting the population as a whole. Additionally, the Department considered defining "public health" surveillance, investigation, or intervention only in the negative—that is, by listing activities that are excluded—but decided not to adopt this approach to ensure that stakeholders understand what public health surveillance, investigation, or intervention means.

Modify Prohibition To Presume That Reproductive Health Care Is Lawful Absent Actual Knowledge

The Department considered adding a provision that would allow regulated entities to presume that certain requests for PHI are about reproductive health care that was lawful under the circumstances in which such health care was provided where it was provided by someone other than the regulated entity receiving the PHI request, unless the regulated entity had actual knowledge that such health care was not lawful under the circumstances in which it was provided. However, in consultation with Federal partners, the Department decided to finalize a second exception to the presumption to permit uses or disclosures of PHI where privacy interests are reduced, as compared to the societal interest in the PHI for certain non-health care purposes. This exception is available where factual information supplied by the person requesting the use or disclosure of PHI demonstrates to the regulated entity a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which such health care was provided.

Administrative Requests by Law Enforcement

The Department received reports that not all regulated entities are interpreting the administrative request provision correctly and proposed a clarification to 45 CFR 164.512(f)(1)(ii)(C). To address concerns that disclosures currently made under Federal agencies' interpretations of the Privacy Act of 1974 [FN448] would not be permitted under the NPRM proposal, the Department considered adding qualifying language to paragraph 45 CFR 164.512(f)(1)(ii)(C) to state that PHI may be disclosed by a Federal agency in response to an administrative request from law enforcement where the Federal agency is authorized, but not required, to disclose under applicable law (see, e.g., the Privacy Act and OMB 1975 Guidelines [FN449]). However, the Department determined that the contemplated change was not necessary because the intent of the Privacy Rule was adequately captured in the clarification proposed in the NPRM and finalized in this rule at 45 CFR 164.512(f)(1)(ii)(C). As finalized, this provision

permits disclosures to law enforcement in response to "an administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law."

Scope of Prohibited Conduct

In response to public comments on the 2023 Privacy Rule NPRM, the Department considered several approaches to outlining prohibited conduct. One approach was creating a category of "highly sensitive PHI" and prohibiting its use and disclosure in certain proceedings based on the mere act of, for example, obtaining, providing, or aiding that category of health care. The Department did not adopt this category based on many concerns expressed in public comments. For example, distinguishing between the sensitivity of different types of PHI would require complicated subjective determinations, and prohibiting or limiting uses or disclosures of highly sensitive PHI for certain purposes could negatively affect efforts to eliminate data segmentation and further stigmatize the types of health care included in the "highly sensitive" category.

Another approach the Department considered was to require an attestation for all requested uses and discloses of PHI under 45 CFR 164.512(d)-(g)(1), rather than limiting the requirement to only requested uses and disclosures of PHI potentially related to reproductive health care under such provisions. This would have reduced the burden on ***33060** regulated entities to screen requested PHI for whether it contained information potentially related to reproductive health care and increased the burden on persons requesting PHI to evaluate and attest to all requests for use and disclosure of PHI under 45 CFR 164.512(d)-(g)(1). However, in recognition of the importance of oversight and law enforcement entities' ability to obtain PHI for legitimate inquiries, the Department decided not to require an attestation for all requests under these provisions.

Requiring an Attestation Under Penalty of Perjury

The Department requested comments about the possibility of adding a required penalty of perjury statement to strengthen the attestation requirement but did not propose this statement in the 2023 Privacy Rule NPRM. After reviewing public comments on this topic, the Department considered adding a requirement that the attestation be signed by the person requesting the use or disclosure of PHI under penalty of perjury but did not adopt such a requirement in the final rule. As discussed in greater detail above, a person who knowingly and in violation of the Administrative Simplification provisions of HIPAA obtains or discloses IIHI relating to another individual or discloses IIHI to another person is subject to criminal liability.[FN450] Thus, a person who knowingly and in violation of HIPAA [FN451] falsifies an attestation (e.g., makes material misrepresentations about the intended uses of the PHI requested) to obtain (or cause to be disclosed) an individual's IIHI could be subject to criminal penalties as outlined in the statute. The Department believes such penalties are sufficient to hold persons who knowingly submit false attestations accountable for their actions and deter such submissions entirely.

Right To Request Restrictions

In the 2023 Privacy Rule NPRM, the Department requested comments regarding the right of individuals to request restrictions of uses and disclosures of their PHI. We did not propose any changes to this provision in the 2023 Privacy Rule NPRM, nor are we proposing or finalizing any modifications to it at this time. We appreciate the comments we received regarding expanding the rights to request disclosures and will take them under advisement when we consider future modifications to the Privacy Rule.

C. Regulatory Flexibility Act—Small Entity Analysis

The Department has examined the economic implications of this final rule as required by the RFA. If a rule has a significant economic impact on a substantial number of small entities, the RFA requires agencies to analyze regulatory options that would reduce the economic effect of the rule on small entities.

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The Act defines "small entities" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, and (3) a small government jurisdiction of less than 50,000

population. A few commenters raised concerns about the effects of the proposed rule on small or rural providers and requested additional analysis, guidance, or technical assistance from the Department to aid these entities. The Department did not receive any public comments on the small business analysis assumptions used in the NPRM. Accordingly, we are not changing the baseline assumptions for this final rule. We have updated our analysis of small entities for consistency with revisions to the RIA for the costs and savings for covered entities. The Department has determined that roughly 90 percent or more of all health care providers meet the SBA size standard for a small business or are a nonprofit organization. Therefore, the Department estimates that there are 696,898 small entities affected by the final rule.[FN452] The SBA size standard for health care providers ranges between a maximum of $16 million and $47 million in annual receipts, depending upon the type of entity.[FN453]

With respect to health insurers, the SBA size standard is a maximum of $47 million in annual receipts, and for third party administrators it is $45.5 million.[FN454] While some insurers are classified as nonprofit, it is possible they are dominant in their market. For example, a number of Blue Cross/Blue Shield insurers are organized as nonprofit entities; yet they dominate the health insurance market in the states where they are licensed.[FN455]

For the reasons stated below, we do not expect that the cost of compliance will be significant for small entities. Nor do we expect that the cost of compliance will fall disproportionately on small entities. Although many of the covered entities affected by this final rule are small entities, they will not bear a disproportionate cost burden compared to the other entities subject to the rule. The projected total costs are discussed in detail in the RIA. The Department does not view this as a substantial burden because the result of the changes will be annualized costs per covered entity of approximately $184 [= $142.6 million [FN456]/774,331 covered entities]. In the context of the RFA, HHS generally considers an economic impact exceeding 3 percent of annual revenue to be significant, and 5 percent or more of the affected small entities within an identified industry to represent a substantial number. The quantified impact of $184 per covered entity would only apply to covered entities whose annual revenue is $6,133 or less. We believe almost all, if not all covered entities have annual revenues that exceed this amount. Accordingly, the Department has determined that this final rule is unlikely to affect a substantial number of small entities that meet the RFA threshold. Thus, this analysis concludes, and the Secretary certifies, that the rule will not result in a significant economic effect on a substantial number of small entities.

D. Executive Order 13132—Federalism

As required by E.O. 13132 on Federalism, the Department has examined the provisions in both the proposed and final regulation for their effects on the relationship between the Federal Government and the states. In the Department's view, the final regulation may have federalism implications because it may have direct effects on the states, the relationship between the Federal Government and states, and on the distribution of power and responsibilities among various ***33061** levels of government relating to the disclosure of PHI.

The changes from this final rule flow from and are consistent with the underlying statute, which authorizes the Secretary to issue regulations that govern the privacy of PHI. The statute provides that, with limited exceptions, such regulations supersede contrary provisions of state law unless the provision of state law imposes more stringent privacy protections than the Federal law.[FN457]

Section 3(b) of E.O. 13132 recognizes that national action limiting the policymaking discretion of states will be imposed only where there is constitutional and statutory authority for the action and the national activity is appropriate when considering a problem of national significance. The privacy of PHI is of national concern by virtue of the scope of interstate health commerce. As described in the preamble to the proposed rule and this final rule, recent state actions affecting reproductive health care have undermined the longstanding expectation among individuals in all states that their highly sensitive reproductive health information will remain private and not be used against them for seeking or obtaining legal health care. These state actions thus directly threaten the trust that is essential to ensuring access to, and quality of, lawful health care. HIPAA's provisions reflect this position by authorizing the Secretary to promulgate regulations to implement the Privacy Rule.

Section 4(a) of E.O. 13132 expressly contemplates preemption when there is a conflict between exercising state and Federal authority under a Federal statute. Section 4(b) of the E.O. authorizes preemption of state law in the Federal rulemaking context when "the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute." The approach in this regulation is consistent with the standards in the E.O. because it supersedes state authority only when such authority is inconsistent with standards established pursuant to the grant of Federal authority under the statute.

State and local laws that impinge on the privacy protections for PHI of individuals who obtain lawful reproductive health care undermine Congress' directive to develop a health information system for the purpose of improving the effectiveness of the health care system, which requires that all individuals who receive health care legally are assured a minimum level of privacy for their PHI. Congress established specific, narrow exceptions to preemption that did not include the use or disclosure of an individual's medical records for law enforcement purposes generally. Nor did Congress include a specific exception to preemption that would permit states to use PHI against that individual, health care providers, or third parties merely for seeking, obtaining, providing, or facilitating lawful health care.[FN458] Both the personal and public interest is served by protecting PHI so as not to undermine an individual's access to and quality of lawful health care services and their trust in the health care system.

The Department anticipates that the most significant direct costs on state and local governments would be the cost for state and local government-operated covered entities to revise business associate agreements, revise policies and procedures, update the NPP, update training programs, and process requests for disclosures for which an attestation is required. These costs would be similar in kind to those borne by non-government operated covered entities. In addition, the Department anticipates that approximately half of the states may choose to file a request for an exception to preemption. The longstanding regulatory provisions that govern preemption exception requests under the HIPAA Rules would remain undisturbed by this rule.[FN459] However, based on the legal developments in some states that are described elsewhere in this preamble, the Department anticipates that in the first year of implementation of a final rule, more states will submit requests for exceptions from preemption than have done so in the past. The RIA above addresses these costs in detail.

Pursuant to the requirements set forth in section 8(a) of E.O. 13132, and by the signature affixed to the final rule, the Department certifies that it has complied with the requirements of E.O. 13132, including review and consideration of comments from state and local government officials and the public about the interaction of this rule with state activity, for the final rule in a meaningful and timely manner.

E. Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 [FN460] requires Federal departments and agencies to determine whether a proposed policy or regulation could affect family well-being. If the determination is affirmative, then the Department or agency must prepare an impact assessment to address criteria specified in the law. This final rule is expected to strengthen the stability of the family and marital commitment because it protects individual privacy in the context of sensitive decisions about family planning. The rule may be carried out only by the Federal Government because it would modify Federal health privacy law, ensuring that American families have confidence in the privacy of their information about lawful reproductive health care, regardless of the state where they are located when health care is provided. Such health care privacy is vital for individuals who may become pregnant or who are capable of becoming pregnant.

F. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 [FN461] (PRA), agencies are required to submit to OMB for review and approval any reporting or record-keeping requirements inherent in a proposed or final rule and are required to publish such proposed requirements for public comment. To fairly evaluate whether an information collection should be approved by the OMB, section 3506(c)(2)(A) of the PRA requires that the Department solicit comment on the following issues:

1. Whether the information collection is necessary and useful to carry out the proper functions of the agency;

2. The accuracy of the agency's estimate of the information collection burden;

3. The quality, utility, and clarity of the information to be collected; and

4. Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

The PRA requires consideration of the time, effort, and financial resources necessary to meet the information collection requirements referenced in this section. The Department considered public comments on its assumptions and burden estimates in the 2023 Privacy Rule NPRM and addresses those comments above in the discussion of benefits and costs of this final rule.

In this RIA, the Department is revising certain information collection requirements associated with this final rule and, as such, is revising the information collection last prepared in ***33062** 2023 and approved under OMB control #0945-0003. The revised information collection describes all new and adjusted information collection requirements for covered entities pursuant to the implementing regulation for HIPAA at 45 CFR parts 160 and 164, the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules ("HIPAA Rules").

The estimated annual labor burden presented by the regulatory modifications in the first year of implementation, including nonrecurring and recurring burdens, is 4,584,224 burden hours at a cost of $582,242,165 [FN462] and $20,910,207 of estimated annual labor costs in years two through five. The overall total burden for respondents to comply with the information collection requirements of all of the HIPAA Privacy, Security, and Breach Notification Rules, including nonrecurring and recurring burdens presented by program changes, is 953,982,236 burden hours at a cost of $107,336,705,941, plus $197,364,010 in capital costs for a total estimated annual burden of $107,534,069,951 in the first year following the effective date of the final rule. Details describing the burden analysis for the proposals associated with this RIA are presented below and explained further in the ICR associated with this final rule.

Explanation of Estimated Annualized Burden Hours

Below is a summary of the significant program changes and adjustments made since the approved 2023 ICR; because the ICR addresses regulatory burdens associated with the full suite of HIPAA Rules, the changes and adjustments include updated data and estimates for some provisions of the HIPAA Rules that are not affected by this final rule. These program changes and adjustments form the bases for the burden estimates presented in the ICR associated with this RIA.

Adjusted Estimated Annual Burdens of Compliance

(1) Increasing the number of covered entities from 700,000 to 774,331 based on program change.

(2) Increasing the number of respondents requesting exceptions to state law preemption from 1 to 27 based on an expected reaction by states that have enacted restrictions on reproductive health care access.

(3) Increasing the burden hours by a factor of two for responding to individuals' requests for restrictions on disclosures of their PHI under 45 CFR 164.522 to represent a doubling of the expected requests.

(4) Updating the number of breaches for which notification is required to reflect data in OCR's 2022 Report to Congress [FN463] and related burdens.

(5) Increasing the number of estimated uses and disclosures for research purposes.

(6) Increasing the total number of NPPs distributed by health plans by 50% to total 300,000,000 due to the increase in number of Americans with health coverage.

New Burdens Resulting from Program Changes

In addition to these changes, the Department added new annual burdens as a result of program changes in the final rule:

(1) A nonrecurring burden of 1 hour for each of 350,000 business associate agreements that is likely to be revised as a result of the changes to handling requests for PHI under 45 CFR 164.512(d), (e), (f), and (g)(1), to allocate responsibilities between covered entities and their release-of-information contractors.

(2) A recurring burden of 5 minutes per request for staff to determine whether an attestation is required for disclosure under 45 CFR 164.509.

(3) A recurring burden of 1 hour per request for legal review of whether certain requests identified by staff as potentially requiring an attestation pertain to the lawfulness of reproductive health care.

(4) A recurring burden of 3 hours per request for a percentage of requests requiring legal review that might require additional manager review to determine whether the requirements at 45 CFR 164.509 are met.

(5) A nonrecurring burden of 50 minutes per covered entity to update the required content of its NPP.

(6) A nonrecurring burden of 15 minutes per covered entity for posting an updated NPP online.

(7) A nonrecurring burden of 2.5 hours for each covered entity to update its policies and procedures.

(8) A nonrecurring burden of 90 minutes for each covered entity to update the content of its HIPAA training program.

List of Subjects

45 CFR Part 160

Health care, Health records, Preemption, Privacy, Public health, Reproductive health care.

45 CFR Part 164

Health care, Health records, Privacy, Public health, Reporting and recordkeeping requirements, Reproductive health care.

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter C, parts 160 and 164 as set forth below:

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 160 continues to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d-1320d-9; sec. 264, Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2 (note)); 5 U.S.C. 552; secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279; and sec. 1104 of Pub. L. 111-148, 124 Stat. 146-154.

45 CFR § 160.103

2. Amend § 160.103 by:

a. Revising the definition of “Person”; and

b. Adding in alphabetical order the definitions of “Public health” and “Reproductive health care”.

The revision and additions read as follows:
45 CFR § 160.103

§ 160.103 Definitions.
* * * * *
Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.
* * * * *
Public health, as used in the terms "public health surveillance," "public health investigation," and "public health intervention," means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.

***33063** (3) To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.
* * * * *

PART 164—SECURITY AND PRIVACY
3. The authority citation for part 164 continues to read as follows:

Authority: 42 U.S.C. 1302(a); 42 U.S.C. 1320d-1320d-9; sec. 264, Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note)); and secs. 13400-13424, Pub. L. 111-5, 123 Stat. 258-279.
45 CFR § 164.502
4. Amend § 164.502 by

a. Revising paragraph (a)(1)(vi);

b. Adding paragraph (a)(5)(iii); and

c. Revising paragraph (g)(5).

The addition and revisions read as follows:
45 CFR § 164.502

§ 164.502 Uses and disclosures of protected health information: General rules.
(a) * * *

(1) * * *

(vi) As permitted by and in compliance with any of the following:

(A) This section.

(B) Section 164.512 and, where applicable, § 164.509.

(C) Section 164.514(e), (f), or (g).

* * * * *

(5) * * *

(iii) Reproductive health care—(A) Prohibition. Subject to paragraphs (a)(5)(iii)(B) and (C) of this section, a covered entity or business associate may not use or disclose protected health information for any of the following activities:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

(3) To identify any person for any purpose described in paragraphs (a)(5)(iii)(A)(1) or (2) of this section.

(B) Rule of applicability. The prohibition at paragraph (a)(5)(iii)(A) of this section applies only where the relevant activity is in connection with any person seeking, obtaining, providing, or facilitating reproductive health care, and the covered entity or business associate that received the request for protected health information has reasonably determined that one or more of the following conditions exists:

(1) The reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided.

(2) The reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.

(3) The presumption at paragraph (a)(5)(iii)(C) of this section applies.

(C) Presumption. The reproductive health care provided by another person is presumed lawful under paragraph (a)(5)(iii)(B)(1) or (2) of this section unless the covered entity or business associate has any of the following:

(1) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided.

(2) Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

(D) Scope. For the purposes of this subpart, seeking, obtaining, providing, or facilitating reproductive health care includes, but is not limited to, any of the following: expressing interest in, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, administering, authorizing, providing coverage for, approving, counseling about, assisting, or otherwise taking action to engage in reproductive health care; or attempting any of the same.

* * * * *

(g) * * *

(5) Implementation specification: Abuse, neglect, endangerment situations. Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative, provided that the conditions at paragraphs (g)(5)(i) and (ii) of this section are met:

(i) Paragraphs (g)(5)(i)(A) and (B) of this section both apply.

(A) The covered entity has a reasonable belief that any of the following is true:

(1) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person.

(2) Treating such person as the personal representative could endanger the individual.

(B) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(ii) The covered entity does not have a reasonable belief under paragraph (g)(5)(i)(A) of this section if the basis for their belief is the provision or facilitation of reproductive health care by such person for and at the request of the individual.

* * * * *45 CFR § 164.509

5. Add § 164.509 to read as follows:

45 CFR § 164.509

§ 164.509 Uses and disclosures for which an attestation is required.

(a) Standard: Attestations for certain uses and disclosures of protected health information to persons other than covered entities or business associates. (1) A covered entity or business associate may not use or disclose protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), without obtaining an attestation that is valid under paragraph (b)(1) of this section from the person requesting the use or disclosure and complying with all applicable conditions of this part.

(2) A covered entity or business associate that uses or discloses protected health information potentially related to reproductive health care for purposes specified in § 164.512(d), (e), (f), or (g)(1), in reliance on an attestation that is defective under paragraph (b)(2) of this section, is not in compliance with this section.

(b) Implementation specifications: General requirements—(1) Valid attestations. (i) A valid attestation is a document that meets the requirements of paragraph (c)(1) of this section.

(ii) A valid attestation verifies that the use or disclosure is not otherwise prohibited by § 164.502(a)(5)(iii).

(iii) A valid attestation may be electronic, provided that it meets the requirements in paragraph (c)(1) of this section, as applicable.

(2) Defective attestations. An attestation is not valid if the document submitted has any of the following defects:

(i) The attestation lacks an element or statement required by paragraph (c) of this section.

(ii) The attestation contains an element or statement not required by paragraph (c) of this section

(iii) The attestation violates paragraph (b)(3) of this section.

***33064** (iv) The covered entity or business associate has actual knowledge that material information in the attestation is false.

(v) A reasonable covered entity or business associate in the same position would not believe that the attestation is true with respect to the requirement at paragraph (c)(1)(iv) of this section.

(3) Compound attestation. An attestation may not be combined with any other document except where such other document is needed to satisfy the requirements at paragraph (c)(iv) of this section or at § 164.502(a)(5)(iii)(C), as applicable.

(c) Implementation specifications: Content requirements and other obligations—(1) Required elements. A valid attestation under this section must contain the following elements:

(i) A description of the information requested that identifies the information in a specific fashion, including one of the following:

(A) The name of any individual(s) whose protected health information is sought, if practicable.

(B) If including the name(s) of any individual(s) whose protected health information is sought is not practicable, a description of the class of individuals whose protected health information is sought.

(ii) The name or other specific identification of the person(s), or class of persons, who are requested to make the use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity is to make the requested use or disclosure.

(iv) A clear statement that the use or disclosure is not for a purpose prohibited under § 164.502(a)(5)(iii).

(v) A statement that a person may be subject to criminal penalties pursuant to 42 U.S.C. 1320d-6 if that person knowingly and in violation of HIPAA obtains individually identifiable health information relating to an individual or discloses individually identifiable health information to another person.

(vi) Signature of the person requesting the protected health information, which may be an electronic signature, and date. If the attestation is signed by a representative of the person requesting the information, a description of such representative's authority to act for the person must also be provided.

(2) Plain language requirement. The attestation must be written in plain language.

(d) Material misrepresentations. If, during the course of using or disclosing protected health information in reasonable reliance on a facially valid attestation, a covered entity or business associate discovers information reasonably showing that any representation made in the attestation was materially false, leading to a use or disclosure for a purpose prohibited under § 164.502(a)(5)(iii), the covered entity or business associate must cease such use or disclosure.

* * * * *45 CFR § 164.512

6. Amend § 164.512 by:

a. Revising the introductory text and the paragraph (c) paragraph heading;

b. Adding paragraph (c)(3); and

c. Revising paragraph (f)(1)(ii)(C) introductory text.

The revisions and addition read as follows:

45 CFR § 164.512

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

Except as provided by § 164.502(a)(5)(iii), a covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section and § 164.509. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given verbally.

* * * * *

(c) Standard: Disclosures about victims of abuse, neglect, or domestic violence—* * *

(3) Rule of construction. Nothing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care.

* * * * *

(f) * * *

(1) * * *

(ii) * * *

(C) An administrative request for which response is required by law, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

* * * * *45 CFR § 164.520

7. Amend § 164.520 by:

a. Revising and republish paragraphs (a) and (b); and

b. Adding paragraph (d)(4).

The revisions and additions read as follows:

45 CFR § 164.520

§ 164.520 Notice of privacy practices for protected health information.

* * * * *

(a) Standard: Notice of privacy practices—(1) Right to notice. Except as provided by paragraph (a)(3) or (4) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) Notice requirements for covered entities creating or maintaining records subject to 42 U.S.C. 290dd-2. As provided in 42 CFR 2.22, an individual who is the subject of records protected under 42 CFR part 2 has a right to adequate notice of the uses and disclosures of such records, and of the individual's rights and the covered entity's legal duties with respect to such records.

(3) Exception for group health plans. (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a)

or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO ***33065** offered by the plan, is not required to maintain or provide a notice under this section.

(4) Exception for inmates. An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) Implementation specifications: Content of notice—(1) Required elements. The covered entity, including any covered entity receiving or maintaining records subject to 42 U.S.C. 290dd-2, must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) Header. The notice must contain the following statement as a header or otherwise prominently displayed:

"THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY."

(ii) Uses and disclosures. The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, such as 42 CFR part 2, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law, such as 42 CFR part 2.

(E) A description of the types of uses and disclosures that require an authorization under § 164.508(a)(2)-(a)(4), a statement that other uses and disclosures not described in the notice will be made only with the individual's written authorization, and a statement that the individual may revoke an authorization as provided by § 164.508(b)(5).

(F) A description, including at least one example, of the types of uses and disclosures prohibited under § 164.502(a)(5)(iii) in sufficient detail for an individual to understand the prohibition.

(G) A description, including at least one example, of the types of uses and disclosures for which an attestation is required under § 164.509.

(H) A statement adequate to put the individual on notice of the potential for information disclosed pursuant to this subpart to be subject to redisclosure by the recipient and no longer protected by this subpart

(iii) Separate statements for certain uses or disclosures. If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) or (B) of this section must include a separate statement informing the individual of such activities, as applicable:

(A) In accordance with § 164.514(f)(1), the covered entity may contact the individual to raise funds for the covered entity and the individual has a right to opt out of receiving such communications;

(B) In accordance with § 164.504(f), the group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan;

(C) If a covered entity that is a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of health plan, intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes;

(D) Substance use disorder treatment records received from programs subject to 42 CFR part 2, or testimony relaying the content of such records, shall not be used or disclosed in civil, criminal, administrative, or legislative proceedings against the individual unless based on written consent, or a court order after notice and an opportunity to be heard is provided to the individual or the holder of the record, as provided in 42 CFR part 2. A court order authorizing use or disclosure must be accompanied by a subpoena or other legal requirement compelling disclosure before the requested record is used or disclosed; or

(E) If a covered entity that creates or maintains records subject to 42 CFR part 2 intends to use or disclose such records for fundraising for the benefit of the covered entity, the individual must first be provided with a clear and conspicuous opportunity to elect not to receive any fundraising communications.

(iv) Individual rights. The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction, except in case of a disclosure restricted under § 164.522(a)(1)(vi);

(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by § 164.524;

(D) The right to amend protected health information as provided by § 164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) Covered entity's duties. The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information, to provide individuals with notice of its legal duties and privacy practices, and to notify affected individuals following a breach of unsecured protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) Complaints. The notice must contain a statement that individuals may complain to the covered entity and ***33066** to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) Contact. The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).

(viii) Effective date. The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) Optional elements. (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by § 164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) Revisions to the notice. The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

* * * * *

(d) * * *

* * * * *

(4) The permission in paragraph (d) of this section for covered entities that participate in an organized health care arrangement to issue a joint notice may not be construed to remove any obligations or duties of entities creating or maintaining records subject to 42 U.S.C. 290dd-2, or to remove any rights of patients who are the subjects of such records.

* * * * *45 CFR § 164.535

8. Add § 164.535 to read as follows:

45 CFR § 164.535

§ 164.535 Severability.

If any provision of the HIPAA Privacy Rule to Support Reproductive Health Care Privacy is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall

be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024-08503 Filed 4-22-24; 4:15 pm]

BILLING CODE 4153-01-P

Footnotes

1 Subtitle F of title II of HIPAA (Pub. L. 104-191, 110 Stat. 1936 (Aug. 21, 1996)) added a new part C to title XI of the Social Security Act of 1935 (SSA), Public Law 74-271, 49 Stat. 620 (Aug. 14, 1935), (see sections 1171-1179 of the SSA (codified at 42 U.S.C. 1320d-1320d-8)), as well as promulgating section 264 of HIPAA (codified at 42 U.S.C. 1320d-2 note), which authorizes the Secretary to promulgate regulations with respect to the privacy of individually identifiable health information. The Privacy Rule has subsequently been amended pursuant to the Genetic Information Nondiscrimination Act of 2008 (GINA), title I, section 105, Public Law 110-233, 122 Stat. 881 (May 21, 2008) (codified at 42 U.S.C. 2000ff), and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Public Law 111-5, 123 Stat. 226 (Feb. 17, 2009) (codified at 42 U.S.C. 1390w-4(O)(2)).

2 45 CFR parts 160 and 164, subparts A and E. For a history of the Privacy Rule, see infra Section II.B., "Regulatory History."

3 See also the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C; the HIPAA Breach Notification Rule, 45 CFR part 164, subpart D; and the HIPAA Enforcement Rule, 45 CFR part 160, subparts C, D, and E.

4 45 CFR 160.103 (definition of "Protected health information").

5 42 U.S.C. 1320d. See also 45 CFR 160.103 (definition of "Individually identifiable health information").

6 At times throughout this final rule, the Department uses the terms "health information" or "individuals' health information" to refer generically to health information pertaining to an individual or individuals. In contrast, the Department's use of the term "IIHI" refers to a category of health information defined in HIPAA, and "PHI" is used to refer specifically to a category of IIHI that is defined by and subject to the privacy and security standards promulgated in the HIPAA Rules.

7 See 45 CFR 164.502(2) and (4).

8 See 45 CFR 164.512(i) and 164.502(a)(5)(ii).

9 See 45 CFR 164.501 and 164.508(a)(2).

10 Section 1174(b)(1) of Public Law 104-191 (codified at 42 U.S.C. 1320d-3).

11 597 U.S. 215 (2022).

12 See Melissa Suran, "Treating Cancer in Pregnant Patients After Roe v Wade Overturned," JAMA (Sept. 29, 2022), https://jamanetwork-com.hhsnih.idm.oclc.org/journals/jama/fullarticle/2797062?resultClick=1 and Rita Rubin, "How Abortion Bans Could Affect Care for Miscarriage and Infertility," JAMA (June 28, 2022), https://jamanetwork-com.hhsnih.idm.oclc.org/journals/jama/fullarticle/2793921?resultClick=1.

13 See infra National Committee on Vital and Health Statistics (NCVHS) discussion, Section II.A.1., expressing concern for harm caused by disclosing identifiable health information for non-health care purposes.

14 See Whitney S. Rice et al. " 'Post-Roe' Abortion Policy Context Heightens Imperative for Multilevel, Comprehensive, Integrated Health Education," (Sept. 29, 2022), https://journals.sagepub.com/doi/full/10.1177/10901981221125399 ("New ethical and legal complexities around patient counseling are emerging, particularly in states limiting or eliminating abortion access, due to more extreme abortion restrictions. Clinicians in such contexts may be forced to adhere to legal requirements of states which run counter to well-being and desires of patients, violating the medical principles of beneficence and respect for patient autonomy").

15 88 FR 23506 (Apr. 17, 2023).

16 See 65 FR 67249 (Nov. 11, 2000). See also Presidential Memorandum on Tribal Consultation and Strengthening Nation-to-Nation Relationships (Jan. 26, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/26/memorandum-on-tribal-consultation-and-strengthening-nation-to-nation-relationships/ and Dep't of Health and Human Servs., Tribal Consultation Policy, https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf. See also 88 FR 23506 (Apr. 17, 2023) (notice of Tribal consultation). The Department consulted with representatives of Tribal Nations on May 17, 2023. During the consultation, the representatives raised issues of health inequities and privacy of health information, specifically among American Indians and Alaskan Natives after Dobbs.

17 Letter from U.S. Senator Tammy Baldwin et al. to HHS Sec'y Xavier Becerra (Mar. 7, 2023) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women's Health Organization). Letter from U.S. Senator Patty Murray et al. to HHS Sec'y Xavier Becerra (Sept. 13, 2022) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women's Health Organization). Letter from U.S. Representative Earl Blumenauer et al. to HHS Sec'y Xavier Becerra (Aug. 30, 2022) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women's Health Organization). Letter from U.S. Senator Michael F. Bennet et al. to HHS Sec'y Xavier Becerra (July 1, 2022) (addressing HIPAA privacy regulations and Dobbs v. Jackson Women's Health Organization).

18 See 88 FR 23506, 23510 (Apr. 17, 2023).

19 See id.

20 45 CFR 160.104(a).

21 45 CFR 160.104(c)(2).

22 87 FR 74216 (Dec. 2, 2022).

23 Public Law 116-136, 134 Stat. 281 (Mar. 27, 2020).

24 89 FR 12472 (Feb. 16, 2024).

25 Id. at 12482, 12528, and 12530.

26 Id. at 12482, 12528, and 12530.

27 89 FR 12472 (Feb. 16, 2024).

28 Public Law 104-191, 110 Stat. 1936 (Aug. 21, 1996).

29 See H.R. Rep. No. 104-496, at 66-67 (1996).

30 42 U.S.C. 1320d note (Statutory Notes and Related Subsidiaries: Purpose). Subtitle F also amended related provisions of the SSA.

31 See section 262 of Public Law 104-191, adding section 1172 to the SSA (codified at 42 U.S.C. 1320d-1). See also section 13404 of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115 (Feb. 17, 2009) (codified at 42 U.S.C. 17934) (applying privacy provisions and penalties to business associates of covered entities).

32 42 U.S.C. 1320d2(a)(1).

33 42 U.S.C. 1320d-2(b)(1).

34 42 U.S.C. 1320d-2(a), (c), and (f).

35 42 U.S.C. 1320d-2(d).

36 42 U.S.C. 1320d-2(e).

37 On a resolution waiving points of order against the Conference Report to H.R. 3103, members debated an "erosion of privacy" balanced against the administrative simplification provisions. Thus, from HIPAA's inception, privacy has been a central concern to be addressed as legislative changes eased disclosures of PHI. See 142 Cong. Rec. H9777 and H9780; see also H.R. Rep. No. 104-736, at 177 and 264 (1996); 142 Cong. Rec. H9780 (daily ed. Aug. 1, 1996) (statement of Rep. Sawyer); 142 Cong. Rec. H9792 (daily ed. Aug. 1, 1996) (statement of Rep. McDermott); and 142 Cong. Rec. S9515-16 (daily ed. Aug. 2, 1996) (statement of Sen. Simon).

38 88 FR 23506, 23511 (Apr. 17, 2023).

39 See statement of Rep. Sawyer, supra note 37. See also statement of Sen. Simon, supra note 37.

40 Statement of Rep. Sawyer, supra note 37.

41 See H.R. Rep. No. 104-496 Part 1, at 99-100 (Mar. 25, 1996).

42 42 U.S.C. 1320d-2 note.

43 Id.

44 Id.

45 42 U.S.C. 1320d-7.

46 65 FR 82580 (the exception applies under section 1178(a)(2)(B) of the SSA and section 264(c)(2) of HIPAA).

47 NCVHS serves as the Secretary's statutory public advisory body for health data, statistics, privacy, and national health information policy and HIPAA. NCVHS also advises the Secretary, "reports regularly to Congress on HIPAA implementation, and serves as a forum for interaction between HHS and interested private sector groups on a range of health data issues." Nat'l Comm. On Vital and Health Statistics, "About NCVHS," https://ncvhs.hhs.gov/; see also "NCVHS 60th Anniversary Symposium and History," U.S. Dep't of Health and Human Servs., at 28-29 (Feb. 2011), https://ncvhs.hhs.gov/wp-content/uploads/2014/05/60_years_of_difference.pdf.

48 See section 264(a) and (d) of Public Law 104-191 (codified at 42 U.S.C. 1320d-2 note).

49 Letter from NCVHS Chair Don E. Detmer to HHS Sec'y Donna E. Shalala (June 27, 1997) (forwarding NCVHS recommendations), https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/.

50 Id. at Principal Findings and Recommendations.

51 Id.

52 Id. at Third-Party Disclosures.

53 88 FR 23506, 23513 (Apr. 17, 2023).

54 See section 1174(b)(1) of Public Law 104-191 (codified at 42 U.S.C. 1320d-3).

55 Section 1102 of the SSA (codified at 42 U.S.C. 1302).

56 Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009, Public Law 111-5, 123 Stat. 115 (Feb. 17, 2009) (codified at 42 U.S.C. 201 note).

57 C. Stephen Redhead, Cong. Rsch. Serv., R40161, "The Health Information Technology for Economic and Clinical Health (HITECH) Act," (2009), https://crsreports.congress.gov/product/pdf/R/R40161/9 ("[Health IT], which generally refers to the use of computer applications in medical practice, is widely viewed as a necessary and vital component of health care reform.").

58 H.R. Rep. No. 111-7, at 74 (2009), accompanying H.R. 629, 111th Cong.

59 H.R. 629, Energy and Commerce Recovery and Reinvestment Act of 2009, introduced in the House on January 22, 2009, contained nearly identical provisions to subtitle D of the HITECH Act.

60 Congress enacted the American Recovery and Reinvestment Act of 2009, which included the HITECH Act, on February 17, 2009. While it was the House version of the bill, H.R. 1, that was enacted, the Senate version, S. 336, contained nearly identical provisions to subtitle D of the HITECH Act.

61 S. Rep. No. 111-3 accompanying S. 336, 111th Cong., at 59 (2009).

62 78 FR 5566 (Jan. 25, 2013).

63 Subtitle D of title XIII of the HITECH Act (codified at 42 U.S.C. 17921, 42 U.S.C. 17931-17941, and 42 U.S.C. 17951-17953).

64 78 FR 5566, 5568 (Jan. 25, 2013).

65 Section 3009(a)(1)(B) of the PHSA, as added by section 13101 of the HITECH Act (codified at 42 U.S.C. 300jj-19(a)(1)).

66 Section 13421(b) of the HITECH Act (codified at 42 U.S.C. 17951).

67 Section 3009(a)(1)(A) of the PHSA, as added by section 13101 of the HITECH Act (codified at 42 U.S.C. 300jj-19(a)(1)).

68 See U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Off. for Civil Rights; Statement of Delegation of Authority, 65 FR 82381 (Dec. 28, 2000); U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Off. for Civil Rights; Delegation of Authority, 74 FR 38630 (Aug. 4, 2009); U.S. Dep't of Health and Hum. Servs., Off. of the Sec'y, Statement of Organization, Functions and Delegations of Authority, 81 FR 95622 (Dec. 28, 2016).

69 See 78 FR 5566 (Jan. 25, 2013); 79 FR 7290 (Feb. 6, 2014); 81 FR 382 (Jan. 6, 2016).

70 See U.S. Dep't of Health and Hum. Servs., Off. of the Assistant Sec'y for Plan. and Evaluation, "Recommendations of the Secretary of Health and Human Services, pursuant to section 264 of the Health Insurance Portability and Accountability Act of 1996," Section I.A. (Sept. 1997), https://aspe.hhs.gov/reports/confidentiality-individually-identifiable-health-information.

71 64 FR 59918 (Nov. 3, 1999).

72 65 FR 82462 (Dec. 28, 2000).

73 Id.

74 See Executive Order 13181 (Dec. 20, 2000), 65 FR 81321.

75 See 65 FR 82462, 82471 (Dec. 28, 2000).

76 See id. at 82472.

77 See id.

78 65 FR 82462 (Dec. 28, 2000).

79 45 CFR 164.506 was originally titled "Consent for uses or disclosures to carry out treatment, payment, or health care operations."

80 45 CFR 164.508.

81 45 CFR 164.510.

82 45 CFR 164.512.

83 See 64 FR 59918, 59955 (Nov. 3, 1999).

84 See 45 CFR 164.520, 164.522, 164.524, 164.526, and 164.528.

85 See 65 FR 82462, 82800 (Dec. 28, 2000).

86 See 67 FR 53182 (Aug. 14, 2002).

87 78 FR 5566 (Jan. 25, 2013).

88 81 FR 382 (Jan. 6, 2016).

89 66 FR 12738 (Feb. 28, 2001).

90 67 FR 53182, 53183 (Aug. 14, 2002).

91 67 FR 14775 (Mar. 27, 2002).

92 67 FR 53182 (Aug. 14, 2002). See the final rule for changes in the entirety. The 2002 Privacy Rule was issued before the compliance date for the 2000 Privacy Rule. Thus, covered entities never implemented the 2000 Privacy Rule. Instead, they implemented the 2000 Privacy Rule as modified by the 2002 Privacy Rule.

93 See 67 FR 53182 (Aug. 14, 2002).

94 75 FR 40868 (July 14, 2010).

95 78 FR 5566 (Jan. 25, 2013). In addition to finalizing requirements of the HITECH Act that were proposed in the 2010 NPRM, the Department adopted modifications to the Enforcement Rule not previously adopted in an earlier interim final rule, 74 FR 56123 (Oct. 30, 2009), and to the Breach Notification Rule not previously adopted in an interim final rule, 74 FR 42739 (Aug. 24, 2009). The Department also finalized previously proposed Privacy Rule modifications as required by GINA, 74 FR 51698 (Oct. 7, 2009).

96 See 78 FR 5566 (Jan. 25, 2013) (explaining that the Department was using its general authority under HIPAA to make a number of changes to the Privacy Rule that were intended to increase workability and flexibility, decrease burden, and better harmonize the requirements with those under other Departmental regulations). The Department's general authority to modify the Privacy Rule is codified in HIPAA section 264(c), and OCR conducts rulemaking under HIPAA based on authority granted by the Secretary.

97 See 75 FR 40868, 40871 (July 14, 2010).

98 75 FR 40868, 40871 (July 14, 2010).

99 See 78 FR 5566, 5611 (Jan. 25, 2013).

100 See id. at 5612.

101 Id. at 5616-17. See also 45 CFR 164.512(b)(1).

102 78 FR 5566, 5614 (Jan. 25, 2013). See also 45 CFR 164.502(f) and the definition of "Protected health information" at 45 CFR 160.103, excluding IIHI regarding a person who has been deceased for more than 50 years.

103 In addition to the rulemakings discussed here, the Department has modified the Privacy Rule for workability purposes and in response to changes in circumstances on two other occasions, and it issued another notice of proposed rulemaking in 2021 for the same reasons. See 79 FR 7289 (Feb. 6, 2014), 81 FR 382 (Jan. 6, 2016), and 86 FR 6446 (Jan. 21, 2021).

104 See Letter from NCVHS Chair Simon P. Cohn to HHS Sec'y Michael O. Leavitt (June 22, 2006), https://ncvhs.hhs.gov/rrp/june-22-2006-letter-to-the-secretary-recommendations-regarding-privacy-and-confidentiality-in-the-nationwide-health-information-network/; Letter from NCVHS Chair Simon P. Cohn to HHS Sec'y Michael O. Leavitt (Feb. 20, 2008) (listing categories of health information that are commonly considered to contain sensitive information), https://ncvhs.hhs.gov/wp-content/uploads/2014/05/080220*l*t.pdf; Letter from NCVHS Chair Justine M. Carr to HHS Sec'y Kathleen Sebelius (Nov. 10, 2010) (forwarding NCVHS recommendations), https://ncvhs.hhs.gov/wp-content/uploads/2014/05/101110lt.pdf.

105 88 FR 23506.

106 See Meeting of NCVHS (June 14, 2023), https://ncvhs.hhs.gov/meetings/full-committee-meeting-13/.

107 See Meeting of NCVHS, Briefing on Legislative Developments in Data Privacy (July 21, 2022), https://ncvhs.hhs.gov/meetings/full-committee-meeting-11/.

108 See Meeting of NCVHS, Briefing by Cason Schmit (Dec. 7, 2022), https://ncvhs.hhs.gov/meetings/full-committee-meeting-12/.

109 Letter from NCVHS Chair Jacki Monson to HHS Sec'y Xavier Becerra (June 14, 2023) (forwarding NCVHS recommendations), https://ncvhs.hhs.gov/wp-content/uploads/2023/06/NCVHS-Comments-on-HIPAA-Reproduction-Health-NPRM-Final-508.pdf.

110 See Jennifer Richmond et al., "Development and Validation of the Trust in My Doctor, Trust in Doctors in General, and Trust in the Health Care Team Scales," 298 Social Science & Medicine 114827 (2022), https://www.sciencedirect.com/science/article/abs/pii/S0277953622001332?via%3Dihub; see also Fallon E. Chipidza et al., "Impact of the Doctor-Patient Relationship," The Primary Care Companion for CNS Disorders (Oct. 2015), https://www.psychiatrist.com/pcc/delivery/patient-physician-communication/impact-doctor-patient-relationship/. See Testimony (transcribed) of William G. Plested, III, M.D., Member, Board of Trustees, American Medical Association, Hearing on Confidentiality of Patient Medical Records before House of Representatives Committee on Ways and Means, Subcommittee on Health (Feb. 17, 2000), https://www.govinfo.gov/content/pkg/CHRG-106hhrg66897/html/CHRG-106hhrg66897.htm. ("Trust is the foundation of the patient/physician relationship.")

111 See Am. Med. Ass'n, "Patient Perspectives Around Data Privacy," (2022), https://www.ama-assn.org/system/files/ama-patient-data-privacy-survey-results.pdf.

112 See John C. Moskop et al., "From Hippocrates to HIPAA: Privacy and Confidentiality in Emergency Medicine—Part I: Conceptual, Moral, and Legal Foundations," 45 Ann Emerg. Med.1 (Jan. 2005) (quoting the Oath of Hippocrates, "What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself [. . .]."), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7132445/#bib1.

113 See 64 FR 59918, 60006 (Nov. 3, 1999) (In the 1999 Privacy Rule NPRM, the Department discussed confidentiality as an important component of trust between individuals and health care providers and cited a 1994 consumer privacy survey that indicated that a lack of privacy may deter patients from obtaining preventive care and treatment.). See id. at 60019.

114 See 64 FR 59918, 60006 (Nov. 3, 1999).

115 See "Patient Perspectives Around Data Privacy," supra note 111.

116 Id. at 2.

117 See Testimony (transcribed) of Peter R. Orszag, Director, Congressional Budget Office, Hearing on Comparative Clinical Effectiveness before House of Representatives Committee on Ways and Means, Subcommittee on Health, 2007 WL 1686358 (June 12, 2007) ("because federal health insurance programs play a large role in financing medical care and represent a significant expenditure, the federal government itself has an interest in evaluations of the effectiveness of different health care approaches"); Statement of Sen. Durenberger introducing S.1836, American Health Quality Act of 1991 and reading bill text, 137 Cong. Rec. S26720 (Oct. 17, 1991) ("[T]he Federal Government has a demonstrated interest in assessing the quality of care, access to care, and the costs of care through the evaluative activities of several Federal agencies.").

118 See 65 FR 82462, 82463 (Dec. 28, 2000).

119 See, e.g., Brooke Rockwern et al., Medical Informatics Committee and Ethics, Professionalism and Human Rights Committee of the American College of Physicians, "Health Information Privacy, Protection, and Use in the Expanding Digital Health Ecosystem: A Position Paper of the American College of Physicians," 174 Ann Intern Med. 994 (Jul. 2021) (discussing the need for trust in the health care system as necessary to mitigate a global pandemic); Johanna Birkh[auml]uer et. al, "Trust in the Health Care Professional and Health Outcome: A Meta-Analysis," 12 PLoS One e0170988 (Feb. 7, 2017). See also Eric Boodman, "In a doctor's suspicion after a miscarriage, a glimpse of expanding medical mistrust," STAT News (June 29, 2022), https://www.statnews.com/2022/06/29/doctor-suspicion-after-miscarriage-glimpse-of-expanding-medical-mistrust/ (Sarah Prager, professor of obstetrics and gynecology at the University of Washington, stating that it is a bad precedent if clinical spaces become unsafe for patients because, "[a health care provider's] ability to take care of patients relies on trust, and that will be impossible moving forward.").

120 See "Development and Validation of the Trust in My Doctor, Trust in Doctors in General, and Trust in the Health Care Team Scales," supra note 110; Bradley E. Iott et al., "Trust and Privacy: How Patient Trust in Providers is Related to Privacy Behaviors and Attitudes," 2019 AMIA Annu Symp Proc 487 (Mar. 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7153104/; Pamela Sankar et al., "Patient Perspectives of Medical Confidentiality: a Review of the Literature," 18 J. of Gen. Internal Med. 659 (Aug. 2003), https://pubmed.ncbi.nlm.nih.gov/12911650/.

121 See 65 FR 82462, 82468 (Dec. 28, 2000).

122 See Letter from NCVHS Chair Simon P. Cohn, supra note 104, at 2 (2006) (with forwarded NCVHS recommendations, "Individual trust in the privacy and confidentiality of their personal health information also promotes public health, because individuals with potentially contagious or communicable diseases are not inhibited from seeking treatment.").

123 See Texas Dep't of State Health Servs., "Texas Maternal Mortality and Morbidity Review Committee and Department of State Health Services Joint Biennial Report 2022," at 41 (Dec. 2022) https://www.dshs.texas.gov/sites/default/files/legislative/2022-Reports/2022-MMMRC-DSHS-Joint-Biennial-Report.pdf; Lynn M. Paltrow et al., "Arrests of and forced interventions on pregnant women in the United States, 1973-2005: implications for women's legal status and public health," 38 J. Health Pol. Pol'y Law 299 (2013) (finding that hospital staff are most likely to report pregnant low-income and patients of color, especially Black women, to the authorities.); Terri-ann Monique Thompson et al., "Racism Runs Through It: Examining the Sexual and Reproductive Health Experience of Black Women in the South," 41 Health Affairs 195 (Feb. 2022) (discussing how individual racism affects reproductive health care use by undermining the patient-doctor relationship), https://www.healthaffairs.org/doi/10.1377/hlthaff.2021.01422); Joli Hunt, "Maternal Mortality among Black Women in the United States," Ballard Brief (July 2021), https://ballardbrief.byu.edu/issue-briefs/maternal-mortality-among-black-women-in-the-united-states/ (discussing the disproportionately high rate of Black maternal mortality and morbidity); Austin Frakt, "Bad Medicine: The Harm that Comes from Racism," The New York Times (July 8, 2020), https://www.nytimes.com/2020/01/13/upshot/bad-medicine-the-harm-that-comes-from-racism.html.

124 42 U.S.C. 1320d note and 1320d-2 note.

125 See 67 FR 53182, 53216 (Aug. 14, 2002).

126 Id. at 53226.

127 65 FR 82462, 82464 (Dec. 28, 2000).

128 See 78 FR 5566, 5616 (Jan. 25, 2013).

129 81 FR 382 (Jan. 6, 2016); see, e.g., 78 FR 4297 (Jan. 22, 2013) and 78 FR 4295 (Jan. 22, 2013); see also Colleen Curtis, "President Obama Announces New Measures to Prevent Gun Violence," The White House President Barack Obama (Jan. 16, 2013), https://obamawhitehouse.archives.gov/blog/2013/01/16/president-obama-announces-new-measures-prevent-gun-violence.

130 This PHI includes limited demographic and certain other information needed for the purposes of reporting to NICS. 45 CFR 164.512(k)(7)(iii)(A). In preamble, the Department explained that generally the information described at 45 CFR 164.512(k)(7)(iii)(A) would be limited to the data elements required to create a NICS record and certain other elements to the extent that they are necessary to exclude false matches: Social Security number, State of residence, height, weight, place of birth, eye color, hair color, and race. 81 FR 382, 390 (Jan. 6, 2016).

131 81 FR 382, 386-388 (Jan. 6, 2016).

132 Id. The Department addressed concerns about the possible chilling effect on individuals seeking health care by explaining that (1) the permission is limited to only those covered entities that order the involuntary commitments or make the other adjudications that cause individuals to be subject to the Federal mental health prohibitor, or that serve as repositories of

such information for NICS reporting purposes; (2) the specified regulated entities are permitted to disclose NICS data only to designated repositories or the NICS; (3) the information that may be disclosed is limited to certain demographic or other information that is necessary for NICS reporting; and (4) the rulemaking did not expand the permission to encompass State law prohibitor information.

133 Letter from NCVHS Chair Don E. Detmer to HHS Sec'y Donna E. Shalala (June 27, 1997) (forwarding NCVHS recommendations), https://ncvhs.hhs.gov/rrp/june-27-1997-letter-to-the-secretary-with-recommendations-on-health-privacy-and-confidentiality/.

134 42 U.S.C. 1320d-2 note.

135 See 45 CFR 164.501 (definition of "Psychotherapy notes").

136 See 64 FR 59918, 59941 (Nov. 3, 1999).

137 See id.

138 45 CFR 164.508(a)(2).

139 Council on Ethical and Judicial Affairs, "Ethics, Amendment to Opinion 4.2.7, Abortion H-140.823," Am. Med. Ass'n (2022), https://policysearch.ama-assn.org/policyfinder/detail/`4.2.7Abortion`?uri=®AMADoc®HOD.xml-H-140.823.xml.

140 See Letter from NCVHS Chair Simon P. Cohn (2006), supra note 104.

141 See Letter from NCVHS Chair Simon P. Cohn (2006), supra note 104; Letter from NCVHS Chair Simon P. Cohn (2008), supra note 104; Letter from NCVHS Chair Justine M. Carr (2010), supra note 104.

142 See Letter from NCVHS Chair Justine M. Carr (2010), supra note 104.

143 See LePage v. Center for Reproductive Medicine, SC-2022-0515 (Feb. 16, 2024).

144 410 U.S. 113 (1973).

145 505 U.S. 833 (1992).

146 Dobbs, 597 U.S. 299-302.

147 See, e.g., Carmel Shachar et al., "Informational Privacy After Dobbs," 75 Ala. L. Rev. 1 (2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4570500 and Andrzej Kulczycki, "Dobbs: Navigating the New Quagmire and Its Impacts on Abortion and Reproductive Health Care," Health Education & Behavior (2022), https://doi.org/10.1177/10901981221125430.

148 See, e.g., Kayte Spector-Bagdady & Michelle M. Mello, "Protecting the Privacy of Reproductive Health Information After the Fall of Roe v. Wade," 3 JAMA Network e222656 (June 30, 2022), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2794032; Lisa G. Gill, "What does the overturn of Roe v. Wade mean for you?," Consumer Reports (June 24, 2022), https://www.consumerreports.org/health-privacy/what-does-the-overturn-of-roe-v-wade-mean-for-you-a1957506408/.

149 45 CFR 164.502(a)(1).

150 45 CFR 164.512(a).

151 See Laura J. Faherty et al. "Consensus Guidelines and State Policies: The Gap Between Principle and Practice at the Intersection of Substance Use and Pregnancy," American Journal of Obstetrics & Gynecology Maternal-Fetal Medicine (Aug. 2020) (discussing a concern raised by multiple organizations that pregnant women will hesitate to seek prenatal care and addiction treatment during pregnancy because their concerns that disclosing substance use to health care providers will increase the likelihood that they will face legal penalties); see also "Informational Privacy After Dobbs," supra note 147.

152 See, e.g., Yvonne Lindgren et al., "Reclaiming Tort Law to Protect Reproductive Rights," 75 Alabama L. Rev. 355 (2023), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4435834.

153 See section 3001(c) of the PHSA, as amended by section 4003(b) of the 21st Century Cures Act, Public Law 114-255, 130 Stat. 1165 (codified at 42 U.S.C. 300jj-11(c)). For more information, see Office of the Nat'l Coordinator for Health Info. Tech., "Trusted Exchange Framework and Common Agreement (TEFCA)," https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca; See also 89 FR 8758 (Feb. 8, 2024); "CMS Interoperability and Prior Authorization Final Rule CMS-0057-F," Centers for Medicare & Medicaid (Jan. 17, 2024), https://www.cms.gov/newsroom/fact-sheets/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f.

154 See Eric Boodman, "In a doctor's suspicion after a miscarriage, a glimpse of expanding medical mistrust," STAT News (June 29, 2022), https://www.statnews.com/2022/06/29/doctor-suspicion-after-miscarriage-glimpse-of-expanding-medical-mistrust/#:#:text=Inadoctor'ssuspicionafter,glimpseofexpandingmedicalmistrust&text=Theideathatshe,usedcontraceptivesandtrustedthem.

155 See also Melissa Suran, "As Laws Restricting Health Care Surge, Some US Physicians Choose Between Fight or Flight," JAMA, 329(22):1899-1903 (May 17, 2023) (discussing a maternal-fetal medicine specialist who stated that she moved to another state because of legislation that restricts evidence-based health care and prevents her from fulfilling her ethical obligation to protect her patients' health.), https://pubmed.ncbi.nlm.nih.gov/37195699/.

156 See Off. for Civil Rights, "HHS Office for Civil Rights Resolves Complaints with CVS and Walgreens to Ensure Timely Access to Medications for Women and Support Persons with Disabilities," U.S. Dep't of Health and Human Servs. (June 16, 2023), https://www.hhs.gov/civil-rights/for-providers/compliance-enforcement/agreements/cvs-walgreens/index.html. See also Kathryn Starzyk et al., "More than half of patients with a rheumatic disease or immunologic condition undergoing methotrexate treatment reside in states in which the overturning of Roe v. Wade can jeopardize access to medications with abortifacient potential," 75 Arthritis Rheumatol 328 (Feb. 2023); see also Celine Castronuovo, "Many Female Arthritis Drug Users Face Restrictions After Dobbs," Bloomberg Law (Nov. 14, 2022) (noting that 16 out of 524 patients responding to a survey indicated that they've had trouble getting methotrexate, their arthritis medication, since the Dobbs decision.) https://news.bloomberglaw.com/health-law-and-business/many-female-arthritis-drug-users-face-restrictions-after-dobbs; Interview with Donald Miller, PharmD, "Methotrexate access becomes challenging for some patients following Supreme Court decision on abortion," Pharmacy Times (July 20, 2022), https://www.pharmacytimes.com/view/methotrexate-access-becomes-challenging-for-patients-following-supreme-court-decision-on-abortion; Jamie Ducharme, "Abortion restrictions may be making it harder for patients to get a cancer and arthritis drug," Time (July 6, 2022), https://time.com/6194179/abortion-restrictions-methotrexate-cancer-arthritis/; Katie Shepherd & Frances Stead Sellers, "Abortion bans complicate access to drugs for cancer, arthritis, even ulcers," The Washington Post (Aug. 8, 2022), https://www.washingtonpost.com/health/2022/08/08/abortion-bans-methotrexate-mifepristone-rheumatoid-arthritis/.

157 See Michelle Oberman & Lisa Soleymani Lehmann, "Doctors' duty to provide abortion information," J. of Law and Biosciences. (Sept. 1, 2023) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10474560/; Whitney Arey et al., "Abortion Access and Medically Complex Pregnancies Before and After Texas Senate Bill 8," 141 Obstet Gynecol. 995 (May 1, 2023) (concluding that "Abortion restrictions limit shared decision making, compromise patient care, and

put pregnant people's health at risk."); "1 Year Without Roe," Center for American Progress (Jun. 23, 2023) (where a physician detailed her fear about speaking freely with her patients after Dobbs "worried a vigilante posing as a new patient would attempt to bait her into talking about abortion and attempt to sue her, and she sometimes skirts the topic of abortion when speaking with patients about their health care options.")

158 See Christine Dehlendorf et al., "Disparities in Abortion Rates: A Public Health Approach," Am. J. of Pub. Health (Oct. 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3780732/. See also Kiara Alfonseca, "Why Abortion Restrictions Disproportionately Impact People of Color," ABC News (June 24, 2022), https://abcnews.go.com/Health/abortion-restrictions-disproportionately-impact-people-color/story?id=84467809; Dulce Gonzalez et al., Robert Wood Johnson Foundation, "Perceptions of Discrimination and Unfair Judgment While Seeking Health Care" (Mar. 31, 2021), https://www.rwjf.org/en/insights/our-research/2021/03/perceptions-of-discrimination-and-unfair-judgment-while-seeking-health-care.html; Susan A. Cohen, "Abortion and Women of Color: The Bigger Picture," 11 Guttmacher Pol'y Rev. (Aug. 6, 2008), https://www.guttmacher.org/gpr/2008/08/abortion-and-women-color-bigger-picture; "The Disproportionate Harm of Abortion Bans: Spotlight on Dobbs v. Jackson Women's Health," Center for Reproductive Rights (Nov. 29, 2021), https://reproductiverights.org/supreme-court-case-mississippi-abortion-ban-disproportionate-harm/ ("Abuses such as forced sterilization of Black, Indigenous, and other people of color and individuals with disabilities specifically exacerbate medical mistrust within reproductive healthcare.").

159 See Brief of Amici Curiae for Organizations Dedicated to the Fight for Reproductive Justice—Mississippi in Action, et al. at *35-36, Dobbs, 597 U.S. 215 (discussing the likelihood that individuals, particularly those from marginalized communities who terminate their pregnancies and anyone who assists them may be disproportionally likely to face criminal investigation or arrest, given the rates of incarceration of persons from such communities.); see also Elizabeth Yuko, "Women of Color Will Face More Criminalized Pregnancies in Post-'Roe' America," Rolling Stone (Jul. 7, 2020) ("Historically, we've seen the criminalization of people of color, young people, and people with lower incomes who've had miscarriages and other types of pregnancy losses that the state deemed were their fault [. . .] These groups are the most likely to be reported to law enforcement and investigated"); see also Sentencing Project, State-by-State Data, https://www.sentencingproject.org/research/us-criminal-justice-data/ (last visited Feb. 16, 2024) (U.S. Total: Imprisonment rate per 100,000 residents—355; Black/White disparity—4.8:1; Latinx/White disparity—1.3:1); Racial Disparities in Incarceration, Vera Institute of Justice (Aug. 21, 2023), https://trends.vera.org/ (Prison population rate per 100,000 residents ages 15 to 64. U.S. total incarceration rate 2021 Q2—298, Asian American/Pacific Islander incarceration rate 2021 Q2—100, Black/African American incarceration rate 2021 Q2—1,310, Latinx incarceration rate 2021 Q2—671, Native American incarceration rate 2021 Q2—1,021, White incarceration rate 2021 Q2—281).

160 See Columbia Law Sch. Hum. Rts. Inst. & and Ne. Univ. Sch. of Law Program on Hum. Rts. and the Glob. Econ.," Equal Access to Justice: Ensuring Meaningful Access to Counsel in Civil Cases, Including Immigration Proceedings" (July 2014), https://hri.law.columbia.edu/sites/default/files/publications/equal_access_to_justice_-_cerd_shadow_report.pdf. See also Lauren Hoffman et al., Ctr. For Am. Progress, "Report: State Abortion Bans Will Harm Women and Families' Economic Security Across the US" (Aug. 25, 2022), https://www.americanprogress.org/article/state-abortion-bans-will-harm-women-and-families-economic-security-across-the-us/.

161 See Myasar Ihmud, "Lost in Translation: Language Barriers to Accessing Justice in the American Court System," UIC Law Review (2023) (discussing "access to justice for [limited English proficient (LEP)] individuals is hindered because they are unable to communicate with the court or understand the proceedings. Case law shows that, when unable to communicate with the court, LEP litigants are unable to defend themselves appropriately in criminal or immigration hearings, protect their homes, or keep custody of their children."), https://repository.law.uic.edu/cgi/viewcontent.cgi?article=2908&context=lawreview; see also "Language Access & Cultural Sensitivity," Legal Services Corporation (last visited Feb. 21, 2024) (describing how legal aid organizations should plan for providing meaningful access to language services. As of 2013, "close to 25 million people, about 8 percent of the population, has limited English proficiency."), https://www.lsc.gov/i-am-grantee/model-practices-innovations/language-access-cultural-sensitivity.

162 See, e.g., Gautam Gulati et al., "The experience of law enforcement officers interfacing with suspects who have an intellectual disability—A systematic review," International Journal of Law and Psychiatry (Sept.-Oct. 2020) ("It is not uncommon for people with [intellectual disability] to be suspects or accused persons when interfacing with Law Enforcement Officers (LEOs) and therefore face arrest, interview and/or custody."), https://www.sciencedirect.com/science/article/pii/S016025272030073X.

163 See Leslie Read et al., The Deloitte Ctr. for Health Solutions, "Rebuilding Trust in Health Care: What Do Consumers Want—and Need—Organizations to Do?," at 3 (Aug. 5, 2021) (With focus groups of 525 individuals in the United States who identify as Black, Hispanic, Asian, or Native American, "[f]ifty-five percent reported a negative experience where they lost trust in a health care provider."), https://www2.deloitte.com/us/en/insights/industry/health-care/trust-in-health-care-system.html; Liz Hamel et al., Kaiser Family Foundation, "The Undefeated Survey on Race and Health," at 23 (Oct. 2020) (Percent who say they can trust the health care system to do what is right for them or their community almost all of the time or most of the time: Black adults: 44%; Hispanic adults: 50%; White adults: 55%), https://files.kff.org/attachment/Report-Race-Health-and-COVID-19-The-Views-and-Experiences-of-Black-Americans.pdf; U.S. Dep't of Health and Hum. Servs., Assistant Sec'y for Pol. & Eval., Off. of Health Pol., "Issue Brief: Health Insurance Coverage and Access to Care for LGBTQ+ Individuals: Current Trends and Key Challenges," at 9 (June 2021) (A 2021 survey found that 18 percent of LGBTQ+ individuals reported avoiding going to a doctor or seeking health care out of concern that they would face discrimination or poor treatment because of their sexual orientation or gender identity.), https://aspe.hhs.gov/sites/default/files/2021-07/lgbt-health-ib.pdf; Abigail A. Sewell, "Disaggregating Ethnoracial Disparities in Physician Trust," Soc. Science Rsch. (Nov. 2015), https://pubmed.ncbi.nlm.nih.gov/26463531/; Irena Stepanikova et al., "Patients' Race, Ethnicity, Language, and Trust in a Physician," J. of Health and Soc. Behavior (Dec. 2006), https://pubmed.ncbi.nlm.nih.gov/17240927/.

164 Congress' directions regarding the issuance of standards for the privacy of IIHI are codified at 42 U.S.C. 1320d-2 note. See also 45 CFR 160.104(a).

165 Dep't of Defense, Memorandum Re: Ensuring Access to Reproductive Health Care, at 1 (Oct. 20, 2022) (removed emphasis on "not" in original), https://media.defense.gov/2022/Oct/20/2003099747/-1/-1/1/MEMORANDUM-ENSURING-ACCESS-TO-REPRODUCTIVE-HEALTH-CARE.PDF.

166 Kristin Cohen, "Location, health, and other sensitive information: FTC committed to fully enforcing the law against illegal use and sharing of highly sensitive data", Federal Trade Commission Business Blog (July 11, 2022), https://www.ftc.gov/business-guidance/blog/2022/07/location-health-and-other-sensitive-information-ftc-committed-fully-enforcing-law-against-illegal (last accessed Nov. 15, 2022).

167 Id.

168 See Daniel M. Walker et al., "Interoperability in a Post-Roe Era Sustaining Progress While Protecting Reproductive Health Information," JAMA (Nov. 1, 2022) (discussing that segregation of records for reproductive health care is more difficult than for SUD treatment records because "reproductive health services are often provided in the same settings as other primary and acute care and thus could be inferred or directly reflected in many parts of the record."), https://jamanetwork-com.ezproxyhhs.nihlibrary.nih.gov/journals/jama/fullarticle/2797865; See, e.g., 87 FR 74216, 74221 (Dec. 2, 2022) (noting that 42 CFR part 2 previously resulted in the separation of SUD treatment records previous from other health records, which led to the creation of data "silos" that hampered the integration of SUD treatment records into covered entities' electronic record systems and billing processes. When considering amendments to the relevant statute, some lawmakers argued that the silos perpetuated negative stereotypes about persons with SUD and inhibited coordination of care during the opioid epidemic.). See also Health Info. Tech. Advisory Comm., "Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019," 2019 ONC Ann. Rep., at 37 (Feb. 19, 2020), https://www.healthit.gov/sites/default/files/page/2020-03/HITACAnnualReportforFY19_508.pdf

("The new certification criteria that support the sharing of data via third-party apps will help advance the use of data segmentation, but adoption of this capability by the industry is not yet widespread.").

169 See 88 FR 23746, 23898 (Apr. 18, 2023) (explaining that while there are standards for security labels for document-based exchange that the Office of the National Coordinator for Health Information Technology (ONC) adopted in full in 2020 for the criteria in 45 CFR 170.315(b)(7) and (b)(8) to support the application of security labels at a granular level for sending in and receiving, standards to define the technical requirements for the actions described by the security label vocabularies do not yet exist. In the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule, published in 2020, ONC estimated a cost of the certification criteria and standards adopted for security labels in 45 CFR 170.315(b)(7) and (b)(8). The Department estimated the total cost to developers could range from $2,910,400 to $6,933,600 and that it would be a onetime cost. (85 FR 25926) The criteria do not include the ability for health IT to take the actions described by the security labels. Additionally, ONC did not require that health IT be certified to the criteria described above, making it essentially voluntary. Accordingly, the estimates for health IT developer and health care provider costs were likely significantly lower than they would have been if health IT were required to be certified to the criteria for participation. Thus, the total cost of implementing full segmentation capabilities is likely substantially higher than the per-product cost estimates provided by the Department in that rule). See also 88 FR 23746, 23875 (Apr. 18, 2023) (discussing examples of challenges or technical limitations to electronic health information segmentation that have been described to ONC).

170 See 64 FR 59918, at 59924, 59939, and 59955 (Nov. 3, 1999).

171 See 42 U.S.C. 1320d-6(a).

172 See 42 U.S.C. 1320d-6(b).

173 See 42 U.S.C. 1320d-5. See also 45 CFR part 160, subparts A, D, and E.

174 Press Release, "Breaking Language Barriers: Biden-Harris Administration Announces New Plan to Address Language Barriers and Strengthen Language Access," U.S. Dep't of Health and Human Servs. (Nov. 15, 2023), https://www.hhs.gov/about/news/2023/11/15/breaking-language-barriers-biden-harris-administration-announces-new-plan-address-language-barriers-strengthen-language-access.html.

175 Press Release, "HHS Issues New Proposed Rule to Strengthen Prohibitions Against Discrimination on the Basis of a Disability in Health Care and Human Services Programs," U.S. Dep't of Health and Human Servs. (Sept. 7, 2023), https://www.hhs.gov/about/news/2023/09/07/hhs-issues-new-proposed-rule-to-strengthen-prohibitions-against-discrimination-on-basis-of-disability-in-health-care-and-human-services-programs.html.

176 Press Release, "HHS Issues Proposed Rule to Advance Non-discrimination in Health and Human Service Programs for LGBTQI+ Community," U.S. Dep't of Health and Human Servs. (July 11, 2023), https://www.hhs.gov/about/news/2023/07/11/hhs-issues-proposed-rule-advance-non-discrimination-health-human-service-programs-lgbtqi-community.html.

177 Press Release, "HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care," U.S. Dep't of Health and Human Servs. (July 25, 2022), https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html.

178 See 42 U.S.C. 1320d note.

179 See 42 U.S.C. 1320d-2 note.

180 See 45 CFR 164.512(f)(1)(ii)(C).

181 See, e.g., 45 CFR 164.512(f) and 164.514(d)(3)(iii).

182 See 45 CFR 164.502(g) (describing personal representatives) and 164.524(a)(3) (describing reviewable grounds for denial of access to PHI by a personal representative).

183 Off. for Civil Rights, "Health Information Privacy," U.S. Dep't of Health and Human Servs., https://www.hhs.gov/hipaa/index.html.

184 See 42 U.S.C. 1320d-1320d-8.

185 45 CFR 160.103.

186 See section 1101(3) of Public Law 74-271, 49 Stat. 620 (Aug. 14, 1935) (codified at 42 U.S.C. 1301(3)).

187 1 U.S.C. 8(a). The Department is not opining on whether any state law confers a particular legal status upon a fertilized egg, embryo, or fetus. Rather, the Department cites to this statute to help define the scope of privacy protections that attach pursuant to HIPAA and its implementing regulations.

188 Id.

189 88 FR 23506, 23523 (Apr. 17, 2023).

190 45 CFR 160.103 (definition of "Individual").

191 See Sharon T. Phelan, "The Prenatal Record and the Initial Prenatal Visit," The Glob. Libr. of Women's Med. (last updated Jan. 2008) (PHI about the fetus is included in the mother's PHI), https://www.glowm.com/section-view/heading/ThePrenatalRecordandtheInitialPrenatalVisit/item/107#.Y7WRKofMKUl.

192 See 42 U.S.C. 1320d.

193 45 CFR 160.103 (definition of "Person"). The Department first defined the term "person" in the HIPAA Rules as part of the 2003 Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings Interim Final Rule (2003 Interim Final Rule) to distinguish a "natural person" who could testify in the context of administrative proceedings from an "entity" (defined therein as a "legal person") on whose behalf a person would testify. See 45 CFR 160.502 of the 2003 Interim Final Rule, 68 FR 18895, 18898 (Apr. 17, 2003) (Person is defined to mean a natural person or a legal person).

194 45 CFR 160.103 (definition of "Individual"). The definition of "individual" in the HIPAA Rules was first adopted in the 2000 Privacy Rule.

195 See 45 CFR 164.512(c)(1). This provision explicitly excludes reports of child abuse, which are addressed by 45 CFR 164.512(b)(1).

196 1 U.S.C. 8(a).

197 Public Law 110-233, 122 Stat. 881. See generally Off. for Civil Rights, "Health Information Privacy, Genetic Information," U.S. Dep't of Health and Human Servs. (Content last reviewed June 16, 2017), https://www.hhs.gov/hipaa/for-professionals/special-topics/genetic-information/index.html#:#:text=TheGeneticInformationNondiscriminationAct,intotwosections′orTitles.

198 See 45 CFR 164.524. See also William Baude & Stephen E. Sachs, "The Law of Interpretation," 130 Harv. L. Rev. 1079 (2017).

199 45 CFR 164.502(g).

200 See 45 CFR 164.512(j)(1)(i).

201 42 U.S.C. 1320d-7(a)

202 42 U.S.C. 1320d-7(b).

203 45 CFR 164.501 (definition of "Public health authority").

204 45 CFR 164.514(h).

205 This is unchanged by this final rule.

206 See 45 CFR 164.512(b). The Privacy Rule addresses its interactions with laws governing excepted public health activities in two sections: 45 CFR 164.512(a), Standard: Uses and disclosures required by law, and 45 CFR 164.512(b), Standard: Uses and disclosures for public health activities.

207 45 CFR 164.512(b).

208 45 CFR 164.512(f).

209 88 FR 23506, 23523 (Apr. 17, 2023).

210 The 1996-98 Report of the NCVHS to the Secretary describes various types of activities considered to be public health during the era in which HIPAA was enacted, such as the collection of public health surveillance data on health status and health outcomes and vital statistics information. See Nat'l Comm. On Vital and Health Stats., Report of The National Committee on Vital and Health Statistics, 1996-98, (Dec. 1999), https://ncvhs.hhs.gov/wp-content/uploads/2018/03/90727nv-508.pdf.

211 Id.

212 Id.

213 Richard N. Danila et al., "Legal Authority for Infectious Disease Reporting in the United States: Case Study of the 2009 H1N1 Influenza Pandemic," 105 a.m. J. Public Health 13 (Jan. 2015).

214 See "Reportable Diseases," MedlinePlus, https://medlineplus.gov/ency/article/001929.htm (accessed Oct. 19, 2022). See also Nat'l Notifiable Diseases Surveillance Sys., "What is Case Surveillance?," Ctrs. for Disease Control and Prevention (July 20, 2022), https://www.cdc.gov/nndss/about/index.html.

215 See "Reportable Diseases," supra note 215. Such reporting is a type of public health surveillance activity.

216 See Victims Rts. Law Ctr., "Mandatory Reporting of Non-Accidental Injuries: A State-by-State Guide" (May 2014), http://4e5ae7d17e.nxcli.net/wp-content/uploads/2021/01/Mandatory-Reporting-of-Non-Accidental-Injury-Statutes-by-State.pdf.

217 See, e.g., 38 U.S.C. 1110 (referring to an "injury suffered or disease contracted"); 10 U.S.C. 972 (discussing time lost as a result of "disease or injury"); 38 U.S.C. 3500 (providing education for certain children whose parent suffered "a disease or injury" incurred or aggravated in the Armed Forces); see also 5 U.S.C. 8707 (insurance provision discussing compensation as a result of "disease or injury"); 33 U.S.C. 765 (discussing retirement for disability as a result of "disease or injury"); 15 U.S.C. 2607(c) (requiring chemical manufacturers to maintain records of "occupational disease or injury").

218 45 CFR 164.512(b)(ii).

219 See 65 FR 82462, 82571 (Dec. 28, 2000) (recognizing that "disease management activities" often constitute "health care" under HIPAA); Id. at 82777 (discussing the importance of privacy for information about cancer, a "disease" that causes an "indisputable" "societal burden"); Id. at 82778 (discussing the importance of privacy for information about sexually transmitted diseases, including Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS)); Id. at 82463-64 (noting that numerous states adopted laws protecting health information relating to certain health conditions such as communicable diseases, cancer, HIV/AIDS, and other stigmatized conditions.); Id. at 82731 (finding that there are no persuasive reasons to provide information contained within disease registries with special treatment as compared with other information that may be used to make decisions about an individual).

220 See, e.g., 65 FR 82462, 82517 (Dec. 28, 2000) (discussing tort litigation as information that could implicate IIHI); Id. at 82542 (discussing workers' compensation); Id. at 82527 (separately addressing disclosures about "abuse, neglect or domestic violence" and limiting such disclosures to only two circumstances, even if expressly authorized by state statute or regulation).

221 See "Public Health Professionals Gateway, Public Health Systems & Best Practices, Health Department Governance," Ctrs. for Disease Control and Prevention (Nov. 25, 2022), https://www.cdc.gov/publichealthgateway/sitesgovernance/index.html.

222 See the list of events included in vital events, Nat'l Ctr. for Health Stats., "About the National Vital Statistics System," Ctrs. for Disease Control and Prevention (Jan. 4, 2016), https://www.cdc.gov/nchs/nvss/about_nvss.htm.

223 See Nat'l Ctr. for Health Stats., "Birth Data," Ctrs. for Disease Control and Prevention (Dec. 6, 2022), https://www.cdc.gov/nchs/nvss/births.htm.

224 See Ctrs. For Disease Control and Surveillance, "How Tracking Deaths Protects Health," (July 2018), https://www.cdc.gov/surveillance/pdfs/Tracking-Deaths-protects-healthh.pdf.

225 See Nat'l Ctr. for Health Stats., Ctrs. for Disease Control and Prevention, "State Definitions and Reporting Requirements: For Live Births, Fetal Deaths, and Induced Terminations of Pregnancy," at 5 (1997), https://www.cdc.gov/nchs/data/misc/itop97.pdf.

226 Nat'l Ctr. for Health Stats., Ctrs. for Disease Control and Prevention, "Model State Vital Statistics Act and Regulations," at 8 (1992), https://www.cdc.gov/nchs/data/misc/mvsact92b.pdf.

227 42 U.S.C. 1178(b) (codified in HIPAA at 42 U.S.C. 1320d-7).

228 Section 1178(a) of HIPAA.

229 See 45 CFR 164.512(b)(1)(i); Off. for Civil Rights, "Disclosures for Public Health Activities," U.S. Dep't of Health and Human Servs., https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-public-health-activities/index.html (accessed Oct. 19, 2022).

230 See "Introduction to Public Health Surveillance," Ctrs. for Disease Control and Prevention (Nov. 15, 2018), https://www.cdc.gov/training/publichealth101/surveillance.html.

231 See "Public Health Professionals Gateway, Ten Essential Public Health Services," Ctrs. for Disease Control and Prevention (Dec. 1, 2022), https://www.cdc.gov/publichealthgateway/publichealthservices/essentialhealthservices.html.

232 Section 1178(a) of SSA.

233 "Health, Public Health," Black's Law Dictionary (11th ed. 2019).

234 "Public Health," Stedman's Medical Dictionary 394520.

235 Jonathan Weinstein, In Re Miguel M., 55 N.Y.L. Sch. L. Rev. 389, 390 (2010) (citing Stephen B. Thacker, "Historical Development," in Principles and Practice of Public Health Surveillance 1 (Steven M. Teutsch & R. Elliott Churchill eds., 2d ed., 2000)), https://digitalcommons.nyls.edu/cgi/viewcontent.cgi?article=1599&context=nyls_law_review.

236 See, e.g., Richard A. Goodman et al., "Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations," 31 J. of Law, Med. & Ethics 684, 689-90 (2003); La. Rev. Stat. Ann. Sec. 40:3.1 (2011) (defining threats to public health as nuisances "including but not limited to communicable, contagious, and infectious diseases, as well as illnesses, diseases, and genetic disorders or abnormalities"); N.C. Gen. Stat. sec. 130A-141.1(a) (2010) (defining public health investigations as the "surveillance of an illness, condition, or symptoms that may indicate the existence of a communicable disease or condition").

237 See, e.g., 65 FR 82462, 82464 (Dec. 28, 2000) (noting that reporting of public health information on communicable diseases is not prevented by individuals' right to information privacy); Id. at 82467 (discussing the importance of accurate medical records in recognizing troubling public health trends and in assessing the effectiveness of public health efforts); Id. at 82473 (discussing disclosure to "a department of public health"); Id. at 82525 (recognizing that it may be necessary to disclose PHI about communicable diseases when conducting a public health intervention or investigation); Id. at 82526 (recognizing that an entity acts as a "public health authority" when, in its role as a component of the public health department, it conducts infectious disease surveillance); Stephen B. Thacker, Epidemiology Program Office, Ctrs. for Disease Control and Prevention, "HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services," 52 MMWR 1 (Apr. 11, 2003), https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm (describing what traditionally are considered to be "public health activities" that require PHI).

238 See Miguel M. v. Barron, 950 NE2d 107, at 111 (2011) (explaining "[t]he apparent purpose of the public health exception is to facilitate government activities that protect large numbers of people from epidemics, environmental hazards, and the like, or that advance public health by accumulating valuable statistical information.").

239 88 FR 23510, 23525 (Apr. 17, 2023).

240 See Miguel M. v. Barron at 111, supra note 239 (concluding that "[t]o disclose private information about particular people, for the purpose of preventing those people from harming themselves or others, effects a very substantial invasion of privacy without the sort of generalized public benefit that would come from, for example, tracing the course of an infectious disease.").

241 For example, traditional public health reporting laws grew from colonial requirements that physicians report disease. These requirements transitioned to state regulatory requirements imposed by public health departments on authority granted to them by states. See Ctrs. for Disease Control and Prevention, "Public Health Law 101, Disease Reporting and Public Health Surveillance," at 12 and 14 (Jan. 16, 2009), https://www.cdc.gov/phlp/docs/phl101/PHL101-Unit-5-16Jan09-Secure.pdf. See also, e.g., Code of Georgia 31-12-2 (2021) (authority to require disease reporting).

242 See "Public Health," supra note 235 ("Many cities have a 'public health department' or other agency responsible for maintaining the public health; Federal laws dealing with health are administered by the Department of Health and Human Services."); see also "Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations," supra note 237, at 689.

243 See Camara v. Municipal Ct. of City & Cty. of S.F., 387 U.S. 523, 535-37 (1967) (discussing administrative inspections under the Fourth Amendment, such as those aimed at addressing "conditions which are hazardous to public health and safety," and not "aimed at the discovery of evidence of crime"); 42 U.S.C. 241(d)(D) (prohibiting disclosure of private

information from research subjects in "criminal" and other proceedings); 42 U.S.C. 290dd-2(c) (prohibiting substance abuse records from being used in criminal proceedings).

244 See "Forensic Epidemiology: Law at the Intersection of Public Health and Criminal Investigations," supra note 237, at 687 (discussing reasons why "an association of public health with law enforcement" may be "to the detriment of routine public health practice"). See also 45 CFR 164.512(b)(1)(i) (including "public health investigations" as an activity carried out by a public health authority that is authorized by law to carry out public health activities).

245 See "Improving the Role of Health Departments in Activities Related to Abortion," Am. Pub. Health Ass'n (Oct. 26, 2021), https://www.apha.org/Policies-and-Advocacy/Public-Health-Policy-Statements/Policy-Database/2022/01/07/Improving-Health-Department-Role-in-Activities-Related-to-Abortion.

246 See "Reportable diseases," supra note 215. See also "What is Case Surveillance?," supra note 215.

247 See "Reproductive Health, About Us," Ctrs. for Disease Control and Prevention (Apr. 20, 2022), https://www.cdc.gov/reproductivehealth/drh/about-us/index.htm; and "Reproductive Health, CDCs Abortion Surveillance System FAQs," Ctrs. for Disease Control and Prevention (Nov. 17, 2022), https://www.cdc.gov/reproductivehealth/data_stats/abortion.htm.

248 See 45 CFR 164.502(b).

249 See 45 CFR 164.514(a).

250 45 CFR 164.514(d)(3)(iii)(A); see also 45 CFR 164.514(h)(2)(ii) and (iii).

251 See 45 CFR 164.512(b)(1)(ii).

252 See 45 CFR 164.502(b) and 164.514(d).

253 65 FR 82462, 82527 (Dec. 28, 2000).

254 Public Law 101-647, 104 Stat. 4789 (codified at 18 U.S.C. 3509).

255 Public Law 93-247, 88 Stat. (codified at 42 U.S.C. 5101 note).

256 See 34 U.S.C. 20341(a)(1), originally enacted as part of the Victims of Child Abuse Act of 1990 and codified at 42 U.S.C. 13031, which was editorially reclassified as 34 U.S.C. 20341, Crime Control and Law Enforcement. For the purposes of such mandated reporting, see 34 U.S.C. 20341(c)(1) for definition of "child abuse."

257 88 FR 23506, 23526 (Apr. 17, 2023).

258 65 FR 82462, 82527 (Dec. 28, 2000).

259 See 45 CFR 164.502(g).

260 See 45 CFR 164.502(b) and 164.514(d).

261 See 45 CFR 164.512(e) and (f).

262 See 45 CFR 164.512(e) and (f).

263 65 FR 82462, 82527 (Dec. 28, 2000).

264 45 CFR 160.103 (definition of "Health care").

265 These groupings are (1) "[p]reventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body" and (2) "[the s]ale or dispensing of a drug, device, equipment, or other item in accordance with a prescription." It would also include supplies purchased over the counter or furnished to the individual by a person that does not meet the definition of a health care provider under the HIPAA Rules. 45 CFR 164.103 (definition of "Health care provider").

266 88 FR 23506, 23527-28 (Apr. 17, 2023).

267 88 FR 23506, 23527 (Apr. 17, 2023).

268 65 FR 82571 (Dec. 28, 2000).

269 See "What is Assisted Reproductive Technology?" Centers for Disease Control and Prevention (Oct. 8, 2019), https://www.cdc.gov/art/whatis.html and "Fact Sheet: In Vitro Fertilization (IVF) Use Across the United States," U.S. Dep't of Health and Human Servs. (Mar. 13, 2024), https://www.hhs.gov/about/news/2024/03/13/fact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html.

270 45 CFR 160.103 (definition of "Protected health information").

271 88 FR 23506, 23528 (Apr. 17, 2023).

272 88 FR 23506, 23528-29 (Apr. 17, 2023).

273 42 U.S.C. 17935(e).

274 In the preamble to the 2000 Privacy Rule, we explained that a covered entity could meet HIPAA plain language requirements by organizing material to serve the reader; writing short sentences in the active voice; using pronouns; using common, everyday language; and dividing material into short sections. 65 FR 82462, 82548 (Dec. 28, 2000).

275 89 FR 1192, 1302 (Jan. 9, 2024). See also Off. for Civil Rights, "Information Blocking Regulations Work In Concert with HIPAA Rules and Other Privacy Laws to Support Health Information Privacy," U.S. Dep't of Health and Human Servs. (Apr. 12, 2023), https://www.healthit.gov/buzz-blog/information-blocking/information-blocking-regulations-work-in-concert-with-hipaa-rules-and-other-privacy-laws-to-support-health-information-privacy.

276 See, e.g., Off. for Civil Rights, "Resource for Health Care Providers on Educating Patients about Privacy and Security Risks to Protected Health Information when Using Remote Communication Technologies for Telehealth," U.S. Dep't of Health and Human Servs., https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/resource-health-care-providers-educating-patients/index.html.

277 See 45 CFR 164.502(a)(3) and (e). See also 45 CFR 164.504(e).

278 For information about what a business associate is and the requirements for business associate agreements, see Off. for Civil Rights, "Business Associate Contracts," U.S. Dep't of Health and Human Servs. (Jan. 25, 2013), https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html.

279 Off. for Civil Rights, "Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet," U.S. Dep't of Health and Human Servs. (June 29, 2022), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.

280 88 FR 23506, 23529-33 (Apr. 17, 2023).

281 The Department does not oppose efforts to implement or employ technology that is capable of segmenting data. Rather, the Department's proposal was informed by the recognition that the technology deployed by most regulated entities today is not capable of doing so.

282 See supra discussion of "Public health" for more information on what constitutes a "public health activity" under the Privacy Rule.

283 88 FR 23506, 23532 (Apr. 17, 2023).

284 Id. at 23510, 23522, and 23531.

285 See Griswold v. Connecticut, 381 U.S. 479 (1965); Eisenstadt v. Baird, 405 U.S. 438 (1972); Dobbs, 597 U.S. 345 (Kavanaugh, J., concurring) (Dobbs "does not threaten or cast doubt on" the precedents providing constitutional protection for contraception).

286 See proposed 45 CFR 164.502(a)(5)(iii)(D). See also 88 FR 23506, 23552-53 (Apr. 17, 2023).

287 Section 164.502(a)(5)(iii)(A)(3) incorporates the same language by reference to 45 CFR 164.502(a)(5)(iii)(A)(1) and (A)(2).

288 42 U.S.C. 1320d-7(a)(1) (providing the general rule that, with limited exceptions, a provision or requirement under HIPAA supersedes any contrary provision of state law); see also section 264(c)(2) of Public Law 104-191 (codified at 42 U.S.C. 1320d-2 note) and 45 CFR 160.203.

289 See final 45 CFR 164.509, and discussion below.

290 See 42 U.S.C. 1320d-6.

291 88 FR 23506, 23532-33 (Apr. 17, 2023).

292 See 45 CFR 164.512(d)(1)(i) through (iv) for health oversight activities for which the Privacy Rule permits uses and disclosures of PHI. See also the National Association of Medicaid Fraud Control Units, described at https://www.naag.org/about-naag/namfcu/. All 53 federally certified Medicaid Fraud Control Units voluntarily subscribe to this organization. This final rule does not interfere with any State's ability to meet their statutory obligations to combat health care fraud related to Medicaid.

293 31 U.S.C. 3729-3733.

294 18 U.S.C. 248(e)(5) (definition of "Reproductive health services").

295 45 CFR 160.103 (definition of "Person").

296 Note that in Section V.A.1, the Department is clarifying the definition of "person," although that clarification does not affect the analysis in this paragraph.

297 See 45 CFR 164.514(d)(3)(iii)(A) and 65 FR 82462, 82545, and 82547 (Dec. 28, 2000).

298 45 CFR 164.514(h)(2) and 65 FR 82462, 82546-47 (Dec. 28, 2000).

299 See 45 CFR 164.514(h) and 65 FR 82462, 82546-47 (Dec. 28, 2000).

300 See 65 FR 82462, 82545 (Dec. 28, 2000) ("[. . .] covered entities making disclosures to public officials that are permitted under § 164.512 may rely on the representations of a public official that the information requested is the minimum necessary."); see also id. at 82547 (further discussing verification of identity and authority of persons requesting PHI

in 45 CFR 164.514(h) and the requirements in 45 CFR 164.512 for the circumstances under which covered entities must make reasonable determinations about the sufficiency of proof of identify and authority based on documentary evidence, contrasted with a reasonable reliance on verbal representations when necessary to avert a pending emergency or imminent threat to the health or safety of a person or the public pursuant to 45 CFR 164.512(j)(1)(i)).

301 See 88 FR 23506, 23530 (Apr. 17, 2023).

302 See 42 CFR part 2 and the 2024 Part 2 Rule for more information about Part 2 and the protections afforded to Part 2 records.

303 See the finalized definition of "Reproductive health care" at 45 CFR 160.103.

304 See Off. for Civil Rights, "Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet," U.S. Dep't of Health and Human Servs. (June 29, 2022), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.

305 See 45 CFR 164.502(b). Uses and disclosures of PHI pursuant to 45 CFR 164.512(a) are limited to the relevant requirements of such law. 45 CFR 164.512(a)(1).

306 45 CFR 164.514(b).

307 See 45 CFR 164.506.

308 See 45 CFR 160.103 (definitions of "health plan" and "group health plan").

309 In the 2023 Privacy Rule NPRM, we proposed the Scope of prohibition in 45 CFR 164.502(a)(5)(iii)(B).

310 88 FR 23506, 23509 (Apr. 17, 2023) (citing 65 FR 82464 (Dec. 28, 2000)).

311 Id.

312 See 42 U.S.C. 1320d-5 and 6.

313 See 45 CFR 164.512(a).

314 See 45 CFR 164.512(a).

315 Public Law 100-578, 102 Stat. 2903 (Oct. 31, 1988) (codified at 42 U.S.C. 201 note).

316 See 45 CFR 164.512(a)(1).

317 See 45 CFR 164.103 (definition of "Required by law"). The definition provides additional explanation about what constitutes a mandate contained in law.

318 See 45 CFR 164.512(a)(1).

319 See 45 CFR 164.103 (definition of "Required by law").

320 The Privacy Rule permits but does not require covered entities to disclose PHI in response to an order of a court or administrative tribunal. The Privacy Rule also permits but does not require covered entities to disclose PHI in response to a subpoena, discovery request, or other lawful process, but only when certain conditions are met. See 45 CFR 164.512(e)(1). These provisions cannot be used to make disclosures to law enforcement officials that are restricted by 45 CFR 164.512(f). See 45 CFR 164.512(e)(2).

321 45 CFR 164.512(f)(1).

322 Whether the regulated entity is limited by the minimum necessary standard or the relevant requirements of the law that requires the reporting depends upon whether the regulated entity is making the disclosure pursuant to 45 CFR 164.512(a) or some other permission under 45 CFR 164.512. See 45 CFR 164.502(b)(v).

323 See 45 CFR 164.502(g).

324 See 45 CFR 164.502(g)(3)(i). See also Off. for Civil Rights, "Personal Representatives," U.S. Dep't of Health and Human Servs., https://www.hhs.gov/hipaa/for-individuals/personal-representatives/index.html.

325 See, e.g., 45 CFR 164.510(b)(3) and 164.512(j)(1)(i)(A).

326 See 65 FR 82462, 82471 (Dec. 28, 2000).

327 88 FR 23506, 23533-34 (Apr. 17, 2023).

328 See 45 CFR 164.502(g).

329 See 45 CFR 164.502(g)(3)(i).

330 88 FR 23506, 23534 (Apr. 17, 2023).

331 45 CFR 164.506.

332 45 CFR 164.508.

333 45 CFR 164.510.

334 45 CFR 164.512.

335 45 CFR 164.508(b).

336 88 FR 23506, 23534-37 (Apr. 17, 2023).

337 Pursuant to 45 CFR 164.530(j), regulated entities would be required to maintain a written or electronic copy of the attestation.

338 The Federal plain language guidelines under the Plain Writing Act of 2010 only applies to Federal agencies, but it serves as a helpful resource. See 5 U.S.C. 105 and "Federal plain language guidelines," U.S. Gen. Servs. Admin., https://www.plainlanguage.gov/guidelines/.

339 Proposed 45 CFR 164.509(b)(1)(iv) and (c)(1)(iv).

340 While not explicitly stated in the Privacy Rule, the Department previously issued guidance clarifying that authorizations are permitted to be submitted and signed electronically. See Off. for Civil Rights, "Is a copy, facsimile, or electronically transmitted version of a signed authorization valid under the Privacy Rule?," U.S. Dep't of Health and Human Servs., HIPAA FAQ #475 (Jan. 9, 2023), https://www.hhs.gov/hipaa/for-professionals/faq/475/is-a-copy-of-a-signed-authorization-valid/index.html and Off. for Civil Rights, "How do HIPAA authorizations apply to an electronic health information exchange environment?," U.S. Dep't of Health and Human Servs., HIPAA FAQ #554 (July 26, 2013), https://www.hhs.gov/hipaa/for-professionals/faq/554/how-do-hipaa-authorizations-apply-to-electronic-health-information/index.html.

341 This approach is consistent with 45 CFR 164.514(h), which requires a regulated entity to verify the identity and legal authority of a public official or a person acting on behalf of a public official, and describes the type of documentation

upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to do so. See also 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

342 Proposed 45 CFR 164.509(d).

343 Business associates became directly liable for compliance with certain requirements of the HIPAA Rules under the HITECH Act. Consistent with the HITECH Act, the 2013 Omnibus Rule identified the portions of the HIPAA Rules that apply directly to business associates and for which business associates are directly liable. Prior to the HITECH Act and the Omnibus Rule, these requirements applied to business associates and their subcontractors indirectly through the requirements under 45 CFR 164.504(e) and 164.314(a), which require that covered entities by contract require business associates to limit uses and disclosures and implement HIPAA Security Rule-like safeguards. See 78 FR 5566 (Jan. 25, 2013). See also Off. for Civil Rights, "Direct Liability of Business Associates Fact Sheet," U.S. Dep't of Health and Human Servs. (July 16, 2021), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html.

344 45 CFR 164.504(e) and 164.314(a).

345 45 CFR 164.504(e)(2)(i)(E).

346 65 FR 82462, 82471, and 82875 (Dec. 28, 2000).

347 See 42 U.S.C. 1320d-6(a).

348 45 CFR 164.509(b)(1)(iii) and (c)(1)(vi).

349 45 CFR 164.502(b). The minimum necessary standard of the Privacy Rule applies to all uses and disclosures where a request does not meet one of the specified exceptions in paragraph (b)(2).

350 45 CFR 164.502(b)(1).

351 This approach is consistent with 45 CFR 164.514(h), which requires a covered entity to verify the identity and legal authority of a public official or a person acting on behalf of the public official and describes the type of documentation upon which regulated entities can rely, if such reliance is reasonable under the circumstances, to do so. See also 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

352 E.g., Restatement (Second) Torts § 283, comment b (Am. L. Inst. 1965).

353 45 CFR 164.509(d).

354 See 42 U.S.C. 1320d-6(a).

355 A person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization. Id.

356 See 42 U.S.C. 1320d-6(b).

357 45 CFR 164.400 et seq. The HIPAA Breach Notification Rule, 45 CFR 164.400-414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured PHI.

358 See 42 U.S.C. 1320d-6(a).

359 See 45 CFR 164.512.

360 See 42 U.S.C. 300jj-52(a)(1) (excluding from the definition of "information blocking" practices that are likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information if they are "required by law"; 85 FR 25642, 25794 (May 1, 2020) (explaining that "required by law" specifically refers to interferences that are explicitly required by state or Federal law). See also 89 FR 1192, 1351 (Jan. 9, 2024) (affirming that where applicable law prohibits access, exchange, or use of information, practices in compliance with such law are not considered to be information blocking and citing to compliance with the Privacy Rule as an example of an applicable law).

361 This approach is consistent with 45 CFR 164.514(h), which requires a regulated entity to verify the identity and legal authority of a public official or a person acting on behalf of the public official and describes the type of documentation upon which the regulated entity can rely, if such reliance is reasonable under the circumstances, to do so. See also 45 CFR 164.514(d)(3)(iii)(A), which permits a covered entity to rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when making disclosures to public officials that are permitted under 45 CFR 164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s).

362 45 CFR 164.514(h)(1) requires a regulated entity to verify both the identity of the person requesting PHI and the authority of any such person to have access to PHI, if the identity or authority of such person is not known to the regulated entity. 45 CFR 164.514(h)(2)(ii) describes the information upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to verify the identity of a public official requesting PHI or a person acting on behalf of a public official, while 45 CFR 164.514(h)(2)(iii) describes the information upon which a regulated entity may rely, if such reliance is reasonable under the circumstances, to verify the authority of the public official requesting PHI or a person acting on behalf of a public official.

363 45 CFR 164.512(e)(1)(ii)(A).

364 45 CFR 164.512(e)(1)(ii)(B).

365 45 CFR 164.512(e)(1)(iii) and (iv).

366 See 42 U.S.C. 1320d-6(a).

367 See 42 U.S.C. 1320d-5. See also 45 CFR part 160, subparts A, D, and E.

368 See 42 U.S.C. 1320d-6(b).

369 See 45 CFR 164.514(h); see also 65 FR 82462, 82541, and 82547 (Dec. 28, 2000).

370 45 CFR 164.514(h)(2)(iii)(A).

371 45 CFR 164.514(h)(2)(iii)(B).

372 45 CFR 164.512(a)(1).

373 45 CFR 164.514(d)(3)(iii)(A).

374 42 U.S.C. 1320d-5.

375 42 U.S.C. 1320d-6.

376 45 CFR 165.512(e)(1)(ii).

377 45 CFR 164.512(f)(1)(ii)(C).

378 See 42 U.S.C. 1320d-6(a).

379 65 FR 82462, 82524 (Dec. 28, 2000).

380 See id. at 82471.

381 88 FR 23506, 23537-38 (Apr. 17, 2023).

382 45 CFR 164.512(d).

383 45 CFR 164.512(e).

384 45 CFR 164.512(f).

385 45 CFR 164.512(g)(1).

386 The Privacy Rule only applies to PHI, which is IIHI that is maintained or transmitted by, for, or on behalf of a covered entity. Thus, it does not apply to individuals' health information when it is in the possession of a person that is not a regulated entity, such as a friend, family member, or is stored on a personal cellular telephone or tablet. See Off. for Civil Rights, "Protecting the Privacy and Security of Your Health Information When Using Your Personal Cell Phone or Tablet," U.S. Dep't of Health and Human Servs. (June 29, 2022), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/cell-phone-hipaa/index.html.

387 45 CFR 164.512(d).

388 45 CFR 164.512(e).

389 45 CFR 164.512(f).

390 45 CFR 164.512(g)(1).

391 88 FR 23506, 23538 (Apr. 17, 2023).

392 Id.

393 45 CFR 164.512(c).

394 See 45 CFR 164.502(b) and 164.514(d).

395 See 45 CFR 164.512(e) and (f).

396 88 FR 23506, 23538-39 (Apr. 17, 2023).

397 See 65 FR 82462, 82531 (Dec. 28, 2000).

398 See U.S. Senate Committee on Finance News Release (Dec. 12, 2023), https://www.finance.senate.gov/chairmans-news/wyden-jayapal-and-jacobs-inquiry-finds-pharmacies-fail-to-protect-the-privacy-of-americans-medical-records-hhs-must-update-health-privacy-rules (describing legislative inquiry

into pharmacy chains and release of health information in response to law enforcement). See also Letter from Sen. Wyden and Reps. Jayapal and Jacobs to HHS Sec'y Xavier Becerra (Dec. 12, 2023), https://www.finance.senate.gov/imo/media/doc/hhs_pharmacy_surveillance_letter_signed.pdf (describing findings from Congressional oversight, including survey of chain pharmacies about their processes for responding to law enforcement requests for PHI).

399 See U.S. Senate Committee on Finance News Release, supra note 399 and Letter from Sen. Wyden and Reps. Jayapal and Jacobs, supra note 399; see also Remy Tumin, "Pharmacies Shared Patient Records Without a Warrant, an Inquiry Finds," The New York Times (Dec. 13, 2023), https://www.nytimes.com/2023/12/13/us/pharmacy-records-abortion-privacy.html.

400 See 65 FR 82462, 82531 (Dec. 28, 2000).

401 Public Law 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified at 5 U.S.C. 552a).

402 Off. for Civil Rights, "Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule: A Guide for Law Enforcement," https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf.

403 88 FR 23506, 23539 (Apr. 17, 2023).

404 45 CFR 164.520. Unlike many provisions of the Privacy Rule, 45 CFR 164.520 applies only to covered entities, as opposed to both covered entities and their business associates.

405 86 FR 6446 (Jan. 21, 2021).

406 45 CFR 160.103 (definition of "Organized health care arrangement").

407 88 FR 23506, 23539 (Apr. 17, 2023).

408 89 FR 12472 (Feb. 16, 2024).

409 See also 82 FR 6052, 6082-83 (Jan. 18, 2017); Off. for Civil Rights, "Notice of Privacy Practices for Protected Health Information," U.S. Dep't of Health and Human Servs. (July 26, 2013), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/privacy-practices-for-protected-health-information/index.html.

410 65 FR 82462, 82548-49 (Dec. 28, 2000).

411 Off. for Civil Rights, "Model Notices of Privacy Practices," U.S. Dep't of Health and Human Servs. (Apr. 8, 2013), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/model-notices-privacy-practices/index.html.

412 45 CFR 164.502(d)(2).

413 See 45 CFR part 160, subpart B—Preemption of State Law.

414 58 FR 51735 (Oct. 4, 1993).

415 88 FR 21879 (Apr. 11, 2023).

416 76 FR 3821 (Jan. 21, 2011).

417 Public Law 96-354, 94 Stat. 1164 (codified at 5 U.S.C. 601-612).

418 Public Law 104-4, 109 Stat. 48 (codified at 2 U.S.C. 1501).

419 Id. at sec. 202 (codified at 2 U.S.C. 1532(a)).

420 Also referred to as the Congressional Review Act, 5 U.S.C. 801 et seq.

421 88 FR 3997 (Jan. 23, 2023).

422 64 FR 59918 (Nov. 3, 1999).

423 78 FR 5566 (Jan. 25, 2013).

424 For each occupation performing activities as a result of the final rule, the Department identifies a pre-tax hourly wage using a database maintained by the Bureau of Labor Statistics. See U.S. Dep't of Labor, "Occupational Employment and Wages" (May 2022), https://www.bls.gov/oes/current/oes_nat.htm.

425 This includes 60 days from publication of a final rule to the effective date and an additional 180 days until the compliance date.

a Number of pharmacy establishments is taken from industry statistics.

426 See U.S. Census Bureau, American Community Survey S0101, AGE AND SEX 2022: ACS 5-Year Estimates Subject Tables (females aged 10-44), https://data.census.gov/table/ACSST1Y2022.S0101. The U.S. Census Bureau uses the term "sex" to equate to an individual's biological sex. "Sex—Definition," U.S. Census Bureau (accessed Mar. 20, 2024), https://www.census.gov/glossary/?term=Sex.

427 See "Reproductive and Sexual Health," Sexually active females who received reproductive health services (FP-7.1), Healthypeople.gov, https://wayback.archive-it.org/5774/20220415172039/https://www.healthypeople.gov/2020/leading-health-indicators/2020-lhi-topics/Reproductive-and-Sexual-Health/data.

428 See American Community Survey S0101, AGE AND SEX 2022: ACS 5-Year Estimates Subject Tables (females aged 10-44), supra note 427.

429 See M. Antonia Biggs et al., "Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study," 74(2) JAMA Psychiatry 169, 177 (2017), https://jamanetwork.com/journals/jamapsychiatry/fullarticle/2592320. See also Julia R. Steinberg et al., "The association between first abortion and first-time non-fatal suicide attempt: a longitudinal cohort study of Danish population registries," 6(12) The Lancet Psychiatry 1031-1038 (Dec. 2019).

430 See Julia R. Steinberg et al., "Fatal flaws in a recent meta-analysis on abortion and mental health," 86(5) Contraception 430-7 (Nov. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3646711/ (discussing errors and significant shortcomings of the studies included in the 2011 meta-analysis that render its conclusions invalid).

431 See Lawrence O. Gostin et al., "One Year After Dobbs—Vast Changes to the Abortion Legal Landscape," 4(8) JAMA Health Forum (2023), https://jamanetwork.com/journals/jama-health-forum/fullarticle/2808205 (counting 21 states with post-Dobbs limits that are more restrictive than Roe v. Wade allowed) and Laura Deal, "State Laws Restricting or Prohibiting Abortion," Congressional Research Service (Jan. 22, 2024), https://crsreports.congress.gov/product/pdf/R/R47595. Because of the pace of change in this area, the Department relies on a higher number than JAMA's 2023 figure as a basis for its cost estimates.

432 See 45 CFR 160.201 et seq. for information about exceptions to HIPAA's general preemption authority and the process for requesting such an exception and the criteria for granting it.

433 "Information Collection: Process for Requesting Exception Determinations (states or persons)," U.S. Gen. Servs. Admin. & Off. of Mgmt. and Budget, https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201909-0945-001&icID=10428.

434 See supra, Table 3 of this RIA.

435 Id.

436 Id.

437 This includes 60 days from the date of publication to the effective date, plus 120 days from the effective date to the compliance date.

438 45 CFR 164.520(c)(1)(v)(A).

a Totals may not add up due to rounding.

a Totals may not add up due to rounding.

439 See "One Year After Dobbs—Vast Changes to the Abortion Legal Landscape," supra note 432 (counting 21 states with post-Dobbs limits that are more restrictive than Roe v. Wade allowed) and "State Laws Restricting or Prohibiting Abortion," supra note 432. Because of the pace of change in this area, the Department relies on a higher number than JAMA's 2023 figure as a basis for its cost estimates.

440 See "Trust and Privacy: How Patient Trust in Providers is Related to Privacy Behaviors and Attitudes," supra note 120; Paige Nong et al., "Discrimination, trust, and withholding information from providers: Implications for missing data and inequity," SSM—Population Health (Apr. 7, 2022), https://www.sciencedirect.com/science/article/pii/S2352827322000714; See also S.J. Nass et al., "Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research," Institute of Medicine (US) Committee on Health Research and the Privacy of Health Information: The HIPAA Privacy Rule (2009), https://www.ncbi.nlm.nih.gov/books/NBK9579/.

441 See Danielle Keats Citron & Daniel J. Solove, "Privacy Harms," GWU Legal Studies Research Paper No. 2021-11, GWU Law School Public Law Research Paper No. 2021-11, 102 B.U. L. Rev. 793, 830-861 (Feb. 9, 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3782222.

442 See "Reclaiming Tort Law to Protect Reproductive Rights," supra note 152.

443 See Div. of Reproductive Health, Nat'l Ctr. for Chronic Disease Prevention and Health Promotion, "Women With Chronic Conditions Struggle to Find Medications After Abortion Laws Limit Access," Ctrs. for Disease Control and Prevention (Jan. 4, 2023), https://www.cdc.gov/teenpregnancy/health-care-providers/index.htm; see also Brittni Frederiksen et al., "Abortion Bans May Limit Essential Medications for Women with Chronic Conditions," Kaiser Family Foundation (Nov. 17, 2022), https://www.kff.org/womens-health-policy/issue-brief/abortion-bans-may-limit-essential-medications-for-women-with-chronic-conditions/.

444 See Lynn M. Yee et al., "Association of Health Literacy Among Nulliparous Individuals and Maternal and Neonatal Outcomes," JAMA Network Open (Sept. 1, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783674.

445 See "Texas Maternal Mortality and Morbidity Review Committee and Department of State Health Services Joint Biennial Report 2022," supra note 123.

446 See Helen Levy & Alex Janke, "Health Literacy and Access to Care," J. of Health Commc'n (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4924568/; see also Brief for Zurawski, Zurawski v. State of Texas (No.

D-1-GN-23-000968) (W.D. Tex. 2023), https://reproductiverights.org/wp-content/uploads/2023/03/Zurawski-v-State-of-Texas-Complaint.pdf.

447 See Brief for Zurawski, at 10, supra note 447.

448 Public Law 93-579, 88 Stat. 1896 (Dec. 31, 1974) (codified at 5 U.S.C. 552a).

449 40 FR 28948, 28955 (July 9, 1975).

450 42 U.S.C. 1320d-6(a).

451 A person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization. Id.

452 696,898 = 774,331 x .90.

453 See U.S. Small Business Administration, Table of Small Business Size Standards (Mar. 17, 2023), https://www.sba.gov/sites/sbagov/files/2023-06/TableofSizeStandards_EffectiveMarch17′2023-2˙.pdf.

454 Id.

455 Kaiser Family Foundation, "Market Share and Enrollment of Largest Three Insurers—Large Group Market" (2019), https://www.kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-large-group-market/?currentTimeframe=0&sortModel=#`colId`:`Location`,`sort`:`asc`'.

456 This figure represents annualized costs discounted at a 3% rate.

457 42 U.S.C. 1320d-7(a)(1).

458 42 U.S.C. 1320d-7(a)(2)(A).

459 45 CFR 160.201 through 160.205.

460 Public Law 105-277, 112 Stat. 2681 (Oct. 21, 1998).

461 Public Law 104-13, 109 Stat. 163 (May 22, 1995).

462 This includes an increase of 416 burden hours and $36,442 in costs added to the existing information collection for requesting exemption determinations under 45 CFR 160.204.

463 See Off. for Civil Rights, "Annual Report to Congress on Breaches of Unsecured Protected Health Information," U.S. Dep't of Health and Human Servs. (2022), https://www.hhs.gov/hipaa/for-professionals/breach-notification/reports-congress/index.html.

Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations

OH Const. Art. XVIII, Refs & Annos
Currentness

Const. Art. XVIII, Refs & Annos, OH CONST Art. XVIII, Refs & Annos
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

End of Document

Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 1

O Const XVIII Sec. 1 Classification of cities and villages; transition

Currentness

Municipal corporations are hereby classified into cities and villages. All such corporations having a population of five thousand or over shall be cities; all others shall be villages. The method of transition from one class to the other shall be regulated by law.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (26)

Const. Art. XVIII, § 1, OH CONST Art. XVIII, § 1
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 2

O Const XVIII Sec. 2 General laws for incorporation and government of municipalities; additional laws; referendum

Currentness

General laws shall be passed to provide for the incorporation and government of cities and villages; and additional laws may also be passed for the government of municipalities adopting the same; but no such additional law shall become operative in any municipality until it shall have been submitted to the electors thereof, and affirmed by a majority of those voting thereon, under regulations to be established by law.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (25)

Const. Art. XVIII, § 2, OH CONST Art. XVIII, § 2
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 3

O Const XVIII Sec. 3 Municipal powers of local self-government

Currentness

Subject to the requirements of Section 1 of Article V of this constitution, municipalities shall have authority to exercise all powers of local self-government and to adopt and enforce within their limits such local police, sanitary and other similar regulations, as are not in conflict with general laws.

CREDIT(S)

(2022 HJR 4, am. eff. 11-8-22; 1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (1557)

Const. Art. XVIII, § 3, OH CONST Art. XVIII, § 3
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 4

O Const XVIII Sec. 4 Municipality may acquire public utility or contract for utility services

Currentness

Any municipality may acquire, construct, own, lease and operate within or without its corporate limits, any public utility the products or service of which is or is to be supplied to the municipality or its inhabitants, and may contract with others for any such product or service. The acquisition of any such public utility may be by condemnation or otherwise, and a municipality may acquire thereby the use of, or full title to, the property and franchise of any company or person supplying to the municipality or its inhabitants the service or produce of any such utility.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (246)

Const. Art. XVIII, § 4, OH CONST Art. XVIII, § 4
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 5

O Const XVIII Sec. 5 Referendum on acquiring or operating municipal utility

Currentness

Any municipality proceeding to acquire, construct, own, lease or operate a public utility, or to contract with any person or company therefor, shall act by ordinance and no such ordinance shall take effect until after thirty days from its passage. If within said thirty days a petition signed by ten per centum of the electors of the municipality shall be filed with the executive authority thereof demanding a referendum on such ordinance it shall not take effect until submitted to the electors and approved by a majority of those voting thereon. The submission of any such question shall be governed by all the provisions of section 8 of this article as to the submission of the question of choosing a charter commission.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (49)

Const. Art. XVIII, § 5, OH CONST Art. XVIII, § 5
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Limitation Recognized by Duke Energy Ohio, Inc. v. Hamilton, Ohio App. 12 Dist., Oct. 25, 2021

Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 6

O Const XVIII Sec. 6 Sale of surplus product of municipal utility; limitation

Currentness

Any municipality, owning or operating a public utility for the purpose of supplying the service or product thereof to the municipality or its inhabitants, may also sell and deliver to others any transportation service of such utility and the surplus product of any other utility in an amount not exceeding in either case fifty per cent of the total service or product supplied by such utility within the municipality, provided that such fifty per cent limitation shall not apply to the sale of water or sewage services.

CREDIT(S)

(128 v 1355, am. eff. 11-3-59; 1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (60)

Const. Art. XVIII, § 6, OH CONST Art. XVIII, § 6
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 7

O Const XVIII Sec. 7 Municipal charter

Currentness

Any municipality may frame and adopt or amend a charter for its government and may, subject to the provisions of section 3 of this article, exercise thereunder all powers of local self-government.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (348)

Const. Art. XVIII, § 7, OH CONST Art. XVIII, § 7
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 8

O Const XVIII Sec. 8 Referenda on whether to frame charter and on adoption of proposed charter

Currentness

The legislative authority of any city or village may by a two-thirds vote of its members, and upon petition of ten per centum of the electors shall forthwith, provide by ordinance for the submission to the electors, of the question, "Shall a commission be chosen to frame a charter." The ordinance providing for the submission of such question shall require that it be submitted to the electors at the next regular municipal election if one shall occur not less than sixty nor more than one hundred and twenty days after its passage; otherwise it shall provide for the submission of the question at a special election to be called and held within the time aforesaid. The ballot containing such question shall bear no party designation, and provision shall be made thereon for the election from the municipality at large of fifteen electors who shall constitute a commission to frame a charter; provided that a majority of the electors voting on such question shall have voted in the affirmative. Any charter so framed shall be submitted to the electors of the municipality at an election to be held at a time fixed by the charter commission and within one year from the date of its election, provision for which shall be made by the legislative authority of the municipality in so far as not prescribed by general law. Not less than thirty days prior to such election the clerk of the municipality shall mail a copy of the proposed charter to each elector whose name appears upon the poll or registration books of the last regular or general election held therein. If such proposed charter is approved by a majority of the electors voting thereon it shall become the charter of such municipality at the time fixed therein.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (95)

Const. Art. XVIII, § 8, OH CONST Art. XVIII, § 8
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 9

O Const XVIII Sec. 9 Amendment of charter; referendum

Currentness

Amendments to any charter framed and adopted as herein provided may be submitted to the electors of a municipality by a two-thirds vote of the legislative authority thereof, and upon petitions signed by ten per centum of the electors of the municipality setting forth any such proposed amendment, shall be submitted by such legislative authority. The submission of proposed amendments to the electors shall be governed by the requirements of section 8 as to the submission of the question of choosing a charter commission; and copies of proposed amendments may be mailed to the electors as hereinbefore provided for copies of a proposed charter, or, pursuant to laws passed by the General Assembly, notice of proposed amendments may be given by newspaper advertising. If any such amendment is approved by a majority of the electors voting thereon, it shall become a part of the charter of the municipality. A copy of said charter or any amendment thereto shall be certified to the secretary of state, within thirty days after adoption by a referendum vote.

CREDIT(S)

(1970 SJR 31, am. eff. 1-1-71; 1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (75)

Const. Art. XVIII, § 9, OH CONST Art. XVIII, § 9
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 10

O Const XVIII Sec. 10 Acquiring property exceeding public needs

Currentness

A municipality appropriating or otherwise acquiring property for public use may in furtherance of such public use appropriate or acquire an excess over that actually to be occupied by the improvement, and may sell such excess with such restrictions as shall be appropriate to preserve the improvement made. Bonds may be issued to supply the funds in whole or in part to pay for the excess property so appropriated or otherwise acquired, but said bonds shall be a lien only against the property so acquired for the improvement and excess, and they shall not be a liability of the municipality nor be included in any limitation of the bonded indebtedness of such municipality prescribed by law.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (24)

Const. Art. XVIII, § 10, OH CONST Art. XVIII, § 10
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 11

O Const XVIII Sec. 11 Assessment of benefitted property to pay for improvements

Currentness

Any municipality appropriating private property for a public improvement may provide money therefor in part by assessments upon benefited property not in excess of the special benefits conferred upon such property by the improvements. Said assessments, however, upon all the abutting, adjacent, and other property in the district benefited, shall in no case be levied for more than fifty per centum of the cost of such appropriation.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (3)

Const. Art. XVIII, § 11, OH CONST Art. XVIII, § 11
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

End of Document

Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 12

O Const XVIII Sec. 12 Mortgage bonds to finance municipal utilities

Currentness

Any municipality which acquires, constructs or extends any public utility and desires to raise money for such purposes may issue mortgage bonds therefor beyond the general limit of bonded indebtedness prescribed by law; provided that such mortgage bonds issued beyond the general limit of bonded indebtedness prescribed by law shall not impose any liability upon such municipality but shall be secured only upon the property and revenues of such public utility, including a franchise stating the terms upon which, in case of foreclosure, the purchaser may operate the same, which franchise shall in no case extend for a longer period than twenty years from the date of the sale of such utility and franchise on foreclosure.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (20)

Const. Art. XVIII, § 12, OH CONST Art. XVIII, § 12
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

End of Document

Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 13

O Const XVIII Sec. 13 Laws limiting municipal power to tax and incur debts; financial reports; audits

Currentness

Laws may be passed to limit the power of municipalities to levy taxes and incur debts for local purposes, and may require reports from municipalities as to their financial condition and transactions, in such form as may be provided by law, and may provide for the examination of the vouchers, books and accounts of all municipal authorities, or of public undertakings conducted by such authorities.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (85)

Const. Art. XVIII, § 13, OH CONST Art. XVIII, § 13
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

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Baldwin's Ohio Revised Code Annotated
Constitution of the State of Ohio
Article XVIII. Municipal Corporations (Refs & Annos)

OH Const. Art. XVIII, § 14

O Const XVIII Sec. 14 Municipal elections

Currentness

All elections and submissions of questions provided for in this article shall be conducted by the election authorities prescribed by general law. The percentage of electors required to sign any petition provided for herein shall be based upon the total vote cast at the last preceding general municipal election.

CREDIT(S)

(1912 constitutional convention, adopted eff. 11-15-12)

Notes of Decisions (6)

Const. Art. XVIII, § 14, OH CONST Art. XVIII, § 14
Current through Files 1 to 59 of the 135th General Assembly (2023-2024).

End of Document

W.S.A. Ch. 66, Refs & Annos
Currentness

Editors' Notes

REORGANIZATION OF CHAPTER

<St.1997, Chapter 66, General Municipality Law, was reorganized by 1999 Act 150, effective Jan. 1, 2001. Section renumbering lines and repeal notes provide, where appropriate, the disposition of subject matter of the chapter's sections prior to the reorganization.>

W. S. A. Ch. 66, Refs & Annos, WI ST Ch. 66, Refs & Annos
Current through 2023 Act 272, published April 10, 2024.

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.01. Renumbered in part and repealed in part by 1999 Act 150, §§ 18 to 25, eff. Jan. 1, 2001

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)

W.S.A. 66.01

66.01. Renumbered in part and repealed in part by 1999 Act 150, §§ 18 to 25, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.01, WI ST 66.01
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter I. General Powers; Administration

W.S.A. 66.0101

66.0101. Home rule; manner of exercise

Currentness

(1) Under article XI, section 3, of the constitution, the method of determination of the local affairs and government of cities and villages shall be as prescribed in this section.

(1m) In this section, "charter ordinance" means an ordinance that enacts, amends or repeals the charter, or any part of the charter, of a city or village or that makes the election under sub. (4).

(2)(a) A city or village may enact a charter ordinance. A charter ordinance shall be designated as a charter ordinance, requires a two-thirds vote of the members-elect of the legislative body of the city or village, and is subject to referendum as provided in this section.

(b) A charter ordinance that amends or repeals a city or village charter shall designate specifically the portion of the charter that is amended or repealed. A charter ordinance that makes the election under sub. (4) shall designate specifically each enactment of the legislature or portion of the enactment that is made inapplicable to the city or village by the election.

(3) A charter ordinance shall be published as a class 1 notice, under ch. 985, and shall be recorded by the clerk in a permanent book kept for that purpose, with a statement of the manner of its adoption. A certified copy of the charter ordinance shall be filed by the clerk with the secretary of state. The secretary of state shall keep a separate index of all charter ordinances, arranged alphabetically by city and village and summarizing each ordinance, and annually shall issue the index of charter ordinances filed during the 12 months prior to July 1.

(4) A city or village may elect under this section that any law relating to the local affairs and government of the city or village other than those enactments of the legislature of statewide concern as shall with uniformity affect every city or every village shall not apply to the city or village, and when the election takes effect, the law ceases to be in effect in the city or village.

(5) A charter ordinance does not take effect until 60 days after its passage and publication. If within the 60--day period a petition conforming to the requirements of s. 8.40 and signed by a number of electors of the city or village equal to not less than 7 percent of the votes cast in the city or village for governor at the last general election is filed in the office of the clerk of the city or village demanding that the ordinance be submitted to a vote of the electors, it may not take effect until it is submitted to a referendum and approved by a majority of the electors voting in the referendum. The petition and the proceedings for its submission are governed by s. 9.20(2) to (6).

(6) A charter ordinance may be initiated under s. 9.20(1) to (6), but alternative adoption of the charter ordinance by the legislative body is subject to referendum under sub. (5).

(7) A charter ordinance may be submitted to a referendum by the legislative body, under s. 9.20(4) to (6), without initiative petition, and becomes effective when approved by a majority of the electors voting in the referendum.

(8) A charter ordinance enacted or approved by a vote of the electors controls over any prior or subsequent act of the legislative body of the city or village. If the electors of any city or village by a majority vote have adopted or determined to continue to operate under either ch. 62 or 64, or have determined the method of selection of members of the governing board, the question shall not again be submitted to the electors, nor action taken on the question, within a period of 2 years. Any election to change or amend the charter of any city or village, other than a special election as provided in s. 9.20(4), shall be held at the time provided by statute for holding the spring election.

(9)(a) The legislative body of a city or village, by resolution adopted by a two-thirds vote of its members-elect may, and upon petition complying with s. 9.20 shall, submit to the electors under s. 9.20(4) to (6) the question of holding a charter convention under one or more plans proposed in the resolution or petition.

(b) The ballot shall be in substantially the following form:

Shall a charter convention be held?

YES ☐ NO ☐

If a charter convention is held what plan do you favor?

PLAN 1 ☐ PLAN 2 ☐

[Repeat for each plan proposed.]

Mark an [X] in the square to the RIGHT of the plan that you select.

(c) If a majority of the electors voting vote for a charter convention, the convention shall be held pursuant to the plan favored by a majority of the total votes cast for all plans. If no plan receives a majority, the 2 plans receiving the highest number of votes shall be again submitted to the electors and a convention shall be held pursuant to the plan favored by a majority of the votes cast.

(d) A charter convention may adopt a charter or amendments to the existing charter. The charter or charter amendments adopted by the convention shall be certified, as soon as practicable, by the presiding officer and secretary of the convention to the city or village clerk and shall be submitted to the electors as provided under s. 9.20(4) to (6), without the alternative provided in s. 9.20(4) to (6), and take effect when approved by a majority of the electors voting.

(10) Nothing in this section shall be construed to impair the right of cities or villages under existing or future authority to enact ordinances or resolutions other than charter ordinances.

(11) Sections 62.13 and 62.50 and chapter 589, laws of 1921, and chapter 423, laws of 1923, shall be construed as enactments of statewide concern for the purpose of providing uniform regulation of police, fire, and combined protective services departments.

(12) Every charter ordinance enacted under s. 66.01, 1943 stats., which was adopted by the governing body prior to December 31, 1944, and which also was published prior to that date in the official newspaper of the city or village, or, if there was none, in a newspaper having general circulation in the city or village, shall be valid as of the date of the original publication notwithstanding the failure to publish the ordinance under s. 10.43(5) and (6), 1943 stats.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (58)

W. S. A. 66.0101, WI ST 66.0101
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0103

66.0103. Code of ordinances

Currentness

(1) The governing body of a city, village, town or county may authorize the preparation of a code of some or all of its general ordinances. The code may be enacted by an ordinance that incorporates the code by reference. A copy of the code shall be available for public inspection not less than 2 weeks before it is enacted. After the code is enacted, a copy shall be maintained and available for public inspection in the office of the city, village, town or county clerk.

(2) Publication of a code enacted under sub. (1), in book or pamphlet form, meets the publication requirements of ss. 59.14, 60.80, 61.50(1) and 62.11(4)(a).

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

W. S. A. 66.0103, WI ST 66.0103
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
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W.S.A. 66.0104

66.0104. Prohibiting ordinances that place certain limits or requirements on a landlord

Currentness

(1) In this section:

(ah) “Habitability violation” means any of the following conditions if the condition constitutes an ordinance violation:

1. The rental property or rental unit lacks hot or cold running water.

2. Heating facilities serving the rental property or rental unit are not in safe operating condition or are not capable of maintaining a temperature, in all living areas of the property or unit, of at least 67 degrees Fahrenheit during all seasons of the year in which the property or unit may be occupied. Temperatures in living areas shall be measured at the approximate center of the room, midway between floor and ceiling.

3. The rental property or rental unit is not served by electricity, or the electrical wiring, outlets, fixtures, or other components of the electrical system are not in safe operating condition.

4. Any structural or other conditions in the rental property or rental unit that constitute a substantial hazard to the health or safety of the tenant, or create an unreasonable risk of personal injury as a result of any reasonably foreseeable use of the property or unit other than negligent use or abuse of the property or unit by the tenant.

5. The rental property or rental unit is not served by plumbing facilities in good operating condition.

6. The rental property or rental unit is not served by sewage disposal facilities in good operating condition.

7. The rental property or rental unit lacks working smoke detectors or carbon monoxide detectors.

8. The rental property or rental unit is infested with rodents or insects.

9. The rental property or rental unit contains excessive mold.

(ax) “Premises” has the meaning given in s. 704.01(3).

(b) “Rental agreement” has the meaning given in s. 704.01(3m).

(c) “Tenancy” has the meaning given in s. 704.01(4).

(2)(a) No city, village, town, or county may enact an ordinance that places any of the following limitations on a residential landlord:

1. Prohibits a landlord from, or places limitations on a landlord with respect to, obtaining and using or attempting to obtain and use any of the following information with respect to a tenant or prospective tenant:

a. Monthly household income.

b. Occupation.

c. Rental history.

d. Credit information.

e. Court records, including arrest and conviction records, to which there is public access.

f. Social security number or other proof of identity.

2. Limits how far back in time a prospective tenant's credit information, conviction record, or previous housing may be taken into account by a landlord.

3. Prohibits a landlord from, or places limitations on a landlord with respect to, entering into a rental agreement for a premises with a prospective tenant during the tenancy of the current tenant of the premises.

4. Prohibits a landlord from, or places limitations on a landlord with respect to, showing a premises to a prospective tenant during the tenancy of the current tenant of the premises.

(b) No city, village, town, or county may enact an ordinance that places requirements on a residential landlord with respect to security deposits or earnest money or pretenancy or posttenancy inspections that are additional to the requirements under administrative rules related to residential rental practices.

(c) No city, village, town, or county may enact an ordinance that limits a residential tenant's responsibility, or a residential landlord's right to recover, for any damage or waste to, or neglect of, the premises that occurs during the tenant's occupancy of the premises, or for any other costs, expenses, fees, payments, or damages for which the tenant is responsible under the rental agreement or applicable law.

(d)1.a. No city, village, town, or county may enact an ordinance that requires a landlord to communicate to tenants any information that is not required to be communicated to tenants under federal or state law.

b. Subdivision 1.a. does not apply to an ordinance that has a reasonable and clearly defined objective of regulating the manufacture of illegal narcotics.

2. No city, village, town, or county may enact an ordinance that requires a landlord to communicate to the city, village, town, or county any information concerning the landlord or a tenant, unless any of the following applies:

a. The information is required under federal or state law.

b. The information is required of all residential real property owners.

(e) No city, village, town, or county may enact an ordinance that does any of the following:

1. Requires that a rental property or rental unit be inspected except upon a complaint by any person, as part of a program of inspections under subd. 1m., under s. 66.0119, or as required under state or federal law.

1m. A city, village, town, or county may establish a rental property inspection program under this subdivision. Under the program, the governing body of the city, village, town, or county may designate districts in which there is evidence of blight, high rates of building code complaints or violations, deteriorating property values, or increases in single-family home conversions to rental units. A city, village, town, or county may require that a rental property or rental unit located in a district designated under this subdivision be initially inspected and periodically inspected. If no habitability violation is discovered during a program inspection or if a habitability violation is discovered during a program inspection and the violation is corrected within a period of not less than 30 days established by the city, village, town, or county, the city, village, town, or county may not perform a program inspection of the property for at least 5 years. If a habitability violation is discovered during a program inspection and the violation is not corrected within the period established by the city, village, town, or county, the city, village, town, or county may require the rental property or unit to be inspected annually under the program. If a habitability violation is discovered during an inspection conducted upon a complaint and the violation is not corrected within a period of not less than 30 days established by the city, village, town, or county, the city, village, town, or county may require the rental property or unit to be inspected annually under the program. If, at a rental property or unit subject to annual program inspections, no habitability violation is discovered during 2 consecutive annual program inspections, the city, village, town, or county, except as provided in this subdivision, may not perform a program inspection of the property for at least 5 years. No rental property or unit that is less than 8 years old may be inspected under this subdivision. A city, village, town, or county may provide a period of less than 30 days for the correction of a habitability violation under this subdivision if the violation exposes a tenant to imminent danger. A city, village, town, or county shall provide an extension to the period for correction of a habitability violation upon a showing of good cause. A city, village, town, or county shall provide in a notice of a habitability violation an explanation

of the violation including a specification of the violation and the exact location of the violation. No inspection of a rental unit may be conducted under this subdivision if the occupant of the unit does not consent to allow access unless the inspection is under a special inspection warrant under s. 66.0119.

2. Charges a fee for conducting an inspection of a residential rental property unless all of the following are satisfied:

a. The amount of the fee does not exceed $75 for an inspection of a vacant unit under subd. 1m. or an inspection of the exterior and common areas of a property under subd. 1m., $90 for any other initial program inspection under subd. 1m., or $150 for any other 2nd or subsequent program inspection under subd. 1m. No fee may be charged for a program inspection under subd. 1m. if no habitability violation is discovered during the inspection or, if a violation is discovered during the inspection, the violation is corrected within the period established by the city, village, town, or county under subd. 1m. No fee may be charged for an inspection of the exterior and common areas if the property owner voluntarily allows access for the inspection and no habitability violation is discovered during the inspection or, if a violation is discovered during the inspection, the violation is corrected within the period established by the city, village, town, or county under subd. 1m. No fee may be charged for a reinspection that occurs after a habitability violation has been corrected. No fee may be charged to a property owner if a program inspection does not occur because an occupant of the property does not allow access to the property. Annually, a city, village, town, or county may increase the fee amounts under this subd. 2. a. by not more than the percentage change in the U.S. consumer price index for all urban consumers, U.S. city average, as determined by the federal department of labor, for the previous year or 2 percent, whichever is greater.

am. The amount of the fee does not exceed $150 for an inspection under s. 66.0119, except that if a habitability violation is discovered during the inspection and the violation is not corrected within a period of not less than 30 days established by the city, village, town, or county, the fee may not exceed $300. No fee may be charged for an inspection under s. 66.0119 if no habitability violation is discovered. Annually, a city, village, town, or county may increase the fee amounts under this subd. 2. am. by not more than the percentage change in the U.S. consumer price index for all urban consumers, U.S. city average, as determined by the federal department of labor, for the previous year or 2 percent, whichever is greater.

b. The fee is charged at the time that the inspection is actually performed.

3. Charges a fee for a subsequent reinspection of a residential rental property that is more than twice the fee charged for an initial reinspection.

4. Except as provided in this subdivision, requires that a rental property or rental unit be certified, registered, or licensed or requires that a residential rental property owner register or obtain a certification or license related to owning or managing the residential rental property. A city, village, town, or county may require that a rental unit or residential rental property owner be registered if the registration requires only one name of an owner or authorized contact person and an address, telephone number, and, if available, an electronic mail address or other information necessary to receive communications by other electronic means at which the person may be contacted. No city, village, town, or county, except a 1st class city, may charge a fee for registration under this subdivision except a one-time registration fee that reflects the actual costs of operating a registration program, but that does not exceed $10 per building, and a one-time fee for the registration of a change of ownership or management of a building or change of contact information for a building that reflects the actual and direct costs of registration, but that does not exceed $10 per building.

(f) No city, village, town, or county may impose an occupancy or transfer of tenancy fee on a rental unit.

(2m) If a city, village, town, or county has in effect an ordinance that authorizes the inspection of a rental property or rental unit upon a complaint from an inspector or other employee or elected official of the city, village, town, or county, the city, village, town, or county shall maintain for each inspection performed upon a complaint from an employee or official a record of the name of the person making the complaint, the nature of the complaint, and any inspection conducted upon the complaint.

(3)(a) If a city, village, town, or county has in effect on December 21, 2011, an ordinance that is inconsistent with sub. (2)(a) or (b), the ordinance does not apply and may not be enforced.

(b) If a city, village, town, or county has in effect on March 1, 2014, an ordinance that is inconsistent with sub. (2)(c) or (d), the ordinance does not apply and may not be enforced.

(c) If a city, village, town, or county has in effect on March 2, 2016, an ordinance that is inconsistent with sub. (2)(e) or (f), the ordinance does not apply and may not be enforced.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (4)

W. S. A. 66.0104, WI ST 66.0104
Current through 2023 Act 272, published April 10, 2024.

End of Document

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Chapter 66. General Municipality Law (Refs & Annos)
Subchapter I. General Powers; Administration

W.S.A. 66.0105

66.0105. Jurisdiction of overlapping extraterritorial powers

Currentness

The extraterritorial powers granted to cities and villages by statute, including ss. 30.745, 62.23(2) and (7a), 66.0415, 236.10 and 254.57, may not be exercised within the corporate limits of another city or village. Wherever these statutory extraterritorial powers overlap, the jurisdiction over the overlapping area shall be divided on a line all points of which are equidistant from the boundaries of each municipality concerned so that not more than one municipality shall exercise power over any area.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (4)

W. S. A. 66.0105, WI ST 66.0105
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Yellow Flag - Negative Treatment
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W.S.A. 66.0107

66.0107. Power of municipalities to prohibit criminal conduct

Currentness

(1) The board or council of any town, village or city may:

(a) Prohibit all forms of gambling and fraudulent devices and practices.

(b) Seize anything devised solely for gambling or found in actual use for gambling and destroy the device after a judicial determination that it was used solely for gambling or found in actual use for gambling.

(bm) Enact and enforce an ordinance to prohibit the possession of marijuana, as defined in s. 961.01(14), subject to the exceptions in s. 961.41(3g)(intro.), and provide a forfeiture for a violation of the ordinance; except that if a complaint is issued regarding an allegation of possession of more than 25 grams of marijuana, or possession of any amount of marijuana following a conviction in this state for possession of marijuana, the subject of the complaint may not be prosecuted under this paragraph for the same action that is the subject of the complaint unless the charges are dismissed or the district attorney declines to prosecute the case.

(bn) Enact and enforce an ordinance to prohibit the possession of a controlled substance specified in s. 961.14(4)(tb) and provide a forfeiture for a violation of the ordinance, except that if a complaint is issued regarding an allegation of possession of a controlled substance specified in s. 961.14(4)(tb) following a conviction in this state for possession of a controlled substance, the subject of the complaint may not be prosecuted under this paragraph for the same action that is the subject of the complaint unless the charges are dismissed or the district attorney declines to prosecute the case.

(bp) Enact and enforce an ordinance to prohibit conduct that is the same as that prohibited by s. 961.573(1) or (2), 961.574(1) or (2), or 961.575(1) or (2) and provide a forfeiture for violation of the ordinance.

(2) Except as provided in sub. (3), nothing in this section may be construed to preclude cities, villages and towns from prohibiting conduct which is the same as or similar to that prohibited by chs. 941 to 948.

(3) The board or council of a city, village or town may not, by ordinance, prohibit conduct which is the same as or similar to conduct prohibited by s. 944.21.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (11)

W. S. A. 66.0107, WI ST 66.0107
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0109

66.0109. Penalties under county and municipal ordinances

Currentness

If a statute requires that the penalty under any county or municipal ordinance conform to the penalty provided by statute the ordinance may impose only a forfeiture and may provide for imprisonment if the forfeiture is not paid.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (3)

W. S. A. 66.0109, WI ST 66.0109
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.011. Repealed by 1991 Act 315, § 69, eff. June 24, 1992

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Subchapter I. General Powers; Administration

W.S.A. 66.011

66.011. Repealed by 1991 Act 315, § 69, eff. June 24, 1992

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.011, WI ST 66.011
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0111

66.0111. Bond or cash deposit under municipal ordinances

Currentness

(1) If a person is arrested for the violation of a city, village or town ordinance and the action is to be in circuit court, the chief of police or police officer designated by the chief, marshal or clerk of court may accept from the person a bond, in an amount not to exceed the maximum penalty for the violation, with sufficient sureties, or a cash deposit, for appearance in the court having jurisdiction of the offense. A receipt shall be issued for the bond or cash deposit.

(2)(a) If the person released fails to appear, personally or by an authorized attorney or agent, before the court at the time fixed for hearing the case, the bond and money deposited, or an amount that the court determines to be an adequate penalty, plus costs, including any applicable fees prescribed in ch. 814, may be declared forfeited by the court or may be ordered applied to the payment of any penalty which is imposed after an ex parte hearing, together with the costs. In either event, any surplus shall be refunded to the person who made the deposit.

(b) This subsection does not apply to violations of parking ordinances. Bond or cash deposit given for appearance to answer a charge under any parking ordinance may be forfeited in the manner determined by the governing body.

(3) This section shall not be construed as a limitation upon the general power of cities, villages and towns in all cases of alleged violations of city, village or town ordinances to authorize the acceptance of bonds or cash deposits or upon the general power to accept stipulations for forfeiture of bonds or deposits or pleas where arrest was had without warrant or where action has not been started in court.

(4) This section does not apply to ordinances enacted under ch. 349.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 271

Note: Reference to bail is deleted and replaced by reference to cash deposit. This is consistent with other statutes dealing with municipal ordinances, which generally do not use the term bail, but rather refer to cash deposit or a variation of that term.

Notes of Decisions (5)

W. S. A. 66.0111, WI ST 66.0111
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0113

66.0113. Citations for certain ordinance violations

Currentness

(1) Adoption; content. (a) Except as provided in sub. (5), the governing body of a county, town, city, village, town sanitary district or public inland lake protection and rehabilitation district may by ordinance adopt and authorize the use of a citation under this section to be issued for violations of ordinances, including ordinances for which a statutory counterpart exists.

(b) An ordinance adopted under par. (a) shall prescribe the form of the citation which shall provide for the following:

1. The name and address of the alleged violator.

2. The factual allegations describing the alleged violation.

3. The time and place of the offense.

4. The section of the ordinance violated.

5. A designation of the offense in a manner that can be readily understood by a person making a reasonable effort to do so.

6. The time at which the alleged violator may appear in court and a statement describing whether the appearance is mandatory.

7. A statement which in essence informs the alleged violator:

a. That the alleged violator may make a cash deposit of a specified amount to be mailed to a specified official within a specified time.

b. That if the alleged violator makes such a deposit, he or she need not appear in court unless appearance is mandated by the court or he or she is subsequently summoned.

c. That, if the alleged violator makes a cash deposit and does not appear in court, he or she either will be deemed to have tendered a plea of no contest and submitted to a forfeiture, plus costs, fees, and surcharges imposed under ch. 814, not to exceed the amount of the deposit or will be summoned into court to answer the complaint if the court does not accept the plea of no contest.

d. That, if the alleged violator does not make a cash deposit and does not appear in court at the time specified, the court may issue a summons or a warrant for the defendant's arrest or consider the nonappearance to be a plea of no contest and enter judgment under sub. (3)(d), or the municipality may commence an action against the alleged violator to collect the forfeiture, plus costs, fees, and surcharges imposed under ch. 814.

e. That if the court finds that the violation involves an ordinance that prohibits conduct that is the same as or similar to conduct prohibited by state statute punishable by fine or imprisonment or both, and that the violation resulted in damage to the property of or physical injury to a person other than the alleged violator, the court may summon the alleged violator into court to determine if restitution shall be ordered under s. 800.093.

8. A direction that if the alleged violator elects to make a cash deposit, the alleged violator shall sign an appropriate statement which accompanies the citation to indicate that he or she read the statement required under subd. 7. and shall send the signed statement with the cash deposit.

9. Such other information as may be deemed necessary.

(c) An ordinance adopted under par. (a) shall contain a schedule of cash deposits that are to be required for the various ordinance violations, plus costs, fees, and surcharges imposed under ch. 814, for which a citation may be issued. The ordinance shall also specify the court, clerk of court, or other official to whom cash deposits are to be made and shall require that receipts be given for cash deposits.

(2) Issuance; filing. (a) Citations authorized under this section may be issued by law enforcement officers of the county, town, city, village, town sanitary district or public inland lake protection and rehabilitation district. In addition, the governing body of a county, town, city, village, town sanitary district or public inland lake protection and rehabilitation district may designate by ordinance or resolution other county, town, city, village, town sanitary district or public inland lake protection and rehabilitation district officials who may issue citations with respect to ordinances which are directly related to the official responsibilities of the officials. Officials granted the authority to issue citations may delegate, with the approval of the governing body, the authority to employees. Authority delegated to an official or employee shall be revoked in the same manner by which it is conferred.

(b) The issuance of a citation by a person authorized to do so under par. (a) shall be deemed adequate process to give the appropriate court jurisdiction over the subject matter of the offense for the purpose of receiving cash deposits, if directed to do so, and for the purposes of sub. (3)(b) and (c). Issuance and filing of a citation does not constitute commencement of an action. Issuance of a citation does not violate s. 946.68.

(3) Violator's options; procedure on default. (a) The person named as the alleged violator in a citation may appear in court at the time specified in the citation or may mail or deliver personally a cash deposit in the amount, within the time, and to the court, clerk of court, or other official specified in the citation. If a person makes a cash deposit, the person may nevertheless appear in court at the time specified in the citation, but the cash deposit may be retained for application against any forfeiture or restitution, plus costs, fees, and surcharges imposed under ch. 814 that may be imposed.

(b) If a person appears in court in response to a citation, the citation may be used as the initial pleading, unless the court directs that a formal complaint be made, and the appearance confers personal jurisdiction over the person. The person may plead guilty, no contest, or not guilty. If the person pleads guilty or no contest, the court shall accept the plea, enter a judgment of guilty, and impose a forfeiture, plus costs, fees, and surcharges imposed under ch. 814. If the court finds that the violation meets the conditions in s. 800.093(1), the court may order restitution under s. 800.093. A plea of not guilty shall put all matters in the case at issue, and the matter shall be set for trial.

(c) If the alleged violator makes a cash deposit and fails to appear in court, the citation may serve as the initial pleading and the violator shall be considered to have tendered a plea of no contest and submitted to a forfeiture, plus costs, fees, and surcharges imposed under ch. 814, not exceeding the amount of the deposit. The court may either accept the plea of no contest and enter judgment accordingly or reject the plea. If the court finds that the violation meets the conditions in s. 800.093(1), the court may summon the alleged violator into court to determine if restitution shall be ordered under s. 800.093. If the court accepts the plea of no contest, the defendant may move within 10 days after the date set for the appearance to withdraw the plea of no contest, open the judgment, and enter a plea of not guilty if the defendant shows to the satisfaction of the court that the failure to appear was due to mistake, inadvertence, surprise, or excusable neglect. If the plea of no contest is accepted and not subsequently changed to a plea of not guilty, no additional costs, fees, or surcharges may be imposed against the violator under s. 814.78. If the court rejects the plea of no contest, an action for collection of the forfeiture, plus costs, fees, and surcharges imposed under ch. 814, may be commenced. A city, village, town sanitary district, or public inland lake protection and rehabilitation district may commence action under s. 66.0114(1) and a county or town may commence action under s. 778.10. The citation may be used as the complaint in the action for the collection of the forfeiture, plus costs, fees, and surcharges imposed under ch. 814.

(d) If the alleged violator does not make a cash deposit and fails to appear in court at the time specified in the citation, the court may issue a summons or warrant for the defendant's arrest or consider the nonappearance to be a plea of no contest and enter judgment accordingly if service was completed as provided under par. (e) or the county, town, city, village, town sanitary district, or public inland lake protection and rehabilitation district may commence an action for collection of the forfeiture, plus costs, fees, and surcharges imposed under ch. 814. A city, village, town sanitary district, or public inland lake protection and rehabilitation district may commence action under s. 66.0114(1) and a county or town may commence action under s. 778.10. The citation may be used as the complaint in the action for the collection of the forfeiture, plus costs, fees, and surcharges imposed under ch. 814. If the court considers the nonappearance to be a plea of no contest and enters judgment accordingly, the court shall promptly mail a copy or notice of the judgment to the defendant. The judgment shall allow the defendant not less than 20 days from the date of the judgment to pay any forfeiture, plus costs, fees, and surcharges imposed under ch. 814. If the defendant moves to open the judgment within 6 months after the court appearance date fixed in the citation, and shows to the satisfaction of the court that the failure to appear was due to mistake, inadvertence, surprise, or excusable neglect, the court shall reopen the judgment, accept a not guilty plea and set a trial date.

(e) A judgment may be entered under par. (d) if the summons or citation was served as provided under s. 968.04(3)(b)2. or by personal service by a county, town, city, village, town sanitary district or public inland lake protection and rehabilitation district employee.

(4) Relationship to other laws. The adoption and authorization for use of a citation under this section does not preclude the governing body from adopting any other ordinance or providing for the enforcement of any other law or ordinance relating to the same or any other matter. The issuance of a citation under this section does not preclude proceeding under any other ordinance or law relating to the same or any other matter. Proceeding under any other ordinance or law relating to the same or any other matter does not preclude the issuance of a citation under this section.

(5) Municipal court. If the action is to be in municipal court, the citation under s. 800.02(2) shall be used.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (4)

W. S. A. 66.0113, WI ST 66.0113
Current through 2023 Act 272, published April 10, 2024.

End of Document

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W.S.A. 66.0114

66.0114. Actions for violation of ordinances

Currentness

(1) Collection of forfeitures and penalties. (a) An action for violation of an ordinance or bylaw enacted by a city, village, town sanitary district or public inland lake protection and rehabilitation district is a civil action. All forfeitures and penalties imposed by an ordinance or bylaw of the city, village, town sanitary district or public inland lake protection and rehabilitation district, except as provided in ss. 345.20 to 345.53, may be collected in an action in the name of the city or village before the municipal court or in an action in the name of the city, village, town sanitary district or public inland lake protection and rehabilitation district before a court of record. If the action is in municipal court, the procedures under ch. 800 apply and the procedures under this section do not apply. If the action is in a court of record, it shall be commenced by warrant or summons under s. 968.04 or, if applicable, by citation under s. 778.25 or 778.26. A law enforcement officer may arrest the offender in all cases without warrant under s. 968.07. If the action is commenced by warrant the affidavit may be the complaint. The affidavit or complaint is sufficient if it alleges that the defendant has violated an ordinance or bylaw, specifying the ordinance or bylaw by section, chapter, title or otherwise with sufficient plainness to identify the ordinance or bylaw. The judge may release a defendant without a cash deposit or may permit him or her to execute an unsecured appearance bond upon arrest. In arrests without a warrant or summons a statement on the records of the court of the offense charged is the complaint unless the court directs that a formal complaint be issued. In all actions under this paragraph the defendant's plea shall be guilty, not guilty or no contest and shall be entered as not guilty on failure to plead. A plea of not guilty on failure to plead puts all matters in the case at issue, any other provision of law notwithstanding. The defendant may enter a not guilty plea by certified mail.

(b) Local ordinances, except as provided in this paragraph or ss. 345.20 to 345.53, may contain a provision for stipulation of guilt or no contest of any or all violations under those ordinances, may designate the manner in which the stipulation is to be made, and may fix the penalty to be paid. When a person charged with a violation for which stipulation of guilt or no contest is authorized makes a timely stipulation and pays the required penalty, plus costs, fees, and surcharges imposed under ch. 814, to the designated official, the person need not appear in court and no witness fees or other additional costs, fees, or surcharges may be imposed under ch. 814 unless the local ordinance so provides. A court appearance is required for a violation of a local ordinance in conformity with s. 346.63(1).

(bm) The official receiving the penalties shall remit all moneys collected to the treasurer of the city, village, town sanitary district, or public inland lake protection and rehabilitation district in whose behalf the sum was paid, except that all jail surcharges imposed under ch. 814 shall be remitted to the county treasurer, within 20 days after their receipt by the official. If timely remittance is not made, the treasurer may collect the payment of the officer by action, in the name of the office, and upon the official bond of the officer, with interest at the rate of 12 percent per year from the date on which it was due. In the case of any other costs, fees, and surcharges imposed under ch. 814, the treasurer of the city, village, town sanitary district, or public inland lake protection and rehabilitation district shall remit to the secretary of administration the amount required by law to be paid on the actions entered during the preceding month on or before the first day of the next succeeding month. The governing body of the city, village, town sanitary district, or public inland lake protection and rehabilitation district shall by ordinance designate the official to receive the penalties and the terms under which the official qualifies.

(c) If the circuit court finds a defendant guilty in a forfeiture action based on a violation of an ordinance, the court shall render judgment as provided under ss. 800.09 and 800.095. If the court finds the violation meets the conditions in s. 800.093(1)(a) and (b), the court may hold a hearing to determine if restitution shall be ordered under s. 800.093.

(2) Appeals. Appeals in actions in courts of record to recover forfeitures and penalties imposed by any ordinance or bylaw of a city, village, town sanitary district or public inland lake protection and rehabilitation district may be taken either by the defendant or by the city, village, town sanitary district or public inland lake protection and rehabilitation district. Appeals from circuit court in actions to recover forfeitures for ordinances enacted under ch. 349 shall be to the court of appeals. An appeal by the defendant shall include a bond to the city, village, town sanitary district or public inland lake protection and rehabilitation district with surety, to be approved by the judge, conditioned that if judgment is affirmed in whole or in part the defendant will pay the judgment and all costs and damages awarded against the defendant on the appeal. If the judgment is affirmed in whole or in part, execution may issue against both the defendant and the surety.

(3) Costs and fees; forfeitures to go to treasury. (a) Fees in forfeiture actions in circuit court for violations of ordinances are prescribed in s. 814.63(1) and (2).

(b) All forfeitures and penalties recovered for the violation of an ordinance or bylaw of a city, village, town, town sanitary district, or public inland lake protection and rehabilitation district shall be paid into the city, village, town, town sanitary district, or public inland lake protection and rehabilitation district treasury for the use of the city, village, town, town sanitary district, or public inland lake protection and rehabilitation district, except as provided in par. (c) and sub. (1)(bm). The judge shall report and pay into the treasury, quarterly, or at more frequent intervals if required, all moneys collected belonging to the city, village, town, town sanitary district, or public inland lake protection and rehabilitation district. The report shall be certified and filed in the office of the treasurer. The judge is entitled to duplicate receipts, one of which he or she shall file with the city, village, or town clerk, or with the town sanitary district or the public inland lake protection and rehabilitation district.

(c) The entire amount in excess of $150 of any forfeiture imposed for the violation of any traffic regulation in conformity with ch. 348 shall be transmitted to the county treasurer if the violation occurred on an interstate highway, a state trunk highway, or a highway over which the local highway authority does not have primary maintenance responsibility. The county treasurer shall then make payment to the secretary of administration as provided in s. 59.25(3)(L).

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (61)

W. S. A. 66.0114, WI ST 66.0114
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0115

66.0115. Outstanding unpaid forfeitures

Currentness

(1) In this section, "municipality" means a county, city, village or town. Except as provided under sub. (2), any municipality may refuse to issue any license or permit to a person who has not paid an overdue forfeiture resulting from a violation of an ordinance of the municipality. Any municipality, by written agreement between itself and any other city, village or town within the county in which the municipality is located, may refuse to issue any license or permit to a person who has not paid an overdue forfeiture resulting from a violation of an ordinance of any municipality which is a party to the agreement. No municipality may refuse to issue a license or permit to a person who is appealing the imposition of a forfeiture.

(2) A municipality may not refuse to issue any of the following licenses under sub. (1):

(a) A marriage license issued under s. 765.12.

(b) A hunting or fishing license issued under ch. 29.

(c) A dog license issued under s. 174.07.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (1)

W. S. A. 66.0115, WI ST 66.0115
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0117

66.0117. Judgment against local governmental units

Currentness

(1) In this section:

(a) "Local governmental unit" means a city, village, town, county, school district, technical college district, town sanitary district or public inland lake protection and rehabilitation district.

(b) "Statement" means all of the following:

1. A certified transcript of a judgment.

2. A judgment creditor's affidavit of the amount due on a judgment, of payments made on the judgment and that the judgment has not been appealed.

(2)(a) If a final judgment for the payment of money is recovered against a local governmental unit, or an officer of the local governmental unit, when the judgment is to be paid by the local governmental unit, the judgment creditor may file a statement with the clerk of circuit court. The clerk of circuit court shall send a copy of the statement to the appropriate municipal clerk.

(b) If a statement is filed under par. (a), the amount due, with costs and interest to the time when the money will be available for payment, shall be added to the next tax levy, and shall, when received, be paid to satisfy the judgment. If the judgment is appealed after filing the transcript with the clerk of circuit court, and before the tax is collected, the money shall not be collected on that levy. If the municipal clerk fails to include the proper amount in the first tax levy, he or she shall include it or the portion required to complete it in the next levy.

(3) In the case of school districts, town sanitary districts or public inland lake protection and rehabilitation districts a statement shall be filed with the clerk of the town, village or city in which the district or any part of it lies, and levy shall be made against the taxable property of the district.

(4) No process for the collection of a judgment shall issue until after the time when the money, if collected upon the first tax levy under sub. (2)(b), is available for payment, and then only by leave of court upon motion.

(5) If by reason of dissolution or other cause, pending action, or after judgment, a statement cannot be filed with the clerk described in sub. (2)(a) or (3), it shall be filed with the clerk or clerks whose duty it is to make up the tax roll for the property liable.

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 29

Note: Creates a definition for s. 66.0117, relating to judgments against local governmental units. The definition differs from the current language of s. 66.09 by removing a community center from the list of local governmental bodies to which the law applies. It appears that a community center is not treated as a local governmental unit anywhere else in the statutes. The term community center first appeared in this section when separate statutes were consolidated and revised in chapter 396, laws of 1921.

Notes of Decisions (23)

W. S. A. 66.0117, WI ST 66.0117
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0119

66.0119. Special inspection warrants

Currentness

(1)(a) "Inspection purposes" includes such purposes as building, housing, electrical, plumbing, heating, gas, fire, health, safety, environmental pollution, water quality, waterways, use of water, food, zoning, property assessment, meter and obtaining data required to be submitted in an initial site report or feasibility report under subch. III of ch. 289 or s. 291.23, 291.25, 291.29 or 291.31 or an environmental impact statement related to one of those reports. "Inspection purposes" also includes purposes for obtaining information specified in s. 196.02(5m) by or on behalf of the public service commission.

(b) "Peace officer" means a state, county, city, village, town, town sanitary district or public inland lake protection and rehabilitation district officer, agent or employee charged under statute or municipal ordinance with powers or duties involving inspection of real or personal property, including buildings, building premises and building contents, and means a local health officer, as defined in s. 250.01(5), or his or her designee.

(c) "Public building" has the meaning given in s. 101.01(12).

(2) A peace officer may apply for, obtain and execute a special inspection warrant issued under this section. Except in cases of emergency where no special inspection warrant is required, special inspection warrants shall be issued for inspection of personal or real properties which are not public buildings or for inspection of portions of public buildings which are not open to the public only upon showing that consent to entry for inspection purposes has been refused.

(3) The following forms for use under this section are illustrative and not mandatory:

AFFIDAVIT

STATE OF WISCONSIN

... County

In the ... court of the ... of ...

A. F., being duly sworn, says that on the ... day of ..., ... (year), in said county, in and upon certain premises in the (city, town or village) of ... and more particularly described as follows: (describe the premises) there now exists a necessity to determine if said premises comply with (section ... of the Wisconsin statutes) or (section ... of ordinances of said municipality) or both. The facts tending to establish the grounds for issuing a special inspection warrant are as follows: (set forth brief statement of

reasons for inspection, frequency and approximate date of last inspection, if any, which shall be deemed probable cause for issuance of warrant).

Wherefore, the said A. F. prays that a special inspection warrant be issued to search such premises for said purpose.

...(Signed) A. F.

Subscribed and sworn to before me this ... day of ..., ... (year)

... Judge of the ... Court.

SPECIAL INSPECTION WARRANT

STATE OF WISCONSIN

... County

In the ... court of the ... of ...

THE STATE OF WISCONSIN, To the sheriff or any constable or any peace officer of said county:

Whereas, A. B. has this day complained (in writing) to the said court upon oath that on the ... day of ..., ... (year), in said county, in and upon certain premises in the (city, town or village) of ... and more particularly described as follows: (describe the premises) there now exists a necessity to determine if said premises comply with (section ... of the Wisconsin statutes) or (section ... of ordinances of said municipality) or both and prayed that a special inspection warrant be issued to search said premises.

Now, therefore, in the name of the state of Wisconsin you are commanded forthwith to search the said premises for said purposes.

Dated this ... day of ..., ... (year),

... Judge of the ... Court.

ENDORSEMENT ON WARRANT

Received by me ..., ... (year), at ... o'clock ... M.

... Sheriff (or peace officer).

RETURN OF OFFICER

STATE OF WISCONSIN

... Court

... County.

I hereby certify that by virtue of the within warrant I searched the named premises and found the following things (describe findings).

Dated this ... day of ..., ... (year)

... Sheriff (or peace officer).

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (4)

W. S. A. 66.0119, WI ST 66.0119
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.012

66.012. Renumbered 66.0215 and amended by 1999 Act 150, § 31, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.012, WI ST 66.012
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0121

66.0121. Orders; action; proof of demand

Currentness

No action may be brought upon a city, village, town or school district order until 30 days after a demand for the payment of the order has been made. If an action is brought and the defendant fails to appear and defend the action, judgment shall not be entered without affirmative proof of the demand. If judgment is entered without proof of the demand, the judgment is void.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0121, WI ST 66.0121
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0123

66.0123. Recreation authority

Currentness

(1) In this section, "governmental unit" means a town board or school board.

(2) A governmental unit may, after compliance with s. 65.90, provide funds for the establishment, operation and maintenance of a department of public recreation.

(3)(a) A governmental unit may delegate the power to establish, maintain and operate a department of public recreation to a recreation board, which shall consist of 3 members and shall be appointed by the chairperson or other presiding officer of the governmental unit. The first appointments shall be made so that one member serves one year, one serves 2 years and one serves 3 years. After the first appointments, terms are 3 years.

(b) When 2 or more of the governmental units desire to conduct, jointly, a department of public recreation, the joint recreation board shall consist of not less than 3 members selected by the presiding officers of the governmental units acting jointly. Appointments shall be made for terms as provided in par. (a).

(c) The members of a recreation board shall serve gratuitously.

(d) A recreation board may conduct the activities of the department of public recreation, expend funds, employ a supervisor of recreation, employ assistants, purchase equipment and supplies and generally supervise the administration, maintenance and operation of the department of public recreation and recreational activities authorized by the recreation board.

(4)(a) A recreation board may conduct public recreation activities on property purchased or leased by a governmental unit for recreational purposes and under its own custody, on other public property under the custody of any other public authority, body or board with the consent of the public authority, body or board, or on private property with the consent of its owner. The recreation board, with the approval of the appointing authority, may accept gifts and bequests of land, money or other personal property, and use the gifts and bequests in whole or in part, the income from the gifts and bequests or the proceeds from the sale of any such property in the establishment, maintenance and operation of recreational activities.

(b) A recreation board shall annually submit to the governmental unit a report of the board's activities, including receipts and expenditures. The report shall be submitted not less than 15 days before the annual meeting of the governmental unit.

(c) An audit shall be made of the accounts of the recreation board in the same manner as provided for audits for towns or school districts as the case may be.

(d) The persons selected by the recreation board shall furnish a surety bond in an amount fixed by the governmental unit.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0123, WI ST 66.0123
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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W.S.A. 66.0125

66.0125. Community relations--social development commissions

Currentness

(1) Definitions. In this section:

(a) "Status as a victim of domestic abuse, sexual assault, or stalking," for purposes of discrimination in housing, has the meaning given in s. 106.50(1m)(u).

(b) "Local governmental unit" means a city, village, town, school district, or county.

(2) Creation. Each local governmental unit is authorized and urged to either establish by ordinance a community relations-social development commission or to participate in a commission established on an intergovernmental basis within the county under enabling ordinances adopted by the participating local governmental units. A school district may establish or participate in a commission by resolution. An intergovernmental commission may be established in cooperation with a nonprofit corporation located in the county and composed primarily of public and private welfare agencies devoted to any of the purposes set forth in this section. An ordinance or resolution establishing a commission shall substantially embody the language of sub. (3). Each local governmental unit may appropriate money to defray the expenses of the commission. If the commission is established on an intergovernmental basis within the county, the provisions of s. 66.0301, relating to local cooperation, apply as optional authority and may be utilized by participating local governmental units to effectuate the purposes of this section, but a contract between local governmental units is not necessary for the joint exercise of any power authorized for the joint performance of any duty required in this section.

(3) Purpose and functions of commission. (a) The purpose of the commission is to study, analyze, and recommend solutions for the major social, economic, and cultural problems that affect people residing or working within the local governmental unit, including problems of the family, youth, education, the aging, juvenile delinquency, health and zoning standards, discrimination in employment and public accommodations and facilities on the basis of sex, class, race, religion, sexual orientation, or ethnic or minority status and discrimination in housing on the basis of sex, class, race, religion, sexual orientation, ethnic or minority status, or status as a victim of domestic abuse, sexual assault, or stalking.

(b) The commission may:

1. Include within its studies problems related to pornography, industrial strife and the inciting or fomenting of class, race or religious hatred and prejudice.

2. Encourage and foster participation in the fine arts.

(c) The commission shall:

1. Recommend to the local governmental unit's governing body and chief executive or administrative officer the enactment of such ordinances or other action as they deem necessary:

a. To establish and keep in force proper health standards for the community and beneficial zoning for the community area in order to facilitate the elimination of, and prevent the start and spread of, blighted areas.

b. To ensure to all residents of a local governmental unit, regardless of sex, race, sexual orientation, or color, the right to enjoy equal employment opportunities and to ensure to those residents, regardless of sex, race, sexual orientation, color, or status as a victim of domestic abuse, sexual assault, or stalking, the right to possess equal housing opportunities.

2. Cooperate with state and federal agencies and nongovernmental organizations having similar or related functions.

3. Examine the need for, initiate, participate in and promote publicly and privately sponsored studies and programs in any field of human relationship that will aid in accomplishing the purposes and duties of the commission.

4. Have authority to conduct public hearings within the local governmental unit and to administer oaths to persons testifying before it.

5. Employ such staff as is necessary to implement the duties assigned to it.

(4) Composition of commission. The commission shall be nonpartisan and composed of citizens residing in the local governmental unit, including representatives of the clergy and minority groups. The composition of the commission and the method of appointing and removing commission members shall be determined by the governing body of the local governmental unit creating or participating in the commission. Notwithstanding s. 59.10(4) or 66.0501(2), a member of the local governmental unit's governing body may serve on the commission, except that a county board member in a county having a population over 750,000 may not accept compensation for serving on the commission. Of the persons first appointed, one-third shall hold office for one year, one-third for 2 years, and one-third for 3 years from the first day of February next following their appointment, and until their respective successors are appointed and qualified. All succeeding terms shall be for 3 years. Any vacancy shall be filled for the unexpired term in the same manner as original appointments. Every person appointed as a member of the commission shall take and file the official oath.

(5) Organization. The commission shall meet in January, April, July and October of each year, and may meet at such additional times as the members determine or the chairperson directs. Annually, it shall elect from its membership a chairperson, vice chairperson and secretary. A majority of the commission shall constitute a quorum. Members of the commission shall receive no

compensation, but each member shall be entitled to actual and necessary expenses incurred in the performance of commission duties. The commission may appoint consulting committees consisting of either members or nonmembers or both, the appointees of which shall be reimbursed their actual and necessary expenses. All expense accounts shall be paid by the commission on certification by the chairperson or acting chairperson.

(6) Open meetings. All meetings of the commission and its consulting committees shall be publicly held and open to all citizens at all times as required by subch. V of ch. 19.

(7) Designation of commissions as cooperating agencies under federal law. (a) The commission may be the official agency of the local governmental unit to accept assistance under title II of the federal economic opportunity act of 1964. [1] No assistance shall be accepted with respect to any matter to which objection is made by the legislative body creating the commission, but if the commission is established on an intergovernmental basis and objection is made by any participating legislative body, assistance may be accepted with the approval of a majority of the legislative bodies participating in the commission.

(b) The commission may be the official agency of the local governmental unit to accept assistance from the community relations service of the U.S. department of justice under title X of the federal civil rights act of 1964 [2] to provide assistance to communities in resolving disputes, disagreements or difficulties relating to discriminatory practices based on sex, race, color or national origin which may impair the rights of persons in the local governmental unit under the constitution or laws of the United States or which affect or may affect interstate commerce.

(8) Other powers of the county board of supervisors. County boards may appropriate county funds for the operation of community relations-social development commissions established or reconstituted under this section, including those participated in on an equal basis by nonprofit corporations located in the county and comprised primarily of public and private welfare agencies devoted to any of the purposes set forth in this section. The legislature finds that the expenditure of county funds for the establishment or support of such commissions is for a public purpose.

(9) Intent. It is the intent of this section to promote fair and friendly relations among all the people in this state, and to that end race, creed, sexual orientation, or color ought not to be made tests in the matter of the right of any person to earn a livelihood or to enjoy the equal use of public accommodations and facilities and race, creed, sexual orientation, color, or status as a victim of domestic abuse, sexual assault, or stalking ought not to be made tests in the matter of the right of any person to sell, lease, occupy, or use real estate.

(10) Short title. This section shall be known and may be cited as “The Wisconsin Bill of Human Rights”.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

Footnotes

1 42 U.S.C.A. § 2781 et seq. (repealed).

2 42 U.S.C.A. § 2000 et seq.

W. S. A. 66.0125, WI ST 66.0125
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0127

66.0127. Municipal hospital board

Currentness

(1) In a city, village or town in which a municipal hospital is located, the board of trustees or other governing board of the municipal hospital may, except as otherwise provided by ordinance, do any of the following:

(a) Prescribe rules of order for the regulation of its own meetings and deliberations.

(b) Promulgate rules relating to the government, operation and maintenance of the hospital and relating to the employees of the hospital.

(c) Contract for and purchase all fuel, food and other supplies reasonably necessary for the operation and maintenance of the hospital.

(d) Promulgate rules for the admission to and government of patients at the hospital.

(e) Contract for the construction, installation or making of additions or improvements to or alterations of the hospital if the additions, improvements or alterations have been ordered and funds have been provided by the city council or village or town board.

(f) Employ all necessary employees at the hospital.

(g) Audit all accounts and claims against the hospital or against the board of trustees and, if approved, the city, village or town clerk and treasurer shall pay the accounts and claims in the manner provided by s. 66.0607.

(2) All expenditures made under this section shall be within the limits authorized by the governing body of the municipality.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 486

Note: Section 66.50(1)(f) provides that the board of trustees or other governing board of a municipal hospital may engage all necessary employees for a period not to exceed one year under any one contract and at a salary not exceeding the sum of $25 per week, excluding board and laundry, unless a larger salary is expressly authorized by the city council or village or town board. Renumbered s. 66.0127(1)(f) removes these limits on the terms of employee contracts and on employee salaries.

Notes of Decisions (4)

W. S. A. 66.0127, WI ST 66.0127
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W.S.A. 66.0129

66.0129. Hospital facilities lease from nonprofit corporation

Currentness

(1) Powers and duties of governing body. For the purpose of providing adequate hospital facilities in the state of Wisconsin to serve cities, villages and towns and the hospital service area; providing all lands, buildings, improvements, facilities or equipment or other capital items necessary or desirable in connection with the hospital; ultimately acquiring the hospital by the city, village or town; acquiring lands for future hospital development; and refinancing indebtedness created by a nonprofit corporation for acquiring lands or providing hospital buildings or additions or improvements to the hospital buildings, the governing body of a city, village or town may:

(a) Without limitation by any other statute, sell and convey title to a nonprofit corporation any land and any existing buildings on the land owned by the city, village or town for that consideration and upon the terms and conditions that the governing body of the city, village or town determines are in the public interest.

(b) Lease to a nonprofit corporation for terms not exceeding 40 years each any land and existing buildings on the land that are owned by the city, village or town upon the terms, conditions and rentals that the governing body of the city, village or town determines are in the public interest.

(c) Lease or sublease from the nonprofit corporation, for terms not exceeding 40 years, and make available for public use, any lands or any land and existing buildings conveyed or leased to the corporation under pars. (a) and (b), and any new buildings erected upon the land or upon any other land owned by the corporation, upon the terms, conditions and rentals, subject to available appropriations, and ultimate acquisition, that the governing body of the city, village or town determines are in the public interest. With respect to any property conveyed to the nonprofit corporation under par. (a), the lease from the nonprofit corporation may be subject or subordinated to one or more mortgages of the property granted by the corporation.

(d) Apply all net revenues derived from the operation of any lands or buildings to the payment of rentals due and to become due under any lease or sublease made under par. (c).

(e) Pledge and assign all or part of the revenues derived from the operation of any lands or new buildings as security for the payment of rentals due and to become due under any lease or sublease of the new buildings made under par. (c).

(f) Covenant and agree in any lease or sublease made under par. (c) to impose fees, rentals or other charges for the use and occupancy or other operation of the new buildings in an amount which together with other moneys of the city, village or town available for that purpose will produce net revenue sufficient to pay the rentals due and to become due under the lease or sublease.

(g) Apply all or any part of the revenues derived from the operation of any lands or existing buildings to the payment of rentals due and to become due under a lease or sublease made under par. (c).

(h) Pledge and assign all or any part of the revenues derived from the operation of any lands or existing buildings to the payment of rentals due and to become due under a lease or sublease made under par. (c).

(i) Covenant and agree in a lease or sublease made under par. (c) to impose fees, rentals or other charges for the use and occupancy or other operation of any lands or existing buildings in an amount calculated to produce net revenues sufficient to pay the rentals due and to become due under the lease or sublease.

(j) Operate the hospital, until it is ultimately acquired, in a manner that provides revenues sufficient to pay the costs of operation and maintenance of the hospital and the payments due the nonprofit corporation.

(2) Municipal liability. The city, village or town shall be liable for accrued rentals and for any other default under any lease or sublease made under sub. (1)(c) and may be sued therefor on contract.

(3) No debt inclusion. Nothing under this section shall be considered to incur any municipal debt. No obligation under this section shall be included in arriving at constitutional debt limitations.

(4) Powers and duties of nonprofit corporation. In addition to all other powers granted to nonprofit corporations, the nonprofit corporation has the following additional powers and duties when leasing hospital facilities to a city, village or town:

(a) To acquire by purchase, gift or lease real property and buildings on the property from a city, village or town or other person, to construct hospital facilities on the property and to lease the real property and buildings to a city, village or town for terms not exceeding 40 years, and to transfer the land and buildings to the city, village or town upon termination of the lease.

(b) To borrow money and pledge income and rentals as security.

(5) Bids for construction. The nonprofit corporation shall let all contracts exceeding $1,000 for the construction, maintenance or repair of hospital facilities to the lowest responsible bidder after advertising for bids by the publication of a class 2 notice under ch. 985. Section 66.0901 applies to bids and contracts under this subsection.

(6) Definitions. Unless the context otherwise requires, in this section:

(a) “Buildings”, “new buildings” and “existing buildings” include all buildings, structures, improvements, facilities, equipment or other capital items which the governing body of the city, village or town determines are necessary or desirable for the purpose of providing hospital facilities.

(b) “Nonprofit corporation” means a nonstock corporation organized under ch. 181 that is a nonprofit corporation, as defined in s. 181.0103(17).

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (1)

W. S. A. 66.0129, WI ST 66.0129
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W.S.A. 66.013

66.013. Renumbered 66.0201 and amended by 1999 Act 150, § 33, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.013, WI ST 66.013
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0131

66.0131. Local governmental purchasing

Currentness

(1) Definitions. In this section:

(a) "Local governmental unit" means a political subdivision of this state, a special purpose district in this state, an agency or corporation of a political subdivision or special purpose district, or a combination or subunit of any of the foregoing.

(b) "Recycled or recovered content" has the meaning given in s. 16.70(13).

(2) Intergovernmental purchases without bids. Notwithstanding any statute requiring bids for public purchases, any local governmental unit may make purchases from another unit of government, including the state or federal government, without the intervention of bids.

(3) Purchase of recycled materials. (a)1. A local governmental unit shall, to the extent practicable, make purchasing selections using specifications developed by state agencies under s. 16.72(2)(e) to maximize the purchase of products utilizing recycled or recovered materials.

2. Each local governmental unit shall ensure that the average recycled or recovered content of all paper purchased by the local governmental unit measured as a proportion, by weight, of the fiber content of all paper products purchased in a year, is not less than the following:

a. By 1991, 10 percent of all purchased paper.

b. By 1993, 25 percent of all purchased paper.

c. By 1995, 40 percent of all purchased paper.

(4) Purchase of recyclable materials. A local governmental unit shall, to the extent practicable, make purchasing selections using specifications prepared by state agencies under s. 16.72(2)(f).

(5) Life cycle cost estimate. A local governmental unit shall award each order or contract for materials, supplies or equipment on the basis of life cycle cost estimates whenever that action is appropriate. The terms, conditions and evaluation criteria to be applied shall be incorporated into the solicitation of bids or proposals. The life cycle cost formula may include, but is not limited to, the applicable costs of energy efficiency, acquisition and conversion, money, transportation, warehousing and distribution, training, operation and maintenance, and disposition or resale.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (1)

W. S. A. 66.0131, WI ST 66.0131
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0133

66.0133. Energy savings performance contracting

Currentness

(1) Definitions. In this section:

(a) "Energy conservation measure" means a facility alteration or training, service, or operations program designed to reduce energy consumption or operating costs, conserve water resources, improve metering accuracy, or ensure state or local building code compliance.

(b) "Local governmental unit" has the meaning given in s. 19.42(7u).

(bg) "Operational savings" means savings from costs eliminated or avoided as a result of installing equipment or providing services.

(c) "Performance contract" means a contract for the evaluation and recommendation of energy conservation and facility improvement measures, and for the implementation of these measures.

(d) "Qualified provider" means a person, other than a local governmental unit, who is experienced in the design, implementation and installation of energy conservation and facility improvement measures and who has the ability to provide labor and material payment and performance bonds equal to the maximum amount of any payments due under a performance contract entered into by the person.

(2) Authorization; report. (a)1. Except as provided under subd. 2., any local governmental unit may, in accordance with this section, enter into a performance contract with a qualified provider to reduce energy or operating costs, realize operational savings, conserve water resources, ensure state or local building code compliance, or enhance the protection of property of the local governmental unit.

2. A performance contract with a qualified provider under this section may not allow a local governmental unit to increase the square footage of a facility unless the increase is necessary to make mechanical, electrical, or plumbing improvements in order to achieve reductions in energy consumption or to conserve water resources.

(b) Prior to entering into a performance contract for the implementation of any energy conservation or facility improvement measure, a local governmental unit shall obtain a report from a qualified provider containing recommendations concerning the

amount the local governmental unit should spend on energy conservation and facility improvement measures. The report shall contain estimates of all costs of installation, modifications, or remodeling, including costs of design, engineering, maintenance, repairs and financing. In addition, the report shall contain a guarantee specifying a minimum amount by which energy or operating costs of the local governmental unit will be reduced or energy or water metering accuracy will be improved, if the installation, modification or remodeling is performed by that qualified provider.

(c) If, after review of the report under par. (b), the local governmental unit finds that the amount it would spend on the energy conservation and facility improvement measures recommended in the report is not likely to exceed the amount to be saved in energy and operation costs, or the benefits to be obtained by improved metering accuracy, over the remaining useful life of the facility to which the measures apply, the local governmental unit may enter into the contract.

(3) Notice. Notwithstanding ss. 27.065(5)(a), 30.32, 38.18, 43.17(9)(a), 59.52(29)(a), 59.70(11), 60.47(2) to (4), 60.77(6)(a), 61.54, 61.57, 62.15(1), 62.155, 66.0131(2), 66.0923(10), 66.0925(10), 66.0927(11), 66.1333(5)(a)2., 200.11(5)(d) and 200.47(2), before entering into a performance contract under this section, a local governmental unit shall solicit bids or competitive sealed proposals from qualified providers. A local governmental unit may only enter into a performance contract with a qualified provider if the contract is awarded by the governing body of the local governmental unit and if the qualified provider agrees to sign the performance contract and all contracts with subcontractors, including subcontractors who provide billing services under the performance contract. The governing body shall give at least 10 days' notice of the meeting at which the body intends to award a performance contract. The notice shall include a statement of the intent of the governing body to award the performance contract, the names of all potential parties to the proposed performance contract, and a description of the energy conservation and facility improvement measures included in the performance contract and an explanation of how these measures will generate operational savings sufficient to pay for the cost of the measures. At the meeting, the governing body shall review and evaluate the bids or proposals submitted by all qualified providers and may award the performance contract to the qualified provider that best meets the needs of the local governmental unit, which need not be the lowest cost provider.

(4) Installment payment and lease-purchase agreements. A local governmental unit may enter into an installment payment contract or lease-purchase agreement for the purchase and installation of energy conservation or facility improvement measures.

(5) Payment schedule; savings. Each performance contract shall provide that all payments to a qualified provider, except obligations on termination of the contract before its expiration, shall be made no later than the date on which the contract expires. Energy savings shall be guaranteed by the qualified provider for the entire term of the performance contract and may not be guaranteed by a third party. Unless otherwise agreed by the parties, every performance contract shall assume an annual increase of 3 percent in the cost of relevant utility services incurred by the local governmental unit.

(6) Terms of contracts. A performance contract may extend beyond the fiscal year in which it becomes effective, subject to appropriation of moneys, if required by law, for costs incurred in future fiscal years.

(7) Allocation of obligations. Subject to appropriations as provided in sub. (6), each local governmental unit shall allocate sufficient moneys for each fiscal year to make payment of any amounts payable by the local governmental unit under performance contracts during that fiscal year.

(8) Bonds. Each qualified provider under a performance contract shall provide labor and material payment and performance bonds in an amount equivalent to the maximum amount of any payments due under the contract, including payments for work performed by other persons that is necessary to achieve the required guaranteed energy or operational savings.

(9) Use of moneys. Unless otherwise provided by law or ordinance, if a local governmental unit has funding designated for operating and capital expenditures, the local governmental unit may use moneys designated for operating or capital expenditures to make payments under any performance contract, including installment payments or payments under lease-purchase agreements.

(10) Monitoring; reports. During the entire term of each performance contract, the qualified provider entering into the contract shall monitor the reductions in energy consumption and cost savings attributable to the energy conservation and facility improvement measures installed under the contract, and shall periodically prepare and provide a report to the local governmental unit entering into the contract documenting the reductions in energy consumption and cost savings to the local governmental unit.

(11) Energy conservation measures. Energy conservation measures under this section may include the following:

(a) Insulation of a building structure or systems within a building.

(b) Storm windows or doors, caulking or weather stripping, multiglazed windows or doors, heat-absorbing or heat-reflective glazed and coated window or door systems, additional glazing, reductions in glass area, or other window and door system modifications that reduce energy consumption.

(c) Automated or computerized energy control and facility management systems or computerized maintenance management systems.

(d) Heating, ventilating or air conditioning system modifications or replacements.

(e) Replacement or modification of lighting fixtures to increase the energy efficiency of the lighting system without increasing the overall illumination of a facility, unless an increase in illumination is necessary to conform to the applicable state or local building code for the lighting system after the proposed modifications are made.

(f) Energy recovery systems.

(g) Utility management systems and services.

(h) Cogeneration systems that produce steam or forms of energy such as heat, as well as electricity, for use primarily within a building or complex of buildings.

(i) Life safety improvements or systems required to comply with the federal Americans with Disabilities Act.

(ig) Replacement or improvement of energy or water metering systems.

(im) Measures to improve indoor or outdoor water conservation, including measures related to water recycling and reuse, and systems or equipment that implement those measures.

(ir) Measures to improve indoor air quality to meet applicable state and local building code requirements.

(j) Any other facility improvement measure that is designed to provide long-term energy or operating cost reductions or compliance with state or local building codes.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0133, WI ST 66.0133
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W.S.A. 66.0134

66.0134. Labor peace agreements prohibited

Currentness

(1) Definitions. In this section:

(a) "Federal labor laws" means the federal Labor Management Relations Act, 29 USC 141 to 144, and the federal National Labor Relations Act, 29 USC 151 to 169.

(b) "Local governmental unit" means a city, village, town, county, school district, including a 1st class city school district, technical college district, sewerage district, drainage district, or any other special purpose district in this state, or any other public or quasi-public corporation, officer, board, or other public body, an agency or corporation of a political subdivision or special purpose district, or a combination or subunit of any of the foregoing.

(2) Agreements prohibited. Neither the state nor a local governmental unit may enact a statute or ordinance; adopt a policy or regulation; or impose a contract, zoning, permitting, or licensing requirement, or any other condition including a condition of any regulatory approval; that would require any person to accept any provision that is a mandatory or nonmandatory subject of collective bargaining under state or federal labor laws.

(3) Waiver prohibited. Neither the state nor a local governmental unit, nor any of its employees, may require any person to waive the person's rights under state or federal labor laws, or compel or attempt to compel a person to agree to waive the person's rights under state or federal labor laws as a condition of any regulatory approval or other approval by the local governmental unit.

(4) Agreements void. Any agreement entered into, renewed, modified, or extended on or after April 18, 2018, between any person and any labor organization in violation of this section is void.

Credits
<<For credits, see Historical Note field.>>

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W.S.A. 66.0135

66.0135. Interest on late payments

Currentness

(1) Definitions. In this section:

(a) "Agency" means any office, department, board, commission or other body under the control of the governing body of a local governmental unit which expends moneys or incurs obligations on behalf of the local governmental unit.

(b) "Good faith dispute" means any of the following:

1. A contention by an agency, principal contractor or subcontractor that goods delivered or services rendered were of a lesser quantity or quality than ordered or specified by contract, were faulty or were installed improperly.

2. Any other reason giving cause for the withholding of payment by an agency, principal contractor or subcontractor until the dispute is settled.

(c) "Local governmental unit" means a political subdivision of this state, a special purpose district in this state, an agency or corporation of a political subdivision or special purpose district, or a combination or subunit of any of the foregoing.

(d) "Subcontractor" has the meaning given in s. 66.0901(1)(d).

(2) Interest payable to principal contractors. (a) Except as provided in sub. (4) or as otherwise specifically provided, an agency that does not pay timely the amount due on an order or contract shall pay interest on the balance due from the 31st day after receipt of a properly completed invoice or receipt and acceptance of the property or service under the order or contract, whichever is later, or, if the agency does not comply with sub. (7), from the 31st day after receipt of an improperly completed invoice or receipt and acceptance of the property or service under the order or contract, whichever is later, at the rate specified in s. 71.82(1)(a) compounded monthly.

(b) For the purposes of par. (a), a payment is timely if the payment is mailed, delivered or transferred by the later of the following:

1. The date specified on a properly completed invoice for the amount specified in the order or contract.

2. Within 30 days after receipt of a properly completed invoice or receipt and acceptance of the property or service under the order or contract, or, if the agency does not comply with sub. (7), within 30 days after receipt of an improperly completed invoice or receipt and acceptance of the property or service under the order or contract, whichever is later.

(3) Interest payable to subcontractors. (a) Except as provided in sub. (4)(e) or as otherwise specifically provided, principal contractors that engage subcontractors to perform part of the work on an order or contract from an agency shall pay subcontractors for satisfactory work in a timely fashion. A payment is timely if it is mailed, delivered or transferred to the subcontractor no later than 7 days after the principal contractor's receipt of any payment from the agency.

(b) If a subcontractor is not paid in a timely fashion, the principal contractor shall pay interest on the balance due from the 8th day after the principal contractor's receipt of any payment from the agency, at the rate specified in s. 71.82(1)(a) compounded monthly.

(c) Subcontractors receiving payment under this subsection shall pay lower-tier subcontractors, and be liable for interest on late payments, in the same manner as principal contractors are required to pay subcontractors in pars. (a) and (b).

(4) Exceptions. Subsection (2) does not apply to any of the following:

(a) Any portion of an order or contract for which the payment, from federal moneys, has not been received.

(b) An order or contract that is subject to late payment interest or another late payment charge required by another law or rule specifically authorized by law.

(c) An order or contract between 2 or more agencies of the same local governmental unit.

(d) An order or contract which provides for the time of payment and the consequences of nontimely payment, if any deviation from the deadlines established in sub. (2) appears in the original bid or proposal.

(e) An order or contract under which the amount due is subject to a good faith dispute if, before the date on which payment is not timely, notice of the dispute is sent by 1st class mail, personally delivered or sent in accordance with the procedure specified in the order or contract.

(5) Appropriation from which paid. An agency that pays interest under this section shall pay the interest only from the appropriation for administration of the program under which the order or contract was made or entered into, unless otherwise directed by the governing body of the local governmental unit.

(6) Attorney fees. Notwithstanding s. 814.04(1), in an action to recover interest due under this section, the court shall award the prevailing party reasonable attorney fees.

(7) Improper invoices. If an agency receives an improperly completed invoice, the agency shall notify the sender of the invoice within 10 working days after it receives the invoice of the reason that it is improperly completed.

Credits

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W.S.A. 66.0137

66.0137. Provision of insurance

Currentness

(1) Definition. In this section:

(ac) "Board of Regents" means the Board of Regents of the University of Wisconsin System.

(af) "Dies in the line of duty" means a death that occurs, or occurred, as a direct and proximate result of a personal injury sustained by, or a single exposure to a hazardous material or condition experienced by, a law enforcement officer, fire fighter, or emergency medical services practitioner while he or she was engaged in a line of duty activity or that arose out of and as a result of such an individual's performance of a line of duty activity.

(ah) "Emergency medical services practitioner" has the meaning given in s. 256.01(5), except that in this section it applies only to an individual who is employed directly by a political subdivision or by a joint emergency medical services department operated jointly by 2 or more political subdivisions.

(am) "Law enforcement officer" means all of the following:

1. Any person employed by a political subdivision for the purpose of detecting and preventing crime and enforcing laws or ordinances and who is authorized to make arrests for violations of the laws or ordinances that the person is employed to enforce.

2. Any jailer who, under the direction of a sheriff under s. 59.27(1), keeps persons in a county jail.

3. A Marquette University police officer, as defined in s. 175.42(1)(b).

4. A state patrol officer, as that term is defined in s. 252.01(7).

5. A state capitol police officer.

6. A University of Wisconsin System police officer.

7. An officer of the division of criminal investigation.

8. A department of natural resources conservation warden.

9. A county sheriff, undersheriff, or deputy sheriff.

10. A chief of police.

11. A special agent employed by the department of revenue who is authorized to act under s. 73.031.

12. A state fair park police officer duly appointed under s. 42.01(2).

(ap) "Line of duty activity" means any employment-related action taken by a law enforcement officer, fire fighter, or emergency medical services practitioner that is required or authorized by law, rule, regulation, or condition of employment and for which compensation is provided by his or her employing agency or would have been eligible to have been provided by the employing agency if the law enforcement officer, fire fighter, or emergency medical services practitioner had been on duty when he or she took the action in question.

(as) "Local governmental unit" means a political subdivision, school district (as enumerated in s. 67.01(5)), sewerage district, drainage district, and, without limitation because of enumeration, any other political subdivision of the state.

(b) "Municipality" means any city, village, or town.

(c) "Political subdivision" means any municipality or county.

(2) Liability and worker's compensation insurance. The state or a local governmental unit may procure risk management services and liability insurance covering the state or local governmental unit and its officers, agents and employees and worker's compensation insurance covering officers and employees of the state or local governmental unit. A local governmental unit may participate in and pay the cost of risk management services and liability and worker's compensation insurance through a municipal insurance mutual organized under s. 611.23.

(3) Health insurance for unemployed persons. Any political subdivision may purchase health or dental insurance for unemployed persons residing in the political subdivision who are not eligible for medical assistance under s. 49.46, 49.468, 49.47, or 49.471(4)(a).

(4) Self-insured health plans. If a city, including a 1st class city, or a village provides health care benefits under its home rule power, or if a town provides health care benefits, to its officers and employees on a self-insured basis, the self-insured plan shall

comply with ss. 49.493(3)(d), 631.89, 631.90, 631.93(2), 632.722, 632.729, 632.746(10)(a)2. and (b)2., 632.747(3), 632.798, 632.85, 632.853, 632.855, 632.861, 632.867, 632.87(4) to (6), 632.885, 632.89, 632.895(9) to (17), 632.896, and 767.513(4).

(4m) Joint self-insured plans and stop loss insurance. (a) Notwithstanding sub. (1)(as), in this subsection, "local governmental unit" means a city, village, town, county, or school district.

(b) A local governmental unit and one or more other local governmental units, that together have at least 100 employees, may jointly provide health care benefits to their officers and employees on a self insured basis.

(bm) A technical college district and one or more other technical college districts, that together have at least 100 employees, may jointly do any of the following:

1. Provide health care benefits to their officers and employees on a self-insured basis.

2. Procure stop loss insurance.

3. Self-insure stop loss risk.

(c) Any plan under par. (b) or (bm)1. shall comply with the provisions listed in sub. (4).

(4t) Health insurance for protective services employees. If a 1st class city offers health care insurance to employees who are police officers, fire fighters, or emergency medical services practitioners, as defined in s. 256.01(5), the 1st class city shall also offer to the employees who are police officers, fire fighters, or emergency medical services practitioners a high-deductible health plan.

(5) Hospital, accident and life insurance. (a) In this subsection, "local governmental unit" includes the school district operating under ch. 119.

(b) The state or a local governmental unit may provide for the payment of premiums or cost sharing for hospital, surgical and other health and accident insurance and life insurance for employees and officers, their spouses, and dependent children. A local governmental unit may also provide for the payment of premiums or cost sharing for hospital and surgical care for its retired employees. In addition, a local governmental unit may, by ordinance or resolution, elect to offer to all of its employees a health care coverage plan through a program offered by the group insurance board under ch. 40. A local governmental unit that elects to participate under s. 40.51(7) is subject to the applicable sections of ch. 40 instead of this subsection.

(c)1. Except as provided in subds. 2. and 3., if a municipality provides for the payment of premiums for hospital, surgical, and other health insurance for its fire fighters, it shall continue to pay such premiums for the surviving spouse and dependent children of the fire fighter who dies in the line of duty.

1m. Except as provided in subds. 2. and 3., if a political subdivision, the state, the Board of Regents, or Marquette University provides for the payment of premiums for hospital, surgical, and other health insurance for its law enforcement officers or

emergency medical services practitioners, it shall continue to pay such premiums for the surviving spouse and dependent children of the law enforcement officer or emergency medical services practitioner who dies in the line of duty.

2. A political subdivision, the state, the Board of Regents, or Marquette University may not be required to pay the premiums described in subd. 1. or 1m. for a surviving spouse upon the remarriage of the surviving spouse or upon the surviving spouse reaching the age of 65.

3. An individual is not a dependent child for the purposes of subd. 1. or 1m. after the individual reaches the age of 26.

4. Except as needed to administer this paragraph, a political subdivision, the state, the Board of Regents, and Marquette University shall keep confidential any personally identifiable information, as defined in s. 19.62(5), of a surviving spouse and dependent children for whom the political subdivision, the state, the Board of Regents, or university makes a payment under this paragraph.

(d) If a political subdivision pays the premiums described in par. (c)1. or 1m., annually, in order to receive reimbursement, the political subdivision shall report to the department of revenue by March 15 of each year the amounts paid in the previous calendar year.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (15)

W. S. A. 66.0137, WI ST 66.0137
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W.S.A. 66.0139

66.0139. Disposal of abandoned property

Currentness

(1) In this section, "political subdivision" means a city, village, town or county.

(2) A political subdivision may dispose of any personal property which has been abandoned, or remained unclaimed for a period of 30 days, after the taking of possession of the property by an officer of the political subdivision by any means determined to be in the best interest of the political subdivision. If the property is not disposed of in a sale open to the public, the political subdivision shall maintain an inventory of the property, a record of the date and method of disposal, including the consideration received for the property, if any, and the name and address of the person taking possession of the property. The inventory shall be kept as a public record for a period of not less than 2 years from the date of disposal of the property. Any means of disposal other than public auction shall be specified by ordinance. If the disposal is in the form of a sale, all receipts from the sale, after deducting the necessary expenses of keeping the property and conducting the sale, shall be paid into the treasury of the political subdivision.

(3) A political subdivision may safely dispose of abandoned or unclaimed flammable, explosive, or incendiary substances, materials, or devices that pose a danger to life or property in their storage, transportation, or use immediately after taking possession of the substances, materials, or devices without a public auction. The political subdivision, by ordinance or resolution, may establish disposal procedures. Procedures may include provisions authorizing an attempt to return to the rightful owner substances, materials, or devices that have a commercial value in normal business usage and do not pose an immediate threat to life or property. If enacted, a disposal procedure shall include a presumption that if the substance, material, or device appears to be or is reported stolen, an attempt will be made to return the substance, material, or device to the rightful owner.

(4) Except as provided in s. 968.20(3), a 1st class city shall dispose of abandoned or unclaimed dangerous weapons or ammunition without a public auction 12 months after taking possession of them if the owner has not requested their return. Disposal procedures shall be established by ordinance or resolution and may include provisions authorizing an attempt to return to the rightful owner any dangerous weapons or ammunition which appear to be stolen or are reported stolen. If enacted, a disposal procedure shall include a presumption that if the dangerous weapons or ammunition appear to be or are reported stolen an attempt will be made to return the dangerous weapons or ammunition to the rightful owner. The dangerous weapons or ammunition are subject to sub. (5).

(5) A political subdivision may retain or dispose of any abandoned, unclaimed or seized dangerous weapon or ammunition only under s. 968.20.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (2)

W. S. A. 66.0139, WI ST 66.0139
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.014

66.014. Renumbered 66.0203 and amended by 1999 Act 150, § 36, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.014, WI ST 66.014
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0141

66.0141. Accident record systems

Currentness

Every city, village and town having a population of 5,000 or more shall maintain a traffic accident record system whereby traffic accidents occurring within the city, village or town may be located within 100 feet of the occurrence and shall provide a copy of the record quarterly to the county traffic safety commission under s. 83.013(1)(a).

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0141, WI ST 66.0141
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0143

66.0143. Local appeals for exemption from state mandates

Currentness

(1) Definitions. In this section:

(a) "Political subdivision" means a city, village, town, or county.

(b) "State mandate" means a state law that requires a political subdivision to engage in an activity or provide a service, or to increase the level of its activities or services.

(2) Appeals for exemptions. (a) A political subdivision may file a request with the department of revenue for a waiver from a state mandate, except for a state mandate that is related to any of the following:

1. Health.

2. Safety.

(b) An administrative agency, or the department of revenue, may grant a political subdivision a waiver from a state mandate as provided in par. (c).

(c) The political subdivision shall specify in its request for a waiver its reason for requesting the waiver. Upon receipt of a request for a waiver, the department of revenue shall forward the request to the administrative agency that is responsible for administrating the state mandate. The agency shall determine whether to grant the waiver and shall notify the political subdivision and the department of revenue of its decision in writing. If no agency is responsible for administrating the state mandate, the department of revenue shall determine whether to grant the waiver and shall notify the political subdivision of its decision in writing.

(3) Duration of waivers. A waiver is effective for 4 years. The administrative agency may renew the waiver for additional 4-year periods. If a waiver is granted by the department of revenue, the department may renew the waiver under this subsection.

(4) Evaluation. By July 1, 2004, the department of revenue shall submit a report to the governor, and to the appropriate standing committees of the legislature under s. 13.172(3). The report shall specify the number of waivers requested under this section, a

description of each waiver request, the reason given for each waiver request, and the financial effects on the political subdivision of each waiver that was granted.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0143, WI ST 66.0143
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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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W.S.A. 66.0144

66.0144. Advisory referenda

Currentness

No city, village, or town may conduct a referendum for advisory purposes, except as provided under s. 66.0305(6), 66.0307(4)(e), 66.0420(12)(b)2., 66.0422(3)(b), or 196.204(2m)(b) 2. or for an advisory referendum regarding capital expenditures proposed to be funded by the property tax levy of the city, village, or town.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0144, WI ST 66.0144
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0145

66.0145. No preferences in hiring or contracting

Currentness

(1) In this section, "political subdivision" means a county, city, village, or town.

(2) Unless required to secure federal aid, no political subdivision may discriminate against, or grant preferential treatment on the basis of, race, color, ancestry, national origin, or sexual orientation in making employment decisions regarding employees of a political subdivision or contracting for public works.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0145, WI ST 66.0145
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.015

66.015. Renumbered 66.0205 and amended by 1999 Act 150, § 37, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.015, WI ST 66.015
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.016

66.016. Renumbered 66.0207 and amended by 1999 Act 150, § 38, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.016, WI ST 66.016
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.017

66.017. Renumbered 66.0209 and amended by 1999 Act 150, § 39, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.017, WI ST 66.017
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.018

66.018. Renumbered 66.0211 and amended by 1999 Act 150, § 40, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.018, WI ST 66.018
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.019

66.019. Renumbered 66.0213 and amended by 1999 Act 150, § 41, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.019, WI ST 66.019
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.02

66.02. Renumbered 66.0229 and amended by 1999 Act 150, § 42, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.02, WI ST 66.02
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0201

66.0201. Incorporation of villages and cities; purpose and definitions

Currentness

(1) Purpose. It is the policy of this state that the development of territory from town to incorporated status proceed in an orderly and uniform manner and that toward this end each proposed incorporation of territory as a village or city be reviewed as provided in ss. 66.0201 to 66.0213 to assure compliance with certain minimum standards which take into account the needs of both urban and rural areas.

(2) Definitions. In ss. 66.0201 to 66.0213, unless the context requires otherwise:

(am) "Board" means the incorporation review board.

(ar) "Department" means the department of administration.

(bm) "Isolated municipality" means any existing or proposed village or city entirely outside any metropolitan community at the time of its incorporation.

(c) "Metropolitan community" means the territory consisting of any city having a population of 25,000 or more, or any 2 incorporated municipalities whose boundaries are within 5 miles of each other whose populations aggregate 25,000, plus all the contiguous area which has a population density of 100 persons or more per square mile, or which the department has determined on the basis of population trends and other pertinent facts will have a minimum density of 100 persons per square mile within 3 years.

(d) "Metropolitan municipality" means any existing or proposed village or city entirely or partly within a metropolitan community.

(dm) "Population" means the population of a local unit as shown by the last federal census or by any subsequent population estimate certified as acceptable by the department.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

W. S. A. 66.0201, WI ST 66.0201
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Red Flag - Severe Negative Treatment
Unconstitutional or Preempted Held Unconstitutional by State ex rel. Kuehne v. Burdette, Wis.App., Apr. 14, 2009

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W.S.A. 66.0203

66.0203. Procedure for incorporation of villages and cities

Currentness

(1) Notice of intention. At least 10 days and not more than 20 days before the circulation of an incorporation petition, a notice setting forth that the petition is to be circulated and including an accurate description of the territory involved shall be published within the county in which the territory is located as a class 1 notice, under ch. 985.

(2) Petition. (a) The petition for incorporation of a village or city shall be in writing signed by 50 or more persons who are both electors and freeholders in the territory to be incorporated if the population of the proposed village or city includes 300 or more persons; otherwise by 25 or more persons who are both electors and freeholders in the territory to be incorporated.

(b) The petition shall be addressed to and filed with the circuit court of a county in which all or a major part of the territory to be incorporated is located. The incorporation petition is void unless filed within 6 months of the date of publication of the notice of intention to circulate.

(c) The petition shall designate a representative of the petitioners, and an alternate, who shall be an elector or freeholder in the territory, and state that person's address; describe the territory to be incorporated with sufficient accuracy to determine its location and have attached to the petition a scale map reasonably showing the boundaries of the territory; specify the current resident population of the territory by number in accordance with the definition given in s. 66.0201(2)(dm); set forth facts substantially establishing the required standards for incorporation; and request the circuit court to order a referendum and to certify the incorporation of the village or city when it is found that all requirements have been met.

(e) No person who has signed a petition may withdraw his or her name from the petition. No additional signatures may be added after a petition is filed.

(f) The circulation of the petition shall commence not less than 10 days nor more than 20 days after the date of publication of the notice of intention to circulate.

(3) Hearing; costs. (a) Upon the filing of the petition the circuit court shall by order fix a time and place for a hearing giving preference to the hearing over other matters on the court calendar.

(b) The court may by order allow costs and disbursements as provided for actions in circuit court in any proceeding under this subsection.

(c) The court may, upon notice to all parties who have appeared in the hearing and after a hearing on the issue of bond, order the petitioners or any of the opponents to post bond in an amount that it considers sufficient to cover disbursements.

(4) Notice. (a) Notice of the filing of the petition and of the date of the hearing on the petition before the circuit court shall be published in the territory to be incorporated, as a class 2 notice, under ch. 985, and given by certified or registered mail to the clerk of each town in which the territory is located and to the clerk of each metropolitan municipality of the metropolitan community in which the territory is located. The mailing shall be not less than 10 days before the time set for the hearing.

(b) The notice shall contain:

1. A description of the territory sufficiently accurate to determine its location and a statement that a scale map reasonably showing the boundaries of the territory is on file with the circuit court.

2. The name of each town in which the territory is located.

3. The name and post-office address of the representative of the petitioners.

(4m) Incorporations involving portions of 2 towns. If the territory designated in the petition is comprised of portions of only 2 towns, the territory may not be incorporated unless the town board of each town adopts a resolution approving the incorporation.

(5) Parties. Any governmental unit entitled to notice pursuant to sub. (4), any school district which lies at least partly in the territory or any other person found by the court to be a party in interest may become a party to the proceeding prior to the time set for the hearing.

(6) Annexation resolution. Any municipality whose boundaries are contiguous to the territory may also file with the circuit court a certified copy of a resolution adopted by a two-thirds vote of the elected members of the governing body indicating a willingness to annex the territory designated in the incorporation petition. The resolution shall be filed at or prior to the hearing on the incorporation petition, or any adjournment granted for this purpose by the court.

(7) Action. (a) No action to contest the validity of an incorporation on any grounds, whether procedural or jurisdictional, may be commenced after 60 days from the date of issuance of the certificate of incorporation by the secretary of administration.

(b) An action contesting an incorporation shall be given preference in the circuit court.

(8) Function of the circuit court. (a) After the filing of the petition and proof of notice, the circuit court shall conduct a hearing at the time and place specified in the notice, or at a time and place to which the hearing is duly adjourned.

(b) On the basis of the hearing the circuit court shall find if the standards under s. 66.0205 are met. If the court finds that the standards are not met, the court shall dismiss the petition. Subject to par. (c), if the court finds that the standards are met the court shall refer the petition to the board. Upon payment of any fee imposed under s. 16.53(14), the board shall determine whether the standards under s. 66.0207 are met.

(c)1. The court shall determine whether an annexation proceeding that affects any territory included in the incorporation petition has been initiated under s. 66.0217, 66.0219, or 66.0223. A court shall consider an annexation proceeding under s. 66.0223 to have been initiated upon the posting of a meeting notice by a city or village that states that the city or village is considering enacting an ordinance under s. 66.0223.

2. If the court determines that an annexation proceeding described under subd. 1. was initiated before the publication of the notice under sub. (1), the court shall refer the petition to the board when the annexation proceeding is final. If the annexation is determined to be valid, the court shall exclude the annexed territory from the territory proposed to be incorporated when it refers the petition to the board.

3. If the court determines that an annexation proceeding described under subd. 1. was initiated after, and within 30 days after, the publication of the notice under sub. (1), the annexation may not proceed until the validity of the incorporation has been determined. If the incorporation is determined to be valid and complete, the annexation is void. If the incorporation is determined to be invalid, the annexation may proceed.

4. If the court determines that an annexation proceeding described under subd. 1. was initiated on the same date as the publication of the notice under sub. (1), the court shall determine which procedure was begun first on that date and that action may proceed and the other action may not proceed unless the first action fails.

5. If the court determines that an annexation proceeding described under subd. 1. was initiated more than 30 days after the publication of the notice under sub. (1), the annexation is void.

(9) Function of the board. (a) Upon receipt of the petition from the circuit court and payment of any fee imposed under s. 16.53(14), the board shall make any necessary investigation to apply the standards under s. 66.0207.

(b) Within 30 days after the receipt by the board of the petition from the circuit court and payment of any fee imposed under s. 16.53(14), whichever is later, any party in interest may request a hearing. Upon receipt of the request, the board shall schedule a hearing at a place in or convenient to the territory sought to be incorporated.

(c) Notice of the hearing shall be given in the territory to be incorporated by publishing a class 2 notice, under ch. 985, and by mailing the notice to the designated representative of the petitioners or any 5 petitioners and to all town and municipal clerks entitled to receive mailed notice of the petition under sub. (4).

(d) Subject to par. (dm), unless the court sets a different time limit, the board shall prepare its findings and determination, citing the supporting evidence, within 180 days after receipt of the referral from the court and payment of any fee imposed under s. 16.53(14), whichever is later. The findings and determination shall be forwarded by the board to the circuit court. Copies of the

findings and determination shall be sent by certified or registered mail to the designated representative of the petitioners, and to all town and municipal clerks entitled to receive mailed notice of the petition under sub. (4).

(dm) The time period specified or set by the court under par. (d) shall be stayed for a reasonable period of time to allow for alternative dispute resolution of any disagreements between interested parties that result from the filing of an incorporation petition if all interested parties agree to this stay and provide written notice of their agreement to the board and to the circuit court.

(e) The determination of the board made in accordance with the standards under ss. 66.0205, 66.0207 and 66.0217(6)(c) shall be one of the following:

1. The petition as submitted is dismissed.

2. The petition as submitted is granted.

3. The petition as submitted is dismissed with a recommendation that a new petition be submitted to include more or less territory as specified in the department's findings and determination.

(f)1. If the board determines that the petition shall be dismissed under par. (e)1., the circuit court shall issue an order dismissing the petition. Except as provided in subd. 2., if the board grants the petition, the circuit court shall order an incorporation referendum as provided in s. 66.0211.

2. If sub. (4m) applies, the court shall dismiss the petition if the court does not find that the resolutions required under sub. (4m) have been adopted. Paragraph (g) does not apply to this subdivision.

(g) The findings of both the court and the board shall be based upon facts as they existed at the time of the filing of the petition.

(h) Except for an incorporation petition which describes the territory recommended by the board under sub. (9)(e)3., no petition for the incorporation of the same or substantially the same territory may be entertained for one year following the date of dismissal under par. (f) of the petition or the date of any election at which incorporation was rejected by the electors.

(i) If the board fails to make a determination within the time limit under par. (d), the board shall refund the fees imposed by the board under s. 16.53(14) and shall then make a determination as quickly as possible.

(10) Certain towns may become a city or village. A town that is adjacent to a village that contains an electronics and information technology manufacturing zone that is designated under s. 238.396(1m) may become a city or village if the town holds, and approves, an incorporation referendum as described in s. 66.0211(3). None of the other procedures contained in ss. 66.0201 to 66.0213 need to be fulfilled, and no approval by the board under s. 66.0207 is necessary for the town to become a city or village.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (40)

W. S. A. 66.0203, WI ST 66.0203
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W.S.A. 66.0205

66.0205. Standards to be applied by the circuit court

Currentness

Before referring the incorporation petition as provided in s. 66.0203(2) to the board, the court shall determine whether the petition meets the formal and signature requirements and shall further find that the following minimum requirements are met:

(1) Isolated village. Area, one-half square mile; resident population, 150.

(2) Isolated city. Area, one square mile; resident population, 1,000; density, at least 500 persons in any one square mile.

(3) Metropolitan village. Area, 2 square miles; resident population, 2,500; density, at least 500 persons in any one square mile.

(4) Metropolitan city. Area, 3 square miles; resident population, 5,000; density, at least 750 persons in any one square mile.

(5) Standards when near 1st, 2nd or 3rd class city. If the proposed boundary of a metropolitan village or city is within 10 miles of the boundary of a 1st class city or 5 miles of a 2nd or 3rd class city, the minimum area requirements are 4 and 6 square miles for villages and cities, respectively.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (9)

W. S. A. 66.0205, WI ST 66.0205
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0207

66.0207. Standards to be applied by the board

Currentness

(1) Requirements. The board may approve for referendum only those proposed incorporations which meet the following requirements:

(a) *Characteristics of territory.* The entire territory of the proposed village or city shall be reasonably homogeneous and compact, taking into consideration natural boundaries, natural drainage basin, soil conditions, present and potential transportation facilities, previous political boundaries, boundaries of school districts, shopping and social customs. An isolated municipality shall have a reasonably developed community center, including some or all features such as retail stores, churches, post office, telecommunications exchange and similar centers of community activity.

(b) *Territory beyond the core.* The territory beyond the most densely populated one-half square mile specified in s. 66.0205(1) or the most densely populated square mile specified in s. 66.0205(2) shall have an average of more than 30 housing units per quarter section or an assessed value, as defined in s. 66.0217(1)(a) for real estate tax purposes, more than 25 percent of which is attributable to existing or potential mercantile, manufacturing or public utility uses. The territory beyond the most densely populated square mile as specified in s. 66.0205(3) or (4) shall have the potential for residential or other urban land use development on a substantial scale within the next 3 years. The board may waive these requirements to the extent that water, terrain or geography prevents the development.

(2) Additional considerations. In addition to complying with each of the applicable standards set forth in sub. (1) and s. 66.0205 in order to be approved for referendum, a proposed incorporation must be in the public interest as determined by the board upon consideration of the following:

(a) *Tax revenue.* The present and potential sources of tax revenue appear sufficient to defray the anticipated cost of governmental services at a local tax rate which compares favorably with the tax rate in a similar area for the same level of services.

(b) *Level of services.* The level of governmental services desired or needed by the residents of the territory compared to the level of services offered by the proposed village or city and the level available from a contiguous municipality which files a certified copy of a resolution as provided in s. 66.0203(6).

(c) *Impact on the remainder of the town.* The impact, financial and otherwise, upon the remainder of the town from which the territory is to be incorporated.

(d) *Impact on the metropolitan community.* The effect upon the future rendering of governmental services both inside the territory proposed for incorporation and elsewhere within the metropolitan community. There shall be an express finding that the proposed incorporation will not substantially hinder the solution of governmental problems affecting the metropolitan community.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (67)

W. S. A. 66.0207, WI ST 66.0207
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W.S.A. 66.0209

66.0209. Review of incorporation-related orders and decisions

Currentness

(1) The order of the circuit court made under s. 66.0203(8) or (9)(f) may be appealed to the court of appeals.

(2) The decision of the board made under s. 66.0203(9) is subject to judicial review under ch. 227.

(3) Where a proceeding for judicial review is commenced under sub. (2), appeal under sub. (1) may not be taken and the time in which the appeal may be taken does not commence to run until judgment is entered in the proceeding for judicial review.

(4) An incorporation referendum ordered by the circuit court under s. 66.0203(9)(f) may not be stayed pending the outcome of further litigation, unless the court of appeals or the supreme court, upon an appeal or upon the filing of an original action in the supreme court, concludes that a strong probability exists that the order of the circuit court or the decision of the board will be set aside.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

W. S. A. 66.0209, WI ST 66.0209
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.021. Renumbered in part and repealed in part by 1999 Act 150, §§ 44 to 63, eff. Jan. 1, 2001

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W.S.A. 66.021

66.021. Renumbered in part and repealed in part by 1999 Act 150, §§ 44 to 63, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.021, WI ST 66.021
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0211

66.0211. Incorporation referendum procedure

Currentness

(1) Order. The circuit court's order for an incorporation referendum shall specify the voting place and the date of the referendum, which shall be not less than 6 weeks from the date of the order, and name 3 inspectors of election. If the order is for a city incorporation referendum the order shall further specify that 7 alderpersons shall be elected at large from the proposed city. The city council at its first meeting shall determine the number and boundaries of wards in compliance with s. 5.15(1) and (2), and the combination of wards into aldermanic districts. The number of alderpersons per aldermanic district shall be determined by charter ordinance.

(2) Notice of referendum. Notice of the referendum shall be given by publication of the order of the circuit court in a newspaper having general circulation in the territory. Publication shall be once a week for 4 successive weeks. The first publication may not be more than 4 weeks before the referendum.

(3) Return. An incorporation referendum shall be conducted in the same manner as an annexation referendum under s. 66.0217(7) to the extent applicable except that the ballot shall contain the words “For a city [village]” and “Against a city [village]”. The inspectors shall make a return to the circuit court.

(4) Costs. If the referendum is against incorporation, the costs of the election shall be borne by the towns involved in the proportion that the number of electors of each town within the territory proposed to be incorporated, voting in the referendum, bears to the total number of electors in the territory voting in the referendum. If the referendum is for a village or city, the costs shall be charged against the municipality in the apportionment of town assets.

(5) Certification of incorporation. If a majority of the votes in an incorporation referendum are cast in favor of a village or city, the clerk of the circuit court shall certify the fact to the secretary of administration and supply the secretary of administration with a copy of a description of the legal boundaries of the village or city and the associated population and a copy of a plat of the village or city. Within 10 days of receipt of the description and plat, the secretary of administration shall forward 2 copies to the department of transportation and one copy each to the department of administration and the department of revenue. The secretary of administration shall issue a certificate of incorporation and record the certificate.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

W. S. A. 66.0211, WI ST 66.0211
Current through 2023 Act 272, published April 10, 2024.

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West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter II. Incorporation; Municipal Boundaries

W.S.A. 66.0213

66.0213. Powers of new village or city: elections; adjustment of taxes; reorganization as village

Currentness

(1) Village or city powers. A village or city incorporated under ss. 66.0201 to 66.0213 is a body corporate and politic, with powers and privileges of a municipal corporation at common law and conferred by these statutes.

(2) Existing ordinances. Ordinances in force in the territory incorporated or any part of the territory, to the extent not inconsistent with chs. 61 and 62, continue in force until altered or repealed.

(3) Interim officers. All officers of the village or town embracing the territory that is incorporated as a village or city continue in their powers and duties until the first meeting of the board of trustees or common council at which a quorum is present. Until a village or city clerk is chosen and qualified all oaths of office and other papers shall be filed with the circuit court with which the petition was filed. The court shall deliver the oaths and other papers with the petition to the village or city clerk when that clerk qualifies.

(4) First village or city election. (a) Within 10 days after incorporation of the village or city, the county clerk of the county in which the petition was filed shall fix a time for the first election, and where appropriate designate the polling place or places, and name 3 inspectors of election for each place. The time for the election shall be fixed no less than 40 nor more than 50 days after the date of the certificate of incorporation issued by the secretary of administration, irrespective of any other provision in the statutes. Nomination papers shall conform to ch. 8 to the extent applicable. Nomination papers shall be signed by not less than 5 percent nor more than 10 percent of the total votes cast at the referendum election, and be filed no later than 15 days before the time fixed for the election. Ten days' previous notice of the election shall be given by the county clerk by publication in the newspapers selected under s. 66.0211(2) and by posting notices in 3 public places in the village or city, but failure to give notice does not invalidate the election.

(b) The election shall be conducted as prescribed by ch. 6. The inspectors shall make returns to the county clerk who shall, within 14 days after the election, canvass the returns and declare the result. The clerk shall notify the officers-elect and issue certificates of election. If the first election is on the first Tuesday in April the officers elected and their appointees shall commence and hold their offices as for a regular term. Otherwise they shall commence within 14 days and hold their offices until the regular village or city election and the qualification of their successors and the terms of their appointees expire as soon as successors qualify.

(5) Taxes levied before incorporation; how collected and divided. If a village or city is incorporated after the assessment of taxes in any year and before the collection of the taxes, the tax assessed shall be collected by the town treasurer of the town or the town treasurers of the different towns of which the village or city formerly constituted a part, and all moneys collected from the tax levied for town purposes shall be divided between the village or city and the town or the towns, as provided by s. 66.0235(13)(a)1., for the division of property owned jointly by towns and villages.

(6) Reorganization of city as village. If the population of any city falls below 1,000 as determined by the United States census, the council may upon filing of a petition conforming to the requirements of s. 8.40 containing the signatures of at least 15 percent of the electors submit at any general or city election the question whether the city shall reorganize as a village. If three-fifths of the votes cast on the question are for reorganization the mayor and council shall record the return in the office of the register of deeds, file a certified copy with the clerk of the circuit court, and immediately call an election, to be conducted as are village elections, for the election of village officers. Upon the qualification of the officers, the board of trustees shall declare the city reorganized as a village, and the reorganization is effective. The clerk shall certify a copy of the declaration to the secretary of administration who shall file the declaration and endorse a memorandum of the declaration on the record of the certificate of incorporation of the city. Rights and liabilities of the city continue in favor of or against the village. Ordinances, so far as within the power of the village, remain in force until changed.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (20)

W. S. A. 66.0213, WI ST 66.0213
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0215

66.0215. Incorporation of certain towns adjacent to 1st class cities

Currentness

(1) Petition. If the resident population of a town exceeds 5,000 as shown by the last federal census or by a census under sub. (2), if the town is adjacent to a 1st class city and contains an equalized valuation in excess of $20,000,000 and if a petition signed by 100 or more persons, each an elector and taxpayer of the town, containing the signatures of at least 50 percent of the owners of real estate in the town and requesting submission of the question to the electors of the town, is filed with the clerk of the town, the procedure for becoming a 4th class city is initiated.

(2) Referendum. At the next regular meeting of the town board following the filing of the petition under sub. (1), the board by resolution shall provide for a referendum by the electors of the town. The resolution shall conform to the requirements of s. 5.15(1) and (2) and shall determine the numbers and boundaries of each ward of the proposed city and the time of voting, which may not be earlier than 6 weeks after the adoption of the resolution. The resolution may direct that a census be taken of the resident population of the territory on a day not more than 10 weeks previous to the date of the election, exhibiting the name of every head of a family and the name of every person who is a resident in good faith of the territory on that day, and the lot or quarter section of land on which that person resides, which shall be verified by the affixed affidavit of the person taking the census.

(3) Notice of referendum. Notice of the referendum shall be given by publication of the resolution in a newspaper published in the town, if there is one, otherwise in a newspaper designated in the resolution, once a week for 4 successive weeks, the first publication to be not more than 4 weeks before the referendum.

(4) Voting procedure. The referendum shall be conducted in the same manner as elections for supervisors of the town board. The question appearing on the ballot shall be “Shall the town of ... become a 4th class city?”. Below the question shall appear 2 squares. To the left of one square shall appear the words “For a city” and to the left of the other square shall appear the words “Against a city”. The inspectors shall make a return to the clerk of the town.

(5) Certificate of incorporation. If a majority of the votes are cast in favor of a city the clerk shall certify the fact to the secretary of administration, together with the result of the census, if any, and 4 copies of a description of the legal boundaries of the town and 4 copies of a plat of the town. The secretary of administration shall then issue a certificate of incorporation, and record the certificate in a book kept for that purpose. Two copies of the description and plat shall be forwarded by the secretary of administration to the department of transportation and one copy to the department of revenue.

(6) City powers. A city incorporated under this section is a body corporate and politic, with the powers and privileges of a municipal corporation at common law and conferred by ch. 62.

(7) Existing ordinances. Ordinances in force in the territory or any part of the territory, to the extent not inconsistent with ch. 62, continue in force until altered or repealed.

(8) Interim officers. All officers of the town embracing the territory incorporated as a city continue in their powers and duties until the first meeting of the common council at which a quorum is present. Until a city clerk is chosen and qualified all oaths of office and other papers shall be filed with the town clerk, with whom the petition was filed, who shall deliver them with the petition to the city clerk when the city clerk is qualified.

(9) First city election. Within 10 days after incorporation of the city, the town board and the town clerk who received the petition shall fix a time for the first city election, designate the polling place or places, and name 3 inspectors of election for each place. Ten days' previous notice of the election shall be given by the clerk by publication in the newspapers selected under sub. (3) and by posting notices in 3 public places in the city. Failure to give notice does not invalidate the election. The election shall be conducted as is prescribed by chs. 5 to 12. The inspectors shall make returns to the board which shall, within 14 days after the election, canvass the returns and declare the result. The clerk shall notify the officers-elect and issue certificates of election. If the first election is on the first Tuesday in April the officers elected and their appointees commence and hold their offices as for a regular term. Otherwise they commence within 14 days and hold until the regular city election and the qualification of their successors, and the term of their appointees expires as soon as successors qualify.

Credits

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Notes of Decisions (10)

W. S. A. 66.0215, WI ST 66.0215
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.0216. Repealed by 2015 Act 196, § 62, eff. March 2, 2016

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W.S.A. 66.0216

66.0216. Repealed by 2015 Act 196, § 62, eff. March 2, 2016

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0216, WI ST 66.0216
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.02162

66.02162. Incorporation of certain towns contiguous to 3rd class cities or villages

Currentness

(1) Conditions. A town board may initiate the procedure for incorporating its town as a village under this section by adopting a resolution providing for a referendum by the electors of the town on the question of whether the town should become a village if on the date of the adoption of the resolution any of the following is satisfied:

(a) All of the following conditions apply:

1. The most recent federal decennial census shows that the resident population of the town exceeds 6,300.

2. The town is contiguous to a 3rd class city.

3. The most recent data available from the department of revenue show that the equalized value for the town exceeds $600,000,000.

4. In one of the 5 years before the year in which the town board adopts the resolution, the town's equalized value increased more than 7 percent, compared to the town's equalized value for the prior year.

5. The town board of the town is authorized to exercise village powers.

6. The town has entered into, and is bound by, at least 2 separate cooperative boundary agreements under s. 66.0307 with at least 2 municipalities.

7. The town has created at least one tax incremental financing district as authorized under s. 60.23(32).

8. The town has established at least one town sanitary district under subch. IX of ch. 60.

(b) All of the following conditions apply:

1. The most recent federal decennial census shows that the resident population of the town exceeds 2,300.

2. The most recent data available from the department of revenue show that the equalized value for the town exceeds $190,000,000.

3. The area of the town exceeds 40 square miles.

4. The town is contiguous to a village to which all of the following conditions apply:

a. The most recent federal decennial census shows that the resident population of the village is less than 300.

b. The area of the village is less than 2 square miles.

c. The aggregate net tax rate of the village, as determined by the department of revenue under s. 70.114(3), is greater than 36 mills.

5. The village under subd. 4. and the town are located in a county for which the most recent federal decennial census shows that the resident population is less than 150,000.

(2) Referendum resolution. The resolution of the town board required under sub. (1) shall do all of the following:

(a) Certify that the requirements under sub. (1) are satisfied.

(b) Contain a description of the territory to be incorporated sufficiently accurate to determine its location and a statement that a scale map reasonably showing the boundaries of the territory is on file with the town clerk.

(c) Determine the numbers and boundaries of each ward of the proposed village, conforming to the requirements of s. 5.15(1) and (2).

(d) Determine the date of the referendum, which may not be earlier than 6 weeks after the adoption of the resolution.

(3) Notice of referendum. The town clerk shall publish the resolution adopted under sub. (1) in a newspaper published in the town. If no newspaper is published in the town, the town clerk shall publish the resolution in a newspaper designated in the resolution. The town clerk shall publish the resolution once a week for 4 successive weeks, the first publication to be not more than 4 weeks before the referendum.

(4) Voting procedure. The referendum shall be conducted in the same manner as elections for town board supervisors. The question appearing on the ballot shall be: “Shall the town of .... become a village?” Below the question shall appear 2 squares. To the left of one square shall appear the words “For a village,” and to the left of the other square shall appear the words “Against a village.” The inspectors shall make a return to the town clerk.

(5) Certificate of incorporation. If a majority of the votes are cast in favor of a village, the town clerk shall certify that fact to the secretary, together with 4 copies of a description of the legal boundaries of the town, and 4 copies of a plat of the town. The town clerk shall also send the secretary an incorporation fee of $1,000. Upon receipt of the town clerk's certification, the incorporation fee, and other required documents, the secretary shall issue a certificate of incorporation and record the certificate in a book kept for that purpose. The secretary shall provide 2 copies of the description and plat to the department of transportation and one copy to the department of revenue. The town clerk shall also transmit a copy of the certification and the resolution under sub. (1) to the county clerk.

(6) Action. No action to contest the validity of an incorporation under this section on any grounds, whether procedural or jurisdictional, may be commenced after 60 days from the date of issuance of the certificate of incorporation by the secretary. In any such action, the burden of proof as to all issues is upon the person bringing the action to show that the incorporation is not valid. An action contesting an incorporation shall be given preference in the circuit court.

(7) Village powers. A village incorporated under this section is a body corporate and politic, with the powers and privileges of a municipal corporation at common law and conferred by ch. 61.

(8) Existing ordinances. Ordinances in force in the territory or any part of the territory, to the extent not inconsistent with this section or ch. 61, continue in force until altered or repealed.

(9) Existing intergovernmental and cooperative boundary agreements. Intergovernmental cooperation agreements entered into under s. 66.0301 and cooperative boundary agreements approved under s. 66.0307, to which a town incorporating under this section is a party, that are still in effect on the effective date of the incorporation, shall continue in force until altered or repealed, to the extent allowed under the agreements. When incorporated under this section, a village shall be considered the town's successor with respect to such agreements.

(10) Interim officers, first village election. Section 66.0215(8) and (9), as it applies to a town that is incorporated as a city under s. 66.0215, applies to a town that is incorporated as a village under this section.

(11) Sunset. This section does not apply after June 30, 2020.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.02162, WI ST 66.02162
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.02165

66.02165. Limitations on newly created incorporated village or city

Currentness

For a 5-year period after incorporation under this subchapter, a newly incorporated city or village may not add or contract to add any remaining town territory of the town from which the newly incorporated city or village was created by use of consolidation, a boundary agreement, or annexation other than annexation by unanimous approval under s. 66.0217(2), except that the city or village and town territory remaining after incorporation may consolidate as permitted under s. 66.0230.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.02165, WI ST 66.02165
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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W.S.A. 66.0217

66.0217. Annexation initiated by electors and property owners

Currentness

(1) Definitions. In this section, unless the context clearly requires otherwise:

(a) "Assessed value" means the value for general tax purposes as shown on the tax roll for the year next preceding the filing of any petition for annexation.

(b) "Department" means the department of administration.

(c) "Legal description" means a complete description of land to be annexed without internal references to any other document, and shall be described in one of the following ways:

1. By metes and bounds commencing at a monument at the section or quarter section corner or at the end of a boundary line of a recorded private claim or federal reservation in which the annexed land is located and in one of the following ways:

a. By government lot.

b. By recorded private claim.

c. By quarter section, section, township and range.

2. If the land is located in a recorded and filed subdivision or in an area subject to a certified survey map, by reference as described in s. 236.28 or s. 236.34(3).

(d) "Owner" means the holder of record of an estate in possession in fee simple, or for life, in land or real property, or a vendee of record under a land contract for the sale of an estate in possession in fee simple or for life but does not include the vendor under a land contract. A tenant in common or joint tenant is an owner to the extent of his or her interest.

(e) “Petition” includes the original petition and any counterpart of the original petition.

(f) “Real property” means land and the improvements to the land.

(g) “Scale map” means a map that accurately reflects the legal description of the property to be annexed and the boundary of the annexing city or village, and that includes a graphic scale on the face of the map.

(2) Direct annexation by unanimous approval. Except as provided in this subsection and sub. (14), and subject to ss. 66.0301(6)(d) and 66.0307(7), if a petition for direct annexation signed by all of the electors residing in the territory and the owners of all of the real property in the territory is filed with the city or village clerk, and with the town clerk of the town or towns in which the territory is located, together with a scale map and a legal description of the property to be annexed, an annexation ordinance for the annexation of the territory may be enacted by a two-thirds vote of the elected members of the governing body of the city or village without compliance with the notice requirements of sub. (4). In an annexation under this subsection, subject to sub. (6), the person filing the petition with the city or village clerk and the town clerk shall, within 5 days of the filing, mail a copy of the scale map and a legal description of the territory to be annexed to the department and the governing body shall review the advice of the department, if any, before enacting the annexation ordinance. No territory may be annexed by a city or village under this subsection unless the territory to be annexed is contiguous to the annexing city or village.

(3) Other methods of annexation. Subject to ss. 66.0301(6)(d) and 66.0307(7), and except as provided in sub. (14), territory contiguous to a city or village may be annexed to the city or village in the following ways:

(a) *Direct annexation by one-half approval.* A petition for direct annexation may be filed with the city or village clerk if it has been signed by either of the following:

1. A number of qualified electors residing in the territory subject to the proposed annexation equal to at least the majority of votes cast for governor in the territory at the last gubernatorial election, and either of the following:

a. The owners of one-half of the land in area within the territory.

b. The owners of one-half of the real property in assessed value within the territory.

2. If no electors reside in the territory subject to the proposed annexation, by either of the following:

a. The owners of one-half of the land in area within the territory.

b. The owners of one-half of the real property in assessed value within the territory.

(b) *Annexation by referendum.* A petition for a referendum on the question of annexation may be filed with the city or village clerk signed by a number of qualified electors residing in the territory equal to at least 20 percent of the votes cast for governor

in the territory at the last gubernatorial election, and the owners of at least 50 percent of the real property either in area or assessed value. The petition shall conform to the requirements of s. 8.40.

(4) Notice of proposed annexation. (a) An annexation under sub. (3) shall be initiated by publishing in the territory proposed for annexation a class 1 notice, under ch. 985, of intention to circulate an annexation petition. The notice shall contain:

1. A statement of intention to circulate an annexation petition.

2. A legal description of the territory proposed to be annexed and a copy of a scale map.

3. The name of the city or village to which the annexation is proposed.

4. The name of the town or towns from which the territory is proposed to be detached.

5. The name and post-office address of the person causing the notice to be published who shall be an elector or owner in the area proposed to be annexed.

6. A statement that a copy of the scale map may be inspected at the office of the town clerk for the territory proposed to be annexed and the office of the city or village clerk for the city or village to which the territory is proposed to be annexed.

(b) The person who has the notice published shall serve a copy of the notice, within 5 days after its publication, upon the clerk of each municipality affected, upon the clerk of each school district affected and upon each owner of land in a town if that land will be in a city or village after the annexation. Service may be either by personal service or by certified mail with return receipt requested. If required under sub. (6)(a), a copy of the notice shall be mailed to the department as provided in that paragraph.

(5) Annexation petition. (a) An annexation petition under this section shall state the purpose of the petition, contain a legal description of the territory proposed to be annexed and have attached a scale map. The petition shall also specify the population of the territory. In this paragraph, "population" means the population of the territory as shown by the last federal census, by any subsequent population estimate certified as acceptable by the department or by an actual count certified as acceptable by the department.

(b) No person who has signed a petition may withdraw his or her name from the petition. No additional signatures may be added after a petition is filed.

(c) The circulation of the petition shall commence not less than 10 days nor more than 20 days after the date of publication of the notice of intention to circulate. The annexation petition is void unless filed within 6 months of the date of publication of the notice.

(6) Department review of annexations. (a) *Annexations within populous counties.* No annexation proceeding within a county having a population of 50,000 or more is valid unless the person publishing a notice of annexation under sub. (4) mails a copy of the notice to the clerk of each municipality affected and the department, together with any fee imposed under s. 16.53(14), within

5 days of the publication. The department shall within 20 days after receipt of the notice mail to the clerk of the town within which the territory lies and to the clerk of the proposed annexing village or city a notice that states whether in its opinion the annexation is in the public interest or is against the public interest and that advises the clerks of the reasons the annexation is in or against the public interest as defined in par. (c). The annexing municipality shall review the advice before final action is taken.

(b) *Alternative dispute resolution.* The department shall make available on its public website a list of persons who identify themselves to the department as professionals qualified to facilitate alternative dispute resolution of annexation, boundary, and land use disputes. Persons identifying themselves to the department as qualified professionals shall submit to the department a brief description of their qualifications, including membership in relevant professional associations and certifications in areas such as planning and alternative dispute resolution. The department may edit the descriptions for inclusion on the list using any criteria that, in the department's determination, is appropriate. The department may include with the list a disclaimer that the department is not responsible for the accuracy of the descriptions, and that inclusion of a person on the list does not represent endorsement by the department. The department may include links from the list to other websites, such as those of relevant professional associations and county dispute resolution centers.

(c) *Definition of public interest.* For purposes of this subsection "public interest" is determined by the department after consideration of the following:

1. Whether the governmental services, including zoning, to be supplied to the territory could clearly be better supplied by the town or by some other village or city whose boundaries are contiguous to the territory proposed for annexation which files with the circuit court a certified copy of a resolution adopted by a two-thirds vote of the elected members of the governing body indicating a willingness to annex the territory upon receiving an otherwise valid petition for the annexation of the territory.

2. The shape of the proposed annexation and the homogeneity of the territory with the annexing village or city and any other contiguous village or city.

(d) *Direct annexation by unanimous approval.* 1. Upon the request of the town affected by the annexation, the department shall review an annexation under sub. (2) to determine whether the annexation violates any of the following, provided that the town submits its request to the department within 30 days of the enactment of the annexation ordinance:

a. The requirement under sub. (2) regarding the contiguity of the territory to be annexed with the annexing city or village.

b. The requirement under sub. (14)(b).

2. Following its review, and within 20 days of receiving the town's request, the department shall send a copy of its findings to any affected landowner, the town affected by the annexation, and the annexing city or village. If the department does not complete its review and send a copy of its findings within 20 days of receiving the town's request, the effect on the town and the annexing city or village shall be the same as if the department found no violation of the requirements specified in subd. 1. If the department finds that an annexation violates any requirement specified in subd. 1., the town from which territory is annexed may, within 45 days of its receipt of the department's findings, challenge the annexation in circuit court.

3. If the town commences an action to challenge the annexation and the circuit court rules against the town, the town shall pay the court costs and the city's or village's reasonable attorney fees incurred in defending the annexation. If the town commences

an action to challenge the annexation and the circuit court rules in the town's favor and upholds the town's challenge, the city or village shall pay the court costs and the town's reasonable attorney fees incurred in challenging the annexation.

(7) Referendum. (a) *Notice.* 1. Within 60 days after the filing of the petition under sub. (3), the common council or village board may accept or reject the petition and if rejected no further action may be taken on the petition. Acceptance may consist of adoption of an annexation ordinance. Failure to reject the petition obligates the city or village to pay the cost of any referendum favorable to annexation.

2. If the petition is not rejected the clerk of the city or village with whom the annexation petition is filed shall give written notice of the petition by personal service or registered mail with return receipt requested to the clerk of any town from which territory is proposed to be detached and shall give like notice to any person who files a written request with the clerk. The notice shall indicate whether the petition is for direct annexation or whether it requests a referendum on the question of annexation.

3. If the notice indicates that the petition is for a referendum on the question of annexation, the clerk of the city or village shall file the notice as provided in s. 8.37. If the notice indicates that the petition is for a referendum on the question of annexation, the town clerk shall give notice as provided in par. (c) of a referendum of the electors residing in the area proposed for annexation to be held not less than 70 days nor more than 100 days after the date of personal service or mailing of the notice required under this paragraph. If the notice indicates that the petition is for direct annexation, no referendum shall be held unless within 30 days after the date of personal service or mailing of the notice required under this paragraph, a petition conforming to the requirements of s. 8.40 requesting a referendum is filed with the town clerk as provided in s. 8.37, signed by at least 20 percent of the electors residing in the area proposed to be annexed. If a petition requesting a referendum is filed, the clerk shall give notice as provided in par. (c) of a referendum of the electors residing in the area proposed for annexation to be held not less than 70 days nor more than 100 days after the receipt of the petition and shall mail a copy of the notice to the clerk of the city or village to which the annexation is proposed. The referendum shall be held at a convenient place within the town to be specified in the notice.

(b) *Clerk to act.* If more than one town is involved, the city or village clerk shall determine as nearly as is practicable which town contains the most electors in the area proposed to be annexed and shall indicate in the notice required under par. (a) that determination. The clerk of the town so designated shall perform the duties required under this subsection and the election shall be conducted in the town as are other elections.

(c) *Publication of notice.* The notice shall be published in a newspaper of general circulation in the area proposed to be annexed on the publication day next preceding the referendum election and one week prior to that publication.

(d) *How conducted.* The referendum shall be conducted by the town election officials but the town board may reduce the number of election officials for that election. The ballots shall contain the words “For annexation” and “Against annexation” and shall otherwise conform to the provisions of s. 5.64(2). The election shall be conducted as are other town elections in accordance with chs. 6 and 7 to the extent applicable.

(e) *Canvass; statement to be filed.* The election inspectors shall make a statement of the holding of the election showing the whole number of votes cast, and the number cast for and against annexation, attach their affidavit to the statement and immediately file it in the office of the town clerk. They shall file a certified statement of the results in the office of the clerk of each other municipality affected.

(f) *Costs.* If the referendum is against annexation, the costs of the election shall be borne by the towns involved in the proportion that the number of electors of each town within the territory proposed to be annexed, voting in the referendum, bears to the total number of electors in that territory, voting in the referendum.

(g) *Effect.* If the result of the referendum is against annexation, all previous proceedings are nullified. If the result of the referendum is for annexation, failure of any town official to perform literally any duty required by this section does not invalidate the annexation.

(8) Annexation ordinance. (a) An ordinance for the annexation of the territory described in the annexation petition under sub. (3) may be enacted by a two-thirds vote of the elected members of the governing body not less than 20 days after the publication of the notice of intention to circulate the petition and not later than 120 days after the date of filing with the city or village clerk of the petition for annexation or of the referendum election if favorable to the annexation. If the annexation is subject to sub. (6) the governing body shall first review the reasons given by the department that the proposed annexation is against the public interest. An ordinance under this subsection may temporarily designate the classification of the annexed area for zoning purposes until the zoning ordinance is amended as prescribed in s. 62.23(7)(d). Before introduction of an ordinance containing a temporary classification, the proposed classification shall be referred to and recommended by the plan commission. The authority to make a temporary classification is not effective when the county ordinance prevails during litigation as provided in s. 59.69(7).

(b) The ordinance may annex the territory to an existing ward or may create an additional ward.

(c) The annexation is effective upon enactment of the annexation ordinance. The board of school directors in a 1st class city is not required to administer the schools in any territory annexed to the city until July 1 following the annexation.

(9) Filing requirements; surveys. (a) The clerk of a city or village which has annexed territory shall file immediately with the secretary of administration a certified copy of the ordinance, certificate and plat, and shall send one copy to each company that provides any utility service in the area that is annexed. The city or village shall also file with the county clerk or board of election commissioners the report required by s. 5.15(4)(b). The clerk shall record the ordinance with the register of deeds and file a signed copy of the ordinance with the clerk of any affected school district. Failure to file, record or send does not invalidate the annexation and the duty to file, record or send is a continuing one. The ordinance that is filed, recorded or sent shall describe the annexed territory and the associated population. The information filed with the secretary of administration shall be utilized in making recommendations for adjustments to entitlements under the federal revenue sharing program and distribution of funds under ch. 79. The clerk shall certify annually to the secretary of administration and record with the register of deeds a legal description of the total boundaries of the municipality as those boundaries existed on December 1, unless there has been no change in the 12 months preceding.

(b) Within 10 days of receipt of the ordinance, certificate and plat, the secretary of administration shall forward 2 copies of the ordinance, certificate and plat to the department of transportation, one copy to the department of administration, one copy to the department of revenue, one copy to the department of public instruction, one copy to the department, one copy to the department of natural resources, one copy to the department of agriculture, trade and consumer protection and 2 copies to the clerk of the municipality from which the territory was annexed.

(c) Any city or village may direct a survey of its present boundaries to be made, and when properly attested the survey and plat may be filed in the office of the register of deeds in the county in which the city or village is located. Upon filing, the survey and plat are prima facie evidence of the facts set forth in the survey and plat.

(10) Qualifications of electors and owners; elector determination. (a) Under this section, qualifications as to electors and owners shall be determined as of the date of filing a petition, except that all qualified electors residing in the territory proposed for annexation on the day of a referendum election may vote in the election. Residence and ownership shall be bona fide and not acquired for the purpose of defeating or invalidating the annexation proceedings.

(b) For purposes of this section, if a number of electors cannot be determined on the basis of reported election statistics, the number shall be determined in accordance with s. 60.74(6).

(11) Action to contest annexation. (a) An action on any grounds, whether procedural or jurisdictional, to contest the validity of an annexation shall be commenced within the time after adoption of the annexation ordinance provided by s. 893.73(2). During the action, the application of, and jurisdiction over, any county zoning in the area annexed is as provided under s. 59.69(7).

(b) An action contesting an annexation shall be given preference in the circuit court. The court and the parties are encouraged to consider the application of s. 802.12 to an action contesting an annexation.

(c) Except as provided in sub. (6)(d) 2., no action on any grounds, whether procedural or jurisdictional, to contest the validity of an annexation under sub. (2), may be brought by any town.

(12) Validity of plats. If an annexation is declared invalid but before the declaration and subsequent to the annexation a plat is submitted and is approved as required in s. 236.10(1)(a), the plat is validly approved despite the invalidity of the annexation.

(13) Effective date of annexations. Because the creation of congressional, legislative, supervisory and aldermanic districts of equal population is a matter of statewide concern, any annexation action that affects a tract of land that is the subject of an ordinance enacted or resolution adopted by any city during the period from January 1, 1990, to April 1, 1991, or any later date, expressing an intent to not exercise the city's authority to annex territory before April 1, 1991, or the specified later date, taken by a municipality during the period beginning on April 1 of the year commencing after each federal decennial census of population and ending on June 30 of the year commencing after that census, is effective on July 1 of the year commencing after that census or at such later date as may be specified in the annexation ordinance. This subsection first applies to annexations effective after March 31, 1991.

(14) Limitations on annexation authority. (a)1. Except as provided in subd. 2., no territory may be annexed by a city or village under this section unless the city or village agrees to pay annually to the town, for 5 years, an amount equal to the amount of property taxes that the town levied on the annexed territory, as shown by the tax roll under s. 70.65, in the year in which the annexation is final.

2. No payments under subd. 1. must be made if the city or village, and the town, enter into a boundary agreement under s. 66.0225, 66.0301, or 66.0307.

(b)1. No territory may be annexed by a city or village under this section if no part of the city or village is located in the same county as the territory that is subject to the proposed annexation unless one of the following applies:

a. The town board adopts a resolution approving the proposed annexation.

b. The annexation is by unanimous approval under sub. (2).

2. Any subsequent annexation by the city or village in the county of the territory annexed under subd. 1. shall either be approved by the town board or be annexed by unanimous approval under sub. (2).

(15) Law applicable. Section 66.0203(8)(c) applies to annexations under this section.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

LAW REVISION COMMITTEE PREFATORY NOTE--2017 ACT 360

This bill is a remedial legislation proposal, requested by the Legislative Technology Services Bureau and introduced by the Law Revision Committee under s. 13.83(1)(c)4. and 5., stats. After careful consideration of the various provisions of the bill, the Law Revision Committee has determined that this bill makes minor substantive changes in the statutes, and that these changes are desirable as a matter of public policy.

Notes of Decisions (255)

W. S. A. 66.0217, WI ST 66.0217
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter II. Incorporation; Municipal Boundaries

W.S.A. 66.0219

66.0219. Annexation by referendum initiated by city or village

Currentness

As a complete alternative to any other annexation procedure, and subject to sub. (10) and ss. 66.0301(6)(d) and 66.0307(7), unincorporated territory which contains electors and is contiguous to a city or village may be annexed to the city or village under this section. The definitions in s. 66.0217(1) apply to this section.

(1) Procedure for annexation. (a) The governing body of the city or village to which it is proposed to annex territory shall, by resolution adopted by two-thirds of the members-elect, declare its intention to apply to the circuit court for an order for an annexation referendum, and shall publish the resolution in a newspaper having general circulation in the area proposed to be annexed, as a class 1 notice, under ch. 985. The governing body shall prepare a scale map of the territory to be annexed, showing it in relation to the annexing city or village. The resolution shall contain a description of the territory to be affected, sufficiently accurate to determine its location, the name of the municipalities directly affected and the name and post-office address of the municipal official responsible for the publication of the resolution. A copy of the resolution together with the scale map shall be served upon the clerk of the town or towns from which the territory is to be detached within 5 days of the date of publication of the resolution. Service may be either by personal service or by registered mail and if by registered mail an affidavit shall be on file with the annexing body indicating the date on which the resolution was mailed. The annexation is considered commenced upon publication of the resolution.

(b) Application to the circuit court shall be by petition subscribed by the officers designated by the governing body, and shall have attached the scale map, a certified copy of the resolution of the governing body and an affidavit of the publication and filing required under par. (a). The petition shall be filed in the circuit court not less than 30 days but no more than 45 days after the publication of the notice of intention.

(2) Protest to court by electors; hearing. (a) If, prior to the date set for hearing upon an application filed under sub. (1)(b), there is filed with the court a petition signed by a number of qualified electors residing in the territory equal to at least a majority of the votes cast for governor in the territory at the last gubernatorial election or the owners of more than one-half of the real property in assessed value in the territory, protesting against the annexation of the territory, the court shall deny the application for an annexation referendum. If a number of electors cannot be determined on the basis of reported election statistics, the number shall be determined in accordance with s. 60.74(6).

(b) If a petition protesting the annexation is found insufficient the court shall proceed to hear all parties interested for or against the application. The court may adjourn the hearing from time to time, direct a survey to be made and refer any question for examination and report. A town whose territory is involved in the proposed annexation shall, upon application, be a party and is entitled to be heard on any relevant matter.

(3) Dismissal. If for any reason the proceedings are dismissed, the court may order entry of judgment against the city or village for disbursements or any part of disbursements incurred by the parties opposing the annexation.

(4) Referendum election; when ordered and held. (a) If the court, after the hearing, is satisfied that the description of the territory or any survey is accurate and that the provisions of this section have been complied with, it shall make an order so declaring and shall direct a referendum election within the territory described in the order, on the question of whether the area should be annexed. Such order shall be filed as provided in s. 8.37. The order shall direct 3 electors named in the order residing in the town in which the territory proposed to be annexed lies, to perform the duties of inspectors of election.

(b) The referendum election shall be held not less than 70 days nor more than 100 days after the filing of the order as provided in s. 8.37, in the territory proposed for annexation, by the electors of that territory as provided in s. 66.0217(7), so far as applicable. The ballots shall contain the words “For Annexation” and “Against Annexation”. The certification of the election inspectors shall be filed with the clerk of the court, and the clerk of any municipality involved, but need not be filed or recorded with the register of deeds.

(c) All costs of the referendum election shall be borne by the petitioning city or village.

(5) Determination by vote. (a) If a majority of the votes cast at the referendum election is against annexation, no other proceeding under this section affecting the same territory or part of the same territory may be commenced by the same municipality until 6 months after the date of the referendum election.

(b) If a majority of the votes cast at the referendum election is for annexation, the territory shall be annexed to the petitioning city or village upon compliance with s. 66.0217(9).

(6) Temporary zoning of area proposed to be annexed. An interim zoning ordinance to become effective only upon approval of the annexation at the referendum election may be enacted by the governing body of the city or village. The ordinance may temporarily designate the classification of the annexed area for zoning purposes until the zoning ordinance is amended as prescribed in s. 62.23(7)(d). The proposed interim zoning ordinance shall be referred to and recommended by the plan commission prior to introduction. Authority to make a temporary classification is not effective when the county zoning ordinance prevails during litigation as provided in s. 59.69(7).

(7) Appeal. An appeal from the order of the circuit court is limited to contested issues determined by the circuit court. An appeal shall not stay the conduct of the referendum election, if one is ordered, but the statement of the election results and the copies of the certificate and plat may not be filed with the secretary of administration until the appeal has been determined.

(8) Law applicable. Sections 66.0203(8)(c) and 66.0217(11) apply to annexations under this section.

(9) Territory excepted. This section does not apply to any territory located in an area for which a certificate of incorporation was issued before February 24, 1959, by the secretary of state, even if the incorporation of the territory is later held to be invalid by a court.

(10) Limitations on annexation authority. (a)1. Except as provided in subd. 2., no territory may be annexed by a city or village under this section unless the city or village agrees to pay annually to the town, for 5 years, an amount equal to the amount of property taxes that the town levied on the annexed territory, as shown by the tax roll under s. 70.65, in the year in which the annexation is final.

2. No payments under subd. 1. must be made if the city or village, and the town, enter into a boundary agreement under s. 66.0225, 66.0301, or 66.0307.

(b) No territory may be annexed by a city or village under this section if no part of the city or village is located in the same county as the territory that is subject to the proposed annexation unless all of the following occur:

1. The town board adopts a resolution approving the proposed annexation.

2. The county board of the county in which the territory is located adopts a resolution approving the proposed annexation.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

W. S. A. 66.0219, WI ST 66.0219
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.022

66.022. Renumbered 66.0227 and amended by 1999 Act 150, § 66, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.022, WI ST 66.022
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter II. Incorporation; Municipal Boundaries

W.S.A. 66.0221

66.0221. Annexation of and creation of town islands

Currentness

(1) Upon its own motion and subject to sub. (3) and ss. 66.0301(6)(d) and 66.0307(7), a city or village, by a two-thirds vote of the entire membership of its governing body, may enact an ordinance annexing territory which comprises a portion of a town or towns and which was completely surrounded by territory of the city or village on December 2, 1973. The ordinance shall include all surrounded town areas except those that are exempt by mutual agreement of all of the governing bodies involved. The annexation ordinance shall contain a legal description of the territory and the name of the town or towns from which the territory is detached. Upon enactment of the ordinance, the city or village clerk immediately shall file 6 certified copies of the ordinance with the secretary of administration, together with 6 copies of a scale map. The city or village shall also file with the county clerk or board of election commissioners the report required by s. 5.15(4)(b). The secretary of administration shall forward 2 copies of the ordinance and scale map to the department of transportation, one copy to the department of natural resources, one copy to the department of revenue and one copy to the department of administration. This subsection does not apply if the town island was created only by the annexation of a railroad right-of-way or drainage ditch. This subsection does not apply to land owned by a town government which has existing town government buildings located on the land. No town island may be annexed under this subsection if the island consists of over 65 acres or contains over 100 residents. Section 66.0217(11) applies to annexations under this subsection. Except as provided in sub. (2), after December 2, 1973, no city or village may, by annexation, create a town area which is completely surrounded by the city or village.

(2) A city or village may, by annexation, create a town area that is completely surrounded by the city or village if a cooperative plan for boundary change under s. 66.0301(6) or 66.0307, to which the town and the annexing city or village are parties, applies to the territory that is annexed.

(3)(a)1. Except as provided in subd. 2., no territory may be annexed by a city or village under this section unless the city or village agrees to pay annually to the town, for 5 years, an amount equal to the amount of property taxes that the town levied on the annexed territory, as shown by the tax roll under s. 70.65, in the year in which the annexation is final.

2. No payments under subd. 1. must be made if the city or village, and the town, enter into a boundary agreement under s. 66.0225, 66.0301, or 66.0307.

(b) No territory may be annexed by a city or village under this section if no part of the city or village is located in the same county as the territory that is subject to the proposed annexation unless all of the following occur:

1. The town board adopts a resolution approving the proposed annexation.

2. The county board of the county in which the territory is located adopts a resolution approving the proposed annexation.

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

LAW REVISION COMMITTEE PREFATORY NOTE--2017 ACT 360

This bill is a remedial legislation proposal, requested by the Legislative Technology Services Bureau and introduced by the Law Revision Committee under s. 13.83(1)(c)4. and 5., stats. After careful consideration of the various provisions of the bill, the Law Revision Committee has determined that this bill makes minor substantive changes in the statutes, and that these changes are desirable as a matter of public policy.

Notes of Decisions (10)

W. S. A. 66.0221, WI ST 66.0221
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0223

66.0223. Annexation of territory owned by a city or village

Currentness

(1) In addition to other methods provided by law and subject to sub. (2) and ss. 66.0301(6)(d) and 66.0307(7), territory owned by and lying near but not necessarily contiguous to a village or city may be annexed to a village or city by ordinance enacted by the board of trustees of the village or the common council of the city, provided that in the case of noncontiguous territory the use of the territory by the city or village is not contrary to any town or county zoning regulation. The ordinance shall contain the exact description of the territory annexed and the names of the towns from which detached, and attaches the territory to the village or city upon the filing of 7 certified copies of the ordinance with the secretary of administration, together with 7 copies of a plat showing the boundaries of the territory attached. The city or village shall also file with the county clerk or board of election commissioners the report required by s. 5.15(4)(b). Two copies of the ordinance and plat shall be forwarded by the secretary of administration to the department of transportation, one copy to the department of administration, one copy to the department of natural resources, one copy to the department of revenue and one copy to the department of public instruction. Within 10 days of filing the certified copies, a copy of the ordinance and plat shall be mailed or delivered to the clerk of the county in which the annexed territory is located. Sections 66.0203(8)(c) and 66.0217(11) apply to annexations under this section.

(2) No territory may be annexed by a city or village under this section if no part of the city or village is located in the same county as the territory that is subject to the proposed annexation unless all of the following occur:

(a) The town board adopts a resolution approving the proposed annexation.

(b) The county board of the county in which the territory is located adopts a resolution approving the proposed annexation.

(c) The city or village, and the town, enter into a boundary agreement under s. 66.0225, 66.0301, or 66.0307.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

LAW REVISION COMMITTEE PREFATORY NOTE--2017 ACT 360

This bill is a remedial legislation proposal, requested by the Legislative Technology Services Bureau and introduced by the Law Revision Committee under s. 13.83(1)(c)4. and 5., stats. After careful consideration of the various

provisions of the bill, the Law Revision Committee has determined that this bill makes minor substantive changes in the statutes, and that these changes are desirable as a matter of public policy.

Notes of Decisions (2)

W. S. A. 66.0223, WI ST 66.0223
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0225

66.0225. Stipulated boundary agreements in contested boundary actions

Currentness

(1) Definitions. In this section, "municipality" means a city, village, or town.

(2) Contested annexations. Any 2 municipalities whose boundaries are immediately adjacent at any point and who are parties to an action, proceeding, or appeal in court for the purpose of testing the validity of an annexation may enter into a written stipulation, compromising and settling the litigation and determining the portion of the common boundary line between the municipalities that is the subject of the annexation. The court having jurisdiction of the litigation, whether the circuit court, the court of appeals, or the supreme court, may enter a final judgment incorporating the provisions of the stipulation and fixing the common boundary line between the municipalities involved. A stipulation changing boundaries of municipalities shall be approved by the governing body of each municipality and s. 66.0217(9) and (11) shall apply. A change of municipal boundaries under this section is subject to a referendum of the electors residing within the territory whose jurisdiction is subject to change under the stipulation, if within 30 days after the publication of the stipulation to change boundaries in a newspaper of general circulation in that territory, a petition for a referendum conforming to the requirements of s. 8.40 signed by at least 20 percent of the electors residing within that territory is filed with the clerk of the municipality from which the greater area is proposed to be removed and is filed as provided in s. 8.37. The referendum shall be conducted as are annexation referenda. If the referendum election fails, all proceedings under this section are void.

(3) Contested boundary actions. (a) In this subsection, "boundary action" means an action, proceeding, or appeal in court contesting the validity of an annexation, consolidation, detachment, or incorporation.

(b) If 2 municipalities whose boundaries are immediately adjacent at any point are parties to a boundary action, the municipalities may enter into an agreement under s. 66.0301(6) or s. 66.0307 as part of a stipulation to settle the boundary action. The court may approve and make part of the final judgment a stipulation that includes an agreement under s. 66.0301(6) or s. 66.0307.

(4) Authority for certain stipulations. A stipulation that is court-approved under this section before January 19, 2008, that affects the location of a boundary between municipalities, is not invalid as lacking authority to affect the location of the boundary.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0225, WI ST 66.0225
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter II. Incorporation; Municipal Boundaries

W.S.A. 66.0227

66.0227. Detachment of territory

Currentness

Subject to ss. 66.0301(6)(d) and 66.0307(7), territory may be detached from a city or village and attached to a city, village or town to which it is contiguous as follows:

(1) A petition signed by a majority of the owners of three-fourths of the taxable land in area within the territory to be detached or, if there is no taxable land in the territory, by all owners of land in the territory, shall be filed with the clerk of the city or village from which detachment is sought, within 120 days after the date of publication of a class 1 notice, under ch. 985, of intention to circulate a petition of detachment.

(2) An ordinance detaching the territory may be enacted within 60 days after the filing of the petition, by a vote of three-fourths of all the members of the governing body of the detaching city or village and its terms accepted within 60 days after enactment, by an ordinance enacted by a vote of three-fourths of all the members of the governing body of the city, village or town to which the territory is to be attached. The failure of a governing body to adopt the ordinance under this subsection is a rejection of the petition and all proceedings are void.

(3) The governing body of a city, village or town involved may, or if a petition conforming to the requirements of s. 8.40 signed by a number of qualified electors equal to at least 5 percent of the votes cast for governor in the city, village or town at the last gubernatorial election, demanding a referendum, is presented to it within 30 days after the passage of either of the ordinances under sub. (2) shall, submit the question to the electors of the city, village or town whose electors petitioned for detachment, at a referendum election called for that purpose not less than 70 days nor more than 100 days after the filing of the petition, or after the enactment of either ordinance. The petition shall be filed as provided in s. 8.37. If a number of electors cannot be determined on the basis of reported election statistics, the number shall be determined in accordance with s. 60.74(6). The governing body of the municipality shall appoint 3 election inspectors who are resident electors to supervise the referendum. The ballots shall contain the words “For Detachment” and “Against Detachment”. The inspectors shall certify the results of the election by their attached affidavits and file a copy with the clerk of each town, village or city involved, and none of the ordinances may take effect nor be in force unless a majority of the electors approve the question. The referendum election shall be conducted in accordance with chs. 6 and 7 to the extent applicable.

(4) If an area that has been subject to a city or village zoning ordinance is detached from one municipality and attached to another under this section, the zoning ordinance and any regulations, approvals, and conditions imposed under the ordinance continue in effect until the ordinance or the particular regulation, approval, or condition is specifically changed by official action of the

governing body of the municipality. If the detachment or attachment is contested in the courts, the zoning ordinance and any regulations, approvals, and conditions imposed under the ordinance of the detaching municipality continue in effect, and the detaching city or village retains jurisdiction over the zoning in the area affected until final disposition of the court action. This subsection does not expand or modify the authority of a municipality to change a zoning ordinance, any regulation, approval, or condition imposed under a zoning ordinance, or any nonconforming use.

(5) The ordinance, certificate and plat shall be filed and recorded in the same manner as annexations under s. 66.0217(9)(a). The requirements for the secretary of administration are the same as in s. 66.0217 (9)(b).

(6) Because the creation of congressional, legislative, supervisory and aldermanic districts of equal population is a matter of statewide concern, any detachment action that affects a tract of land that is the subject of an ordinance enacted or resolution adopted by a city during the period from January 1, 1990, to April 1, 1991, or any later date, expressing an intent to not exercise the city's authority to annex territory before April 1, 1991, or the specified later date, taken by a municipality during the period beginning on April 1 of the year commencing after each federal decennial census of population and ending on June 30 of the year commencing after that census, is effective on July 1 of the year commencing after that census or at a later date as specified in the detachment ordinance. This subsection first applies to detachments effective after March 31, 1991.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (2)

W. S. A. 66.0227, WI ST 66.0227
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0229

66.0229. Consolidation

Currentness

(1) General procedures. Subject to ss. 66.0301(6)(d) and 66.0307(7), a town, village or city may be consolidated with a contiguous town, village or city, by ordinance, passed by a two-thirds vote of all the members of each board or council, fixing the terms of the consolidation and ratified by the electors at a referendum held in each municipality. The ballots shall bear the words, "for consolidation", and "against consolidation", and if a majority of the votes cast in each municipality are for consolidation, the ordinances shall take effect and have the force of a contract. The ordinance and the result of the referendum shall be certified as provided in s. 66.0211(5); if a town the certification shall be preserved as provided in ss. 66.0211(5) and 66.0235, respectively. Consolidation does not affect the preexisting rights or liabilities of any municipality and actions on those rights or liabilities may be commenced or completed as if there were no consolidation. A consolidation ordinance proposing the consolidation of a town and a city or village shall, within 10 days after its adoption and prior to its submission to the voters for ratification at a referendum, be submitted to the circuit court and the department of administration for a determination of whether the proposed consolidation is in the public interest. The circuit court shall determine whether the proposed ordinance meets the formal requirements of this section and shall then refer the matter to the department of administration, which shall find as prescribed in s. 66.0203 whether the proposed consolidation is in the public interest in accordance with the standards in s. 66.0207. The department's findings have the same status as incorporation findings under ss. 66.0203 to 66.0213.

(2) Town of Rochester in Racine county and the village of Rochester may consolidate. The town of Rochester, in Racine County, and the village of Rochester may consolidate if all of the procedures contained sub. (1) are fulfilled, except that the consolidation ordinance need not be submitted to the circuit court for a determination and the department of administration for a public interest finding, as otherwise required, and the consolidation may be completed without any circuit court determination or department of administration findings.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (30)

W. S. A. 66.0229, WI ST 66.0229
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.023

66.023. Renumbered 66.0307 and amended by 1999 Act 150, § 67, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.023, WI ST 66.023
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0230

66.0230. Town consolidation with a city or village

Currentness

(1)(a) In addition to the method described in s. 66.0229(1) and subject to subs. (2), (3), and (4) and to ss. 66.0301(6)(d) and 66.0307(7), all or part of a town may consolidate with a contiguous city or village by ordinance passed by a two-thirds vote of all of the members of each board or council and ratified by the electors at a referendum held in each municipality.

(b) With regard to the referendum, the ballots shall bear the words "for consolidation," and "against consolidation," and if a majority of the votes cast in each municipality are for consolidation the ordinances shall take effect and have the force of a contract. The ordinance and the result of the referendum shall be certified as provided in s. 66.0211(5).

(c) Consolidation does not affect the preexisting rights or liabilities of any municipality and actions on those rights or liabilities may be commenced or completed as if there were no consolidation.

(2) All or part of a town may consolidate with a city or village under sub. (1) if all of the following apply:

(a) The town, and the city or village, adopt identical resolutions that describe the level of services that residents of the proposed city or village will receive, or have access to, in at least all of the following areas:

1. Public parks services.

2. Public health services.

3. Animal control services.

4. Library services.

5. Fire and emergency rescue services.

6. Law enforcement services.

(b) The town, and the city or village, adopt identical resolutions that relate to the ownership or leasing of government buildings.

(c) The city or village with which the town wishes to consolidate enters into a separate boundary agreement, subject to approval of the town board of the town to be consolidated, with every city, village, and town that borders the proposed consolidated city or village. Each boundary agreement shall determine the boundaries between the parties to the agreement. The boundary agreement shall state the term of the agreement and shall contain the procedures under which the agreement may be amended during its term. A boundary agreement entered into under this paragraph is a binding contract upon the parties.

(d) The consolidating town, and city or village, agree to adopt a comprehensive plan under s. 66.1001 for the consolidated city or village, and the comprehensive plan takes effect on the effective date of the consolidation.

(e) At least some part of the consolidated city or village receives sewage disposal services.

(3) If less than an entire town consolidates with a city or village under sub. (1), the consolidation may not take effect unless the town enters into an agreement with a city, village, or town that has a common boundary with the remnant of the town that is not consolidated under which the town remnant becomes part of the city, village, or town with the common boundary. If a town remnant becomes part of a city or village, an agreement described under this subsection shall be included in each boundary agreement under sub. (2)(c) that is entered into by a city, village, or town that borders the remnant. An agreement entered into under this subsection is a binding contract upon the parties.

(4) In this section, a municipality that borders or has a common boundary with another municipality includes municipalities that intersect at only one point.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0230, WI ST 66.0230
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter II. Incorporation; Municipal Boundaries

W.S.A. 66.0231

66.0231. Notice of certain litigation affecting municipal status or boundaries

Currentness

If a proceeding under ss. 61.187, 61.189, 61.74, 62.075, 66.0201 to 66.0213, 66.0215, 66.02162, 66.0217, 66.0221, 66.0223, 66.0227, 66.0301(6), or 66.0307 or other sections relating to an incorporation, annexation, consolidation, dissolution or detachment of territory of a city or village is contested by instigation of legal proceedings, the clerk of the city or village involved in the proceedings shall file with the secretary of administration 4 copies of a notice of the commencement of the action. The clerk shall file with the secretary of administration 4 copies of any judgments rendered or appeals taken in such cases. The notices or copies of judgments that are required under this section may also be filed by an officer or attorney of any party of interest. If any judgment has the effect of changing the municipal boundaries, the city or village clerk shall also file with the county clerk or board of election commissioners the report required by s. 5.15(4)(b). The secretary of administration shall forward to the department of transportation 2 copies and to the department of revenue and the department of administration one copy each of any notice of action or judgment filed with the secretary of administration under this section.

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

LAW REVISION COMMITTEE PREFATORY NOTE--2017 ACT 360

This bill is a remedial legislation proposal, requested by the Legislative Technology Services Bureau and introduced by the Law Revision Committee under s. 13.83(1)(c)4. and 5., stats. After careful consideration of the various provisions of the bill, the Law Revision Committee has determined that this bill makes minor substantive changes in the statutes, and that these changes are desirable as a matter of public policy.

W. S. A. 66.0231, WI ST 66.0231
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter II. Incorporation; Municipal Boundaries

W.S.A. 66.0233

66.0233. Town participation in actions to test alterations of town boundaries

Currentness

In a proceeding in which territory may be attached to or detached from a town, the town is an interested party, and the town board may institute, maintain or defend an action brought to test the validity of the proceedings, and may intervene or be impleaded in the action.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (18)

W. S. A. 66.0233, WI ST 66.0233
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0235

66.0235. Adjustment of assets and liabilities on division of territory

Currentness

(1) Definition. In this section, "local governmental unit" means town sanitary districts, school districts, technical college districts, towns, villages and cities.

(2) Basis. (a) Except as otherwise provided in this section or in s. 60.79(2)(c) when territory is transferred, in any manner provided by law, from one local governmental unit to another, there shall be assigned to the latter local governmental unit such proportion of the assets and liabilities of the first local governmental unit as the assessed valuation of all taxable property in the territory transferred bears to the assessed valuation of all the taxable property of the entire local governmental unit from which the territory is taken according to the last assessment roll of the local governmental unit. The clerk of a local governmental unit to which territory is transferred, within 30 days of the effective date of the transfer, shall certify to the clerk of the local governmental unit from which territory was transferred and to the clerk of the school district in which the territory is located a metes and bounds description of the land area involved. Upon receipt of the description the clerk of the local governmental unit from which the territory was transferred shall certify to the department of revenue and to the clerk of the school district in which the territory is located the latest assessed value of the real and personal property located within the transferred territory, and shall make any further reports as needed by the department of revenue in the performance of duties required by law.

(b) When the transfer of territory from one local governmental unit to another results from the incorporation of a new city or village, the proportion of the assets and liabilities assigned to the new city or village shall be based on the average assessed valuation for the preceding 5 years of the property transferred in proportion to the average assessed valuation for the preceding 5 years of all the taxable property of the entire local governmental unit from which the territory is taken, according to the assessment rolls of the local governmental unit for those years. The certification by the clerk of the local governmental unit from which territory was transferred because of the incorporation shall include the assessed value of the real and personal property within the territory transferred for each of the last 5 years. The preceding 5 years shall include the assessment rolls for the 5 calendar years prior to the incorporation.

(2c) School districts. (a) *Standard procedure.* 1. When territory is transferred in any manner provided by law from one school district to another, there shall be assigned to each school district involved such proportion of the assets and liabilities of the school districts involved as the equalized valuation of all taxable property in the territory transferred bears to the equalized valuation of all taxable property of the school district from which the territory is taken. The equalized valuation shall be certified by the department of revenue upon application by the clerk of the school district to which the territory is transferred.

2. The clerk of any school district to which territory is transferred, within 30 days of the effective date of the transfer, shall certify to the clerk of the local governmental unit from which the territory was transferred a metes and bounds description of the land area involved. Upon receipt of the description the clerk of the local governmental unit from which the territory was

transferred shall certify to the department of revenue the latest assessed value of the real and personal property located within the transferred territory, file one copy of the certification with the school district clerk and one copy with the department of public instruction and make any further reports as needed by the department of revenue in the performance of duties required by law.

(b) *Alternative procedure.* Two or more school districts may, by identical resolutions adopted by a three-fourths vote of the members of each school board concerned, establish an alternative method to govern any adjustment of their assets and liabilities. The authority of this paragraph applies wherever the boards find that the adoption of the resolution is necessary to provide a more equitable method than is provided in par. (a). The resolutions shall be adopted no later than 120 days after the effective date of the transfer of territory and may be adopted prior to the transfer. The resolutions adopted shall be recorded in the office of the register of deeds.

(2m) Attachment and detachment within 5 years. If territory is attached to or consolidated with a school district, and the territory or any part of the territory is detached from the district within 5 years after the attachment or consolidation, the school district to which it is transferred is entitled, in the apportionment of assets and liabilities, only to the assets or liabilities or proportionate part apportioned to the school district as the result of the original attachment or consolidation.

(3) Real estate. (a) The title to real estate may not be transferred under this section except by agreement, but the value of real estate shall be included in determining the assets of the local governmental unit owning the real estate and in making the adjustment of assets and liabilities.

(b) The right to possession and control of school buildings and sites passes to the school district in which they are situated immediately upon the attachment or detachment of any school district territory becoming effective, except that in 1st class city school districts the right to possession and control of school buildings and sites passes on July 1 following the adoption of the ordinance authorized by s. 66.0217(8). The asset value of school buildings and sites shall be the value of the use of the buildings and sites, which shall be determined at the time of adjustment of assets and liabilities.

(c) When as a result of an annexation a school district is left without a school building, any moneys are received by the school district as a result of the division of assets and liabilities required by this section, which are derived from values that were capital assets, the moneys and interest on the moneys shall be held in trust by the school district and dispensed only for procuring new capital assets or remitted to an operating district as the remainder of the suspended district becomes a part of the operating district, and may not be used to meet current operating expenditures. The boards involved shall, as part of their duties in division of assets and liabilities in school districts, make a written report of the allocation of assets and liabilities to the state superintendent of public instruction and any local superintendent of schools whose territory is involved in the division of assets.

(4) Public utilities. A public utility plant, including any dam, power house, power transmission line and other structures and property operated and used in connection with the plant, belongs to the local governmental unit in which the major portion of the patrons of the utility reside. The value of the utility, unless fixed by agreement of all parties interested shall be determined and fixed by the public service commission upon notice to the local governmental units interested, in the manner provided by law. The commission shall certify the amount of the compensation to the clerks of each local governmental unit interested and that amount shall be used by the apportionment board in adjusting assets and liabilities.

(5) Apportionment board. The boards or councils of the local governmental units, or committees selected for that purpose, acting together, constitute an apportionment board. When a local governmental unit is dissolved because all of its territory is transferred the board or council of the local governmental unit existing at the time of dissolution shall, for the purpose of this

section, continue to exist as the governing body of the local governmental unit until there has been an apportionment of assets by agreement of the interested local governmental units or by an order of the circuit court. After an agreement for apportionment of assets has been entered into between the interested local governmental units, or an order of the circuit court becomes final, a copy of the apportionment agreement, or of the order, certified to by the clerks of the interested local governmental units, shall be filed with the department of revenue, the department of natural resources, the department of transportation, the state superintendent of public instruction, the department of administration, and with any other department or agency of the state from which the town may be entitled by law to receive funds or certifications or orders relating to the distribution or disbursement of funds, with the county treasurer, with the treasurer of any local governmental unit, or with any other entity from which payment would have become due if the dissolved local governmental unit had continued in existence. Subject to ss. 79.006 and 86.303(4), payments of forest crop taxes under s. 77.05, of transportation aids under s. 20.395, of state aids for school purposes under ch. 121, payments for managed forest land under subch. VI of ch. 77 and all payments due from a department or agency of the state, from a county, from a local governmental unit, or from any other entity from which payments would have become due if the dissolved local governmental unit had continued in existence, shall be paid to the interested local governmental unit as provided by the agreement for apportionment of assets or by any order of apportionment by the circuit court and the payments have the same force and effect as if made to the dissolved local governmental unit.

(6) Meeting. The board or council of the local governmental unit to which the territory is transferred shall fix a time and place for meeting and give a written notice of the meeting to the clerk of the local governmental unit from which the territory is taken at least 5 days prior to the date of the meeting. The apportionment may be made only by a majority of the members from each local governmental unit who attend, and in case of committees, the action shall be affirmed by the board or council represented by the committee.

(7) Adjustment, how made. (a) The apportionment board shall determine, except for public utilities, assets and liabilities from the best information obtainable and shall assign to the local governmental unit to which the territory is transferred its proper proportion of assets and liabilities by assigning the excess of liabilities over assets, or by assigning any particular asset or liability to either local governmental unit, or in another manner that meets the requirements of the particular case.

(b) If a proportionate share of any indebtedness existing by reason of municipal bonds or other obligations outstanding is assigned to a local governmental unit, that local governmental unit shall levy and collect upon all its taxable property, in one sum or in annual installments, the amount necessary to pay the principal and interest when due, and shall pay the amount collected to the treasurer of the local governmental unit which issued the bonds or incurred the obligations. The treasurer shall apply the moneys received strictly to the payment of the principal and interest.

(c) If the asset apportioned consists of an aid or tax to be distributed in the future according to population, the apportionment board shall certify to the officer, agency or department responsible for making the distribution each local governmental unit's proportionate share of the asset as determined in accordance with sub. (2). The officer, agency or department shall distribute the aid or tax directly to the several local governmental units according to the certification until the next federal census.

(8) Appeal to court. If the apportionment board is unable to agree, the circuit court of the county in which either local governmental unit is situated may, upon the petition of either local governmental unit, make the adjustment of assets and liabilities under this section, including review of any alternative method provided in sub. (2c)(b) and the correctness of the findings made under sub. (2c)(b).

(9) Transcript of records. If territory is detached from a local governmental unit, the proper officer of the local governmental unit from which the territory was detached shall furnish, upon demand by the proper officer of the local governmental unit

created from the detached territory or to which it is annexed, an authenticated transcript of all public records in that officer's office pertaining to the detached territory. The local governmental unit receiving the transcript shall pay for the transcript.

(10) State trust fund loans. When territory transferred in any manner provided by law from one local governmental unit to another is liable for state trust fund loans secured under subch. II of ch. 24, the clerk of the local governmental unit to which territory is transferred shall within 30 days of the effective date of the transfer certify a metes and bounds description of the transferred area to the clerk of the local governmental unit from which the land was transferred. The clerk of the local governmental unit from which territory was transferred shall then certify to the board of commissioners of public lands the effective date of the transfer of territory, the last preceding assessed valuation of the territory liable for state trust fund loans before transfer of a part of the territory and the assessed valuation of the territory transferred. The board shall in making its annual certifications of the amounts due on account of state trust fund loans distribute annual charges for interest and principal on outstanding loans covered by this subsection in the proportion that the assessed valuation of the territory transferred bears to the assessed valuation of the area liable for state trust fund loans as constituted immediately before the transfer of territory. A transfer of territory effective subsequent to January 1 of any year may not be considered until the succeeding year.

(10a) Corrections. The provisions of sub. (10) are applicable to school districts. Any errors, omissions or other defects in the tax certifications and levies in connection with the repayment of state trust fund loans by school districts for the year 1950 and all subsequent years may be corrected by the school district clerk in the tax levy certifications for following years.

(11) Designating districts. (a) Whenever a transfer of territory from one school district to another results in a change in the name of a school district which is liable for one or more state trust fund loans secured under subch. II of ch. 24, the clerk of the school district to which the territory was transferred shall, within 30 days of the effective date of such transfer, certify to the board of commissioners of public lands and the county clerk:

1. The name of the school district from which territory was transferred;

2. The effective date of such transfer;

3. The name of the school district to which the transfer was made immediately prior to the effective date of the transfer;

4. The name of the school district to which the transfer was made immediately after the effective date of the transfer.

(b) In making the annual certifications of the amounts due on account of state trust fund loans the board of commissioners of public lands shall use the new name of the school district. A transfer of territory effective subsequent to January 1 of any year may not be considered by it until the succeeding year.

(12) Time of transfer. When the governmental classification of a school district is changed, all of the assets and liabilities and the title to all school property shall vest in the new district by operation of law upon the effective date of the change.

(13) Taxes and assessment. (a) *General property taxes.* 1. Subject to subd. 2., if any territory is annexed, detached or incorporated in any year, general property taxes levied against the territory shall be collected by the treasurer of the local governmental unit in which the territory was located on January 1 of such year, and all moneys collected from the tax levied for

local municipal purposes shall be allocated to each of the local governmental units on the basis of the portion of the calendar year the territory was located in each of the local governmental units, and paid accordingly.

2. If a city or village is incorporated after January 1 and before April 1, the procedures described in subd. 1. shall be applied as if the city or village was incorporated on January 1 of the year in which it was incorporated and the territory shall be treated for purposes of ch. 70 as if the incorporation had occurred on January 1.

(aa) *Apportionment when town is nonexistent.* If the town in which territory was located on January 1 is nonexistent when the city or village determines its budget, any taxes certified to the town or required by law to be levied against the territory shall be included in the budget of the city or village and levied against the territory, together with the city or village tax for local municipal purposes.

(b) *Special taxes and assessments.* If territory is transferred from one local governmental unit to another by annexation, detachment, consolidation or incorporation, or returns to its former status by reason of court determination, any special tax or assessment outstanding against property in the territory shall be collected by the treasurer of the local governmental unit in which the property is located, according to the terms of the ordinance or resolution levying the tax or assessment. The special tax or assessment, when collected, shall be paid to the treasurer of the local governmental unit which levied the special tax or assessment, or if the local governmental unit is nonexistent, the collecting treasurer shall apply the collected funds to any obligation for which purpose the tax or assessment was levied and which remains outstanding. If no obligation is outstanding, the collected funds shall be paid into the school fund of the school district in which the territory is located.

(bb) *Apportionment when court returns territory to former status.* If territory which has been annexed, consolidated, detached or incorporated returns to its former status by reason of a final court determination, there shall be an apportionment of general property taxes and current aids and shared revenues between the local governmental units, and no other apportionment of assets and liabilities. The basis of the apportionment shall be determined by the apportionment board subject to appeal to the circuit court. The apportionment shall to the extent practicable equitably adjust the taxes, aids and revenues between the local governmental units involved on the basis of the portion of the calendar year the territory was located in the respective local governmental units.

(c) *Certification by clerk.* The clerk of the local governmental unit which assessed the special and general tax and special assessment shall certify to the clerk of the local governmental unit to which the territory was attached or returned, a list of all the property located in the attached or returned territory to which is charged any uncollected taxes and assessments. The certification shall be made within 30 days after the effective date of the transfer of the property, but failure to certify does not affect the validity of the claim.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (49)

W. S. A. 66.0235, WI ST 66.0235
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.024

66.024. Renumbered 66.0219 and amended by 1999 Act 150, § 68, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.024, WI ST 66.024
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.025

66.025. Renumbered 66.0223 and amended by 1999 Act 150, § 69, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.025, WI ST 66.025
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.026

66.026. Renumbered 66.0231 and amended by 1999 Act 150, § 70, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.026, WI ST 66.026
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.027

66.027. Renumbered 66.0225 and amended by 1999 Act 150, § 71, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.027, WI ST 66.027
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.028

66.028. Renumbered 66.0305 and amended by 1999 Act 150, § 72, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.028, WI ST 66.028
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.029

66.029. Renumbered 66.0233 and amended by 1999 Act 150, § 73, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.029, WI ST 66.029
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0295

66.0295. Renumbered 66.1001 and amended by 1999 Act 150, § 74, eff. Jan. 1, 2001; 1999 Act 186, § 42, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0295, WI ST 66.0295
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.03

66.03. Renumbered 66.0235 and amended by 1999 Act 150, § 75, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.03, WI ST 66.03
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter III. Intergovernmental Cooperation

W.S.A. 66.0301

66.0301. Intergovernmental cooperation

Currentness

(1)(a) Except as provided in pars. (b) and (c), in this section "municipality" means the state or any department or agency thereof, or any city, village, town, county, or school district, the opportunity schools and partnership programs under subch. IX of ch. 115 and subch. II of ch. 119, the superintendent of schools opportunity schools and partnership program under s. 119.33, or any public library system, public inland lake protection and rehabilitation district, sanitary district, farm drainage district, metropolitan sewerage district, sewer utility district, solid waste management system created under s. 59.70(2), local exposition district created under subch. II of ch. 229, local professional baseball park district created under subch. III of ch. 229, local professional football stadium district created under subch. IV of ch. 229, local cultural arts district created under subch. V of ch. 229, long-term care district under s. 46.2895, water utility district, mosquito control district, municipal electric company, county or city transit commission, commission created by contract under this section, taxation district, regional planning commission, housing authority created under s. 66.1201, redevelopment authority created under s. 66.1333, community development authority created under s. 66.1335, or city-county health department.

(b) If the purpose of the intergovernmental cooperation is the establishment of a joint transit commission, "municipality" means any city, village, town or county.

(c) For purposes of sub. (6), "municipality" means any city, village, or town.

(2) Subject to s. 59.794(2), and in addition to the provisions of any other statutes specifically authorizing cooperation between municipalities, unless those statutes specifically exclude action under this section, any municipality may contract with other municipalities and with federally recognized Indian tribes and bands in this state, for the receipt or furnishing of services or the joint exercise of any power or duty required or authorized by law. If municipal or tribal parties to a contract have varying powers or duties under the law, each may act under the contract to the extent of its lawful powers and duties. A contract under this subsection may bind the contracting parties for the length of time specified in the contract. This section shall be interpreted liberally in favor of cooperative action between municipalities and between municipalities and Indian tribes and bands in this state. If a municipality is required to establish or maintain an agency, department, commission, or any other office or position to carry out a municipal responsibility, and the municipality joins with another municipality by entering into an intergovernmental cooperation contract under this subsection to jointly carry out the responsibility, the jointly established or maintained agency, department, commission, or any other office or position to which the contract applies fulfills, subject to sub. (7), the municipality's obligation to establish or maintain such entities or positions until the contract entered into under this subsection expires or is terminated by the parties. In addition, if 2 or more municipalities enter into an intergovernmental cooperation contract and create a commission under this section to jointly or regionally administer a function or project, the

commission shall be considered, subject to sub. (7), to be a single entity that represents, and may act on behalf of, the joint interests of the signatories to the contract entered into under this section.

(3) Any contract under sub. (2) may provide a plan for administration of the function or project, which may include but is not limited to provisions as to proration of the expenses involved, deposit and disbursement of funds appropriated, submission and approval of budgets, creation of a commission, selection and removal of commissioners, and formation and letting of contracts.

(4) A commission created by contract under sub. (2) may finance the acquisition, development, remodeling, construction and equipment of land, buildings and facilities for regional projects under s. 66.0621. Participating municipalities acting jointly or separately may finance the projects, or an agreed share of the cost of the projects, under ch. 67.

(5) No commission created by contract under sub. (2) may, directly or indirectly, do any of the following:

(a) Acquire, construct or lease facilities used or useful in the business of a public utility engaged in production, transmission, delivery or furnishing of heat, light, power, natural gas or communications service, by any method except those set forth under this chapter or ch. 196, 197 or 198.

(b) Establish, lay out, construct, improve, discontinue, relocate, widen or maintain any road or highway outside the corporate limits of a village or city or acquire lands for those purposes except upon approval of the department of transportation and the county board of the county and the town board of the town in which the road is to be located.

(6)(a) Any 2 municipalities whose boundaries are immediately adjacent at any point may enter into a written agreement determining all or a portion of the common boundary line between the municipalities. An agreement under this subsection may include only the provisions authorized under this section and s. 66.0305, and one or more of the following:

1. That specified boundary lines apply on the effective date of the agreement.

2. That specified boundary line changes shall occur during the term of the agreement and the approximate dates by which the changes shall occur.

3. That specified boundary line changes may occur during the term of the agreement and the approximate dates by which the changes may occur.

4. That a required boundary line change under subd. 2. or an optional boundary line change under subd. 3. is subject to the occurrence of conditions set forth in the agreement.

5. That specified boundary lines may not be changed during the term of the agreement.

(b) The maximum term of an agreement under this subsection is 10 years. When an agreement expires, all provisions of the agreement expire, except that any boundary determined under the agreement remains in effect until subsequently changed.

(c)1. Before an agreement under this subsection may take effect, and subject to par. (e), it must be approved by the governing body of each municipality by the adoption of a resolution. Before each municipality may adopt a resolution, each shall hold a public hearing on the agreement or both municipalities shall hold a joint public hearing on the agreement. Before the public hearing may be held, each municipality shall give notice of the pending agreement and public hearing by publishing a class 1 notice, under ch. 985, and by giving notice to each property owner whose property is currently located in that municipality and in, or immediately adjacent to, the territory whose jurisdiction will change. Notice shall be given at least 20 days before the public hearing and notice to property owners shall be made by certified mail.

2. An agreement under this subsection is subject to a referendum of the electors residing within the territory whose jurisdiction is subject to change as a result of the agreement. After each municipality approves the agreement by adoption of a resolution, each municipality shall publish the agreement in the territory whose jurisdiction is subject to change as a result of the agreement as a class 1 notice, under ch. 985. A referendum shall be held if, within 30 days after the publication of the agreement, a petition for a referendum conforming to the requirements of s. 8.40, signed by at least 20 percent of the electors residing within the territory whose jurisdiction is subject to change as a result of the agreement is filed, in accordance with s. 8.37, with the clerk of each municipality that is a party to the agreement. The referendum shall be conducted jointly by the municipalities and shall otherwise be conducted as are annexation referenda. If the agreement is approved in the referendum, it may take effect. If the agreement is not approved in the referendum, it may not take effect.

(d) An agreement under this subsection may provide that, during the term of the agreement, no other procedure for altering a municipality's boundaries may be used to alter a boundary that is affected by the agreement, except an annexation conducted under s. 281.43(1m), regardless of whether the boundary is proposed to be maintained or changed or is allowed to be changed under the agreement. After the agreement has expired, the boundary may be altered.

(e) A boundary change included in an agreement under this subsection shall be accomplished by the enactment of an ordinance by the governing body designated to do so in the agreement. The filing and recording requirements under s. 66.0217(9)(a), as they apply to cities and villages under s. 66.0217(9)(a), apply to municipalities under this subsection. The requirements for the secretary of administration under s. 66.0217(9)(b), as they apply under that section, apply to the secretary of administration when he or she receives an ordinance that is filed under this subsection.

(f) No action to contest the validity of an agreement under this subsection may be commenced after 60 days from the date the agreement becomes effective.

(g) This subsection is the exclusive authority under this section for entering into an agreement that determines all or a portion of the common boundary line between municipalities.

(h) An agreement under this section that has been entered into before January 19, 2008, that affects the location of a boundary between municipalities, is not invalid as lacking authority under this section to affect the location of the boundary.

(7) With regard to a contract entered into under sub. (2) between 2 or more counties, which relates to the provision of services or facilities under a contract with an officer or agency of the state, the contract may not take effect unless it is approved in writing by the officer or chief of the agency that has authority over the contract for the provision of services or facilities. The contract must be approved or disapproved in writing by the officer or chief of the agency with regard to the matters within the scope of the contract for the provision of services or facilities within 90 days after receipt of the contract. Any disapproval shall detail

the specific respects in which the proposed contract fails to demonstrate that the signatories intend to fulfill their contractual responsibilities or obligations. If the officer or chief of the agency fails to approve or disapprove of the contract entered into under sub. (2) within 90 days after receipt, the contract shall be considered approved by the officer or chief of the agency.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (34)

W. S. A. 66.0301, WI ST 66.0301
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter III. Intergovernmental Cooperation

W.S.A. 66.0303

66.0303. Municipal interstate cooperation

Currentness

(1) In this section, "municipality" has the meaning given in s. 66.0301(1)(a), except that with regard to agreements described in s. 66.0304, "municipality" includes a political subdivision, as defined in s. 66.0304(1)(f).

(2) A municipality may contract with municipalities of another state or with federally recognized American Indian tribes or bands located in another state for the receipt or furnishing of services or the joint exercise of any power or duty required or authorized by statute to the extent that laws of the other state or of the United States permit the joint exercise.

(3)(a) Except as provided in par. (b) and s. 66.0825(18), an agreement made under this section shall, prior to and as a condition precedent to taking effect, be submitted to the attorney general who shall determine whether the agreement is in proper form and compatible with the laws of this state. The attorney general shall approve any agreement submitted under this paragraph unless the attorney general finds that it does not meet the conditions set forth in this section and details in writing addressed to the concerned municipal governing bodies the specific respects in which the proposed agreement fails to meet the requirements of law. Failure to disapprove an agreement submitted under this paragraph within 90 days of its submission constitutes approval. The attorney general, upon submission of an agreement, shall transmit a copy of the agreement to the governor who shall consult with any state department or agency affected by the agreement. The governor shall forward to the attorney general any comments the governor may have concerning the agreement.

(b) An agreement under this section between a municipality of this state and a municipality of another state that relates to the receipt, furnishing, or joint exercise of fire fighting or emergency medical services need not be submitted to or approved by the attorney general before the agreement may take effect.

(4) An agreement entered into under this section has the status of an interstate compact, but in any case or controversy involving performance or interpretation of or liability under the agreement, the municipalities party to the agreement are real parties in interest and the state may commence an action to recoup or otherwise make itself whole for any damages or liability which it may incur by reason of being joined as a party. The action by the state may be maintained against any municipality whose act or omission caused or contributed to the incurring of damage or liability by the state.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0303, WI ST 66.0303
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0304

66.0304. Conduit revenue bonds

Currentness

(1) Definitions. In this section:

(a) "Agreement" means a contract entered into under this section by the political subdivisions which form a commission. The contract may be amended according to the terms of the contract, and the amended contract remains an agreement.

(b) "Bond" means any bond, note or other obligation issued or entered into or acquired under this section, including any refunding bond or certificate of participation or lease-purchase, installment sale, or other financing agreement.

(c) "Commission" means an entity created by two or more political subdivisions, who contract with each other under s. 66.0301(2) or 66.0303(2), for the purpose of issuing bonds under this section.

(d) "Member" means a party to an agreement.

(e) "Participant" means any public or private entity or unincorporated association, including a federally recognized Indian tribe or band, that contracts with a commission for the purpose of financing or refinancing a project that is owned, sponsored, or controlled by the public or private entity or unincorporated association.

(f) "Political subdivision" means any city, village, town, or county in this state or any city, village, town, county, district, authority, agency, commission, or other similar governmental entity in another state or office, department, authority, or agency of any such other state or territory of the United States.

(g) "Project" means any capital improvement, purchase of receivables, property, assets, commodities, bonds or other revenue streams or related assets, working capital program, or liability or other insurance program, located within or outside of this state.

(ge) "Public official" means an individual who holds, or has held, a local public office, as that term is defined in s. 19.42(7w), for a political subdivision in this state.

(h) "Revenue" means all moneys and fees received from any source by a commission.

(2) Attorney general review. (a) Before an agreement may take effect, the proposed agreement shall be submitted to the attorney general who shall determine whether the agreement is in proper form and compatible with the laws of this state. Subject to sub. (3)(d), the attorney general shall approve any agreement submitted under this subsection unless the attorney general finds that it does not meet the conditions set forth in this section and details in writing addressed to the concerned political subdivisions' governing bodies the specific respects in which the proposed agreement fails to meet the requirements of law. Failure to disapprove an agreement submitted under this subsection within 90 days of its submission constitutes approval. The attorney general, upon submission of an agreement, shall transmit a copy of the agreement to the governor, who may consult with any state department or agency. The governor shall forward to the attorney general any comments the governor may have concerning the agreement.

(b) No approval is required under this subsection for an amendment to an agreement to take effect, unless the amendment is to add a member or unless otherwise required by the terms of the agreement. A commission may not be dissolved under sub. (4m) without the approval of the attorney general, who shall certify to the commission and the participants that the dissolution resolution provides for the payment of any outstanding bonds or other obligations of the commission.

(3) Creation and organization. (a) Two or more political subdivisions may create a commission for the purpose of issuing bonds by entering into an agreement to do so under s. 66.0301(2) or 66.0303(2), except that upon its creation all of the initial members of a commission shall be political subdivisions that are located in this state. A commission that is created as provided in this section is a unit of government, and a body corporate and politic, that is separate and distinct from, and independent of, the state and the political subdivisions which are parties to the agreement.

(b) A commission shall be governed by a board, the members of which shall be appointed under the terms of the agreement. A majority of the board members shall be public officials or current or former employees of a political subdivision that is located in this state. Board members may be reimbursed for their actual and necessary expenses incurred in performing their duties to the extent provided in the agreement or the bylaws of the commission.

(c) An additional political subdivision may become a member of a commission, and a member may withdraw from a commission, as provided in the agreement. For an agreement to be valid, at least one commission member shall be a political subdivision that is located in this state and a commission shall consist of at least 2 political subdivisions. A commission may not take any action under this paragraph that would invalidate an agreement.

(d) No commission may be created under this section unless its agreement is submitted to the attorney general, under sub. (2), before October 1, 2010. Only one commission may be formed under this section. If more than one agreement is submitted to the attorney general before October 1, 2010, the attorney general must give preference to the agreement that submits with its documents a demonstration of support for its agreement from at least one statewide organization located in this state which represents the interests of political subdivisions and has political subdivisions among its membership.

(4) Powers of a commission. A commission has all of the powers necessary or convenient to carry out the purposes and provisions of this section. In addition to all other powers granted by this section, a commission may do any of the following:

(a) Adopt bylaws for the regulation of its affairs and the conduct of its business.

(b) Sue and be sued in its own name, plead and be impleaded.

(c) Acquire, buy, sell, lease as lessor or lessee, encumber, mortgage, hypothecate, pledge, assign, or transfer any property or interest in property that is located within or outside of this state.

(d) Enter into contracts related to the issuance of bonds.

(e) Issue bonds or refunding bonds, subject to sub. (5), to finance or refinance a project, including funding a reserve fund or capitalized interest, payment of costs of issuance and other costs related to the financing or refinancing, or credit enhancement, and enter into agreements related to the issuance of bonds, including liquidity and credit facilities, remarketing agreements, insurance policies, guaranty agreements, letter of credit or reimbursement agreements, indexing agreements, interest rate swap agreements, currency exchange agreements, commodity swap agreements, and other hedge agreements and any other like agreements, in each case with such payment, interest rate, currency security, remedy, and other terms and conditions as the commission determines.

(f) Employ or appoint agents, employees, finance professionals, and special advisers as the commission finds necessary and fix their compensation.

(g) Accept gifts, loans, or other aid.

(h) Establish and collect fees, plus administrative expenses, from participants who benefit from the commission's services, or services provided by an outside entity, and distribute the fees and expenses as provided in the agreement.

(i) Make loans to, lease property from or to, or enter into any other kind of an agreement with a participant or other entity, in connection with financing or refinancing a project.

(j) Mortgage, pledge, or otherwise encumber the commission's property or its interest in projects.

(k) Assign or pledge any portion of its interests in projects, mortgages, deeds of trust, indentures of mortgage or trust, leases, purchase or sale agreements or other financing agreements, or similar instruments, bonds, notes, and security interests in property, of a participant, or contracts entered into or acquired in connection with bonds.

(L) Issue, obtain, or aid in obtaining, from any person, any insurance or guarantee to, or for, the payment or repayment of interest or principal, or both, on any loan, lease, bond, or other obligation evidencing or securing such a loan, lease, bond, or obligation that is entered into under this section.

(m) Apply on its own behalf or on behalf of a participant to any unit of government for an allocation of volume cap, tax credit, subsidy, grant, loan, credit enhancement, or any other federal, state, or local program in connection with the financing or refinancing of a project.

(n) Invest any bond proceeds or any money held for payment or security of the bonds, or any contract entered into under this section, in any securities or obligations permitted by the resolution, trust agreement, indenture, or other agreement providing for issuance of the bonds or the contract.

(o) At the request of a participant, combine and pledge revenues of multiple projects for repayment of one or more series of bonds issued under this section.

(p) Purchase bonds issued by or on behalf of, or held by, any participant, any state or a department, authority, or agency of the state, or any political subdivision. Bonds purchased under this paragraph may be held by the commission or sold, in whole or in part, separately or together with other bonds issued by the commission.

(4m) Dissolution of a commission. Subject to sub. (2)(b) and subject to providing for the payment of its bonds, including interest on the bonds, and the performance of its other contractual obligations, a commission may be dissolved, by resolution, as provided in the agreement. If the commission is dissolved, the property of the commission shall be transferred to the political subdivisions who are parties to the agreement creating the commission as provided in the agreement.

(5) Issuance of bonds. (a) A commission may not issue bonds unless the issuance is first authorized by a bond resolution. A bond issued under this section shall meet all of the following requirements:

1. The face of the bond shall include the date of issuance and the date of maturity.

2. The face of the bond shall include the statements required under subs. (9)(c) and (11)(d).

3. The date of maturity may not exceed 50 years from the date of issuance.

4. The bond shall bear a rate of interest, either fixed or variable, specified by the resolution. Any variable rate of interest shall be made subject to a maximum rate.

5. Interest and principal shall be paid at the time and place specified in the resolution.

6. Bonds in a single issue may be composed of a single denomination or 2 or more denominations, as provided in the resolution.

7. The bond shall be payable in lawful money of the United States or, if provided in the resolution, another currency.

8. Bonds shall be registered as provided in the resolution.

9. Bonds shall be in the form, and executed in the manner, provided in the resolution.

(am) Notwithstanding par. (a), as an alternative to specifying the matters required to be specified in the bond resolution under par. (a), the resolution may specify members of the board or officers or employees of the commission, by name or position, to whom the commission delegates authority to determine which of the matters under specified par. (a), and any other matters that the commission deems appropriate, for inclusion in the trust agreement, indenture, or other agreement providing for issuance of the bonds as finally executed. A resolution under this paragraph shall specify at least all of the following:

1. The maximum principal amount of bonds to be issued.

2. The maximum term of the bonds.

3. The maximum interest rate to be borne by the bonds.

(b) A bond issued under this section may include, or be subject to, any of the following:

1. Early mandatory or optional redemption or purchase in lieu of redemption or tender, as provided in the resolution.

2. A provision providing a right to tender.

3. A trust agreement or indenture containing any terms, conditions, and covenants that the commission determines to be necessary or appropriate, but such terms, conditions, and covenants may not be in conflict with the resolution.

(c) The commission may purchase any bond issued under this section. Subject to the terms of any agreement with the bondholders, the commission may hold, pledge, resell, or cancel any bond purchased under this paragraph, except that a purchase under this paragraph may not effect an extinguishment of a bond unless the commission cancels the bond or otherwise certifies its intention that the bond be extinguished.

(d) The proceeds of a bond issued under this section may be used for one or more projects located within or outside of this state.

(e) The commission shall send notification to the department of revenue, on a form prescribed by the department, whenever a bond is issued under this section.

(6) Sale of bonds. (a) The sale of bonds under this section shall be conducted as provided in the bond resolution.

(b) A sale may be public or private. Bonds may be sold at the price or prices, and upon the conditions, determined by the commission. The commission shall give due consideration to the recommendations of the participants in the project when determining the conditions of sale.

(c) Bonds that are sold under this section may be serial bonds or term bonds, or both.

(d) If at the time of sale definitive bonds are not available, the commission may issue interim certificates exchangeable for definitive bonds.

(e) The commission shall disclose to any person who purchases a tax-exempt bond issued under this section that the interest received on such a bond is exempt from taxation, as provided in ss. 71.05(1)(c)10., 71.26(1m)(k), 71.36(1m), and 71.45(1t)(k).

(7) Bond security. (a) The commission may secure bonds by a trust agreement or indenture by and between the commission and one or more corporate trustees. A bond resolution, trust agreement, or indenture may contain provisions for pledging properties, revenues, and other collateral; holding and disbursing funds; protecting and enforcing the rights and remedies of bondholders; restricting individual rights of action by bondholders; and amendments, and any other provisions the commission determines to be reasonable and proper for the security of the bondholders or contracts entered into under this section in connection with the bonds.

(b) A pledge of property, revenues, or other collateral by a commission to secure the payment of the principal or redemption price of, or interest on, any bonds, or any reimbursement or similar agreement with any provider of credit enhancement for bonds, or any swap or other agreement entered into in connection with bonds, is binding on the parties and on any successors. The collateral shall immediately be subject to the pledge, and the pledge shall constitute a lien and security interest which shall attach immediately to the collateral and be effective, binding, and enforceable against the pledgor, its successors, purchasers of the collateral, creditors, and all others, to the extent set forth, and in accordance with, the pledge document irrespective of whether those parties have notice of the pledge and without the need for any physical delivery, recordation, filing, or further act.

(8) No personal liability. No board member of the commission is liable personally on the bonds or subject to any personal liability or accountability by reason of the issuance of the bonds, unless the personal liability or accountability is the result of willful misconduct.

(9) Bonds not public debt. (a) Unless otherwise expressly provided in the bond resolution, each issue of bonds by the commission shall be the limited obligation of the commission payable solely from amounts received by the commission from revenues derived from the project to be financed or refinanced or from any contract entered into or investment made in connection with the bonds and pledged to the payment of the bonds.

(b) The state and the political subdivisions who are parties to the agreement creating a commission under this section are not liable on bonds or any other contract entered into under this section, or for any other debt, obligation, or liability of the commission, whether in tort, contract, or otherwise.

(c) The bonds are not a debt of the state or the political subdivisions contracting to create a commission under this section. A bond issue under this section does not obligate the state or a political subdivision to levy any tax or make any appropriation for payment of the bonds. All bonds issued by a commission are payable solely from the funds pledged for their payment in accordance with the bond resolution or trust agreement or indenture providing for their issuance. All bonds shall contain, on their face, a statement regarding the obligations of the state, the political subdivisions who are parties to the agreement creating the commission, and the commission as set forth in this paragraph.

(10) Audits, fiscal year. (a) The board of a commission shall adopt a calendar year as its fiscal year for accounting purposes. The board shall annually prepare a budget for the commission.

(b) A commission shall maintain an accounting system in accordance with generally accepted accounting principles and shall have its financial statements and debt covenants audited annually by an independent certified public accountant, except that the commission by a unanimous vote may decide to have an audit performed under this paragraph every 2 years.

(c) A copy of the budget and audit shall be sent to the governing body of each political subdivision which is a party to the agreement that created the commission and filed with the secretary of administration and the legislative audit bureau.

(11) Limitations. (a) A commission may not issue bonds to finance a capital improvement project in any state or territory of the United States unless a political subdivision within whose boundaries the project is to be located has approved the financing of the project. A commission may not issue bonds to finance a capital improvement project in this state unless all of the political subdivisions within whose boundaries the project is to be located has approved the financing of the project. An approval under this paragraph may be made by the governing body of the political subdivision or, except for a 1st class city or a county in which a 1st class city is located, by the highest ranking executive or administrator of the political subdivision.

(b) This section provides a complete alternative method, to all other methods provided by law, to exercise the powers authorized in this section, including the issuance of bonds, the entering into of contracts related to those bonds, and the financing or refinancing of projects.

(bm) A project may be located outside of the United States or outside a territory of the United States if the borrower, including a co-borrower, of proceeds of bonds issued to finance or refinance the project in whole or in part is incorporated and has its principal place of business in the United States or a territory of the United States. To the extent that this paragraph applies to a borrower, it also applies to a participant if the participant is a nongovernmental entity.

(c) Any action brought to challenge the validity of the issuance of a bond under this section, or the enforceability of a contract entered into under this section, must be commenced in circuit court within 30 days of the commission adopting a resolution authorizing the issuance of the bond or the execution of the contract.

(d) Bonds issued under this section shall not be invalid for any irregularity or defect in the proceedings for their sale or issuance. The bonds shall contain a statement that they have been authorized and issued pursuant to the laws of this state. The statement shall be conclusive evidence of the validity of the bonds.

(12) State Pledge. The state pledges to and agrees with the bondholders, and persons that enter into contracts with a commission under this section, that the state will not limit, impair, or alter the rights and powers vested in a commission by this section, including the rights and powers under sub. (4), before the commission has met and discharged the bonds, and any interest due on the bonds, and has fully performed its contracts, unless adequate provision is made by law for the protection of the bondholders or those entering into contracts with a commission. The commission may include this pledge in a contract with bondholders.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0304, WI ST 66.0304

Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0305

66.0305. Political subdivision revenue sharing

Currentness

(1) Definition. In this section, "political subdivision" means a city, village, town, or county.

(2) Political subdivision revenue sharing agreement. Subject to the requirements of this section, any 2 or more political subdivisions may, by a majority vote of a quorum of their governing bodies, enter into an agreement to share all or a specified part of revenues derived from taxes and special charges, as defined in s. 74.01(4). One or more political subdivisions may enter into agreements under this section with federally recognized American Indian tribes or bands.

(3) Public hearing. At least 30 days before entering into an agreement under sub. (2), a political subdivision shall hold a public hearing on the proposed agreement. Notice of the hearing shall be published as a class 3 notice under ch. 985.

(4) Specifications. (a) An agreement entered into under sub. (2) shall meet all of the following conditions:

1. The term of the agreement shall be for at least 10 years.

2. The boundaries of the area within which the revenues are to be shared in the agreement shall be specified.

3. The formula or other means of determining the amount of revenues to be shared under the agreement shall be specified.

4. The date upon which revenues agreed to be shared under the agreement shall be paid to the appropriate political subdivision shall be specified.

5. The method by which the agreement may be invalidated after the expiration of the minimum period specified in par. (a)1. shall be specified.

(b) An agreement entered into under sub. (2) may address any other appropriate matters, including any agreements with respect to services or agreements with respect to municipal boundaries under s. 66.0225, 66.0301(6), or 66.0307.

(5) Contiguous boundaries. No political subdivision may enter into an agreement under sub. (2) with one or more political subdivisions unless the political subdivision is contiguous to at least one other political subdivision that enters into the agreement.

(6) Advisory referendum. (a) Within 30 days after the hearing under sub. (3), the governing body of a participating political subdivision may adopt a resolution calling for an advisory referendum on the agreement. An advisory referendum shall be held if, within 30 days after the hearing under sub. (3), a petition, signed by a number of qualified electors equal to at least 10 percent of the votes cast for governor in the political subdivision at the last gubernatorial election, is filed with the clerk of a participating political subdivision, requesting an advisory referendum on the revenue sharing plan. The petition shall conform to the requirements of s. 8.40 and shall be filed as provided in s. 8.37. If an advisory referendum is held, the political subdivision's governing body may not vote to approve the agreement under sub. (2) until the report under par. (d) is filed.

(b) The advisory referendum shall be held not less than 70 days nor more than 100 days after adoption of the resolution under par. (a) calling for the referendum or not less than 70 days nor more than 100 days after receipt of the petition under par. (a) by the municipal or county clerk. The municipal or county clerk shall give notice of the referendum by publishing a notice in a newspaper of general circulation in the political subdivision, both on the publication day next preceding the advisory referendum election and one week prior to that publication date.

(c) The advisory referendum shall be conducted by the political subdivision's election officials. The governing body of the political subdivision may specify the number of election officials for the referendum. The ballots shall contain the words “For the revenue sharing agreement” and “Against the revenue sharing agreement” and shall otherwise conform to the provisions of s. 5.64(2). The election shall be conducted as are other municipal or county elections in accordance with chs. 6 and 7, insofar as applicable.

(d) The election inspectors shall report the results of the election, showing the total number of votes cast and the numbers cast for and against the revenue sharing. The election inspectors shall attach their affidavit to the report and immediately file the report in the office of the municipal or county clerk.

(e) The costs of the advisory referendum election shall be borne by the political subdivision that holds the election.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0305, WI ST 66.0305
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter III. Intergovernmental Cooperation

W.S.A. 66.0307

66.0307. Boundary change pursuant to approved cooperative plan

Currentness

(1) Definitions. In this section:

(af) "Comprehensive plan" means an adopted plan that contains the elements under s. 66.1001(2) or, if a municipality has not adopted a plan that contains those elements, a master plan adopted under s. 62.23(2) or (3).

(am) "Department" means the department of administration.

(b) "Municipality" means a city, village or town.

(2) Boundary change authority. Any combination of municipalities may determine the boundary lines between themselves under a cooperative plan that is approved by the department under this section. A single city or village and a single town may use the mediated agreement procedure under sub. (4m) to determine a common boundary line under a cooperative plan that is approved by the department under this section. No boundary of a municipality may be changed or maintained under this section unless the municipality is a party to the cooperative agreement. The cooperative plan shall provide one or more of the following:

(a) That specified boundary line changes shall occur during the planning period and the approximate dates by which the changes shall occur.

(b) That specified boundary line changes may occur during the planning period and the approximate dates by which the changes may occur.

(c) That a required boundary line change under par. (a) or an optional boundary line change under par. (b) shall be subject to the occurrence of conditions set forth in the plan.

(d) That specified boundary lines may not be changed during the planning period.

(3) Cooperative plan. (a) *Who may prepare plan.* The municipalities that propose to set the boundary lines between themselves under this section shall prepare a cooperative plan.

(b) *Purpose of plan.* The cooperative plan shall be made with the general purpose of guiding and accomplishing a coordinated, adjusted and harmonious development of the territory covered by the plan consistent with the comprehensive plan of each participating municipality.

(c) *Content of plan; consistency with comprehensive plan*. The cooperative plan shall describe how it is consistent with each participating municipality's comprehensive plan.

(d) *Content of plan; boundaries and services.* The cooperative plan shall:

1. Identify any boundary change and any existing boundary that may not be changed during the planning period.

2. Identify any conditions that must be met before a boundary change may occur.

3. Include a schedule of the period during which a boundary change shall or may occur.

4. Include a statement explaining how any part of the plan related to the location of boundaries meets the approval criteria under sub. (5)(c) 5.

4m. Identify all highways within the territory covered by the plan of which each participating municipality has jurisdiction.

5. Describe the services to be provided to the territory covered by the plan, identify the providers of those services and indicate whether the provision of any service has received preliminary approval of any relevant governmental regulatory authority.

6. Include a schedule for delivery of the services described under subd. 5.

7. Include a statement explaining how provision under the plan for the delivery of necessary municipal services to the territory covered by the plan meets the approval criterion under sub. (5)(c)3.

8. Designate the municipalities that are participating in the cooperative plan and that are required to ratify any boundary changes by enacting an ordinance under sub. (10).

(e) *Content of plan; compatibility with existing law.* The cooperative plan shall describe how the plan is consistent with current state and federal laws, county shoreland zoning ordinances under s. 59.692, municipal regulations and administrative rules that apply to the territory affected by the plan.

(f) *Content of plan; planning period.* The cooperative plan shall specify the duration of the proposed planning period, which shall be for a period of 10 years, except that the duration of the proposed planning period may be for a period greater than 10 years if a duration greater than 10 years is approved by the department.

(g) *Content of plan; zoning agreement.* The cooperative plan shall include all agreements under sub. (7m).

(h) *Existing plans may be used.* A cooperative plan may be based on, contain elements of or duplicate any existing plan for the same territory.

(4) Procedure for adopting cooperative plan. (a) *Authorizing resolution.* Each municipality that intends to participate in the preparation of a cooperative plan under this section shall adopt a resolution authorizing participation in the preparation of the plan. Notice of each resolution shall be given in writing, within 5 days after the resolution is adopted, to all of the following:

1. The department, the department of natural resources, the department of agriculture, trade and consumer protection and the department of transportation.

2. The clerks of any municipality, school district, technical college district, sewerage district or sanitary district which has any part of its territory within 5 miles of a participating municipality.

3. The clerk of each county in which a participating municipality is located.

4. Any county zoning agency under s. 59.69(2) or regional planning commission whose jurisdiction includes a participating municipality.

(b) *Public hearing.* At least 60 days after adoption under par. (a) of the last resolution by a participating municipality and at least 60 days before submitting a cooperative plan to the department for review and approval under sub. (5), the participating municipalities shall hold a joint hearing on the proposed plan. Notice of the hearing shall be given by each participating municipality by class 3 notice under ch. 985.

(c) *Comment on plan.* Any person may comment on the plan during the hearing and may submit written comments before, at or within 20 days following the hearing. All comments shall be considered by each participating municipality. A county zoning agency under s. 59.69(2) or regional planning commission whose jurisdiction includes any participating municipality shall comment in writing on the plan's effect on the master plan adopted by the regional planning commission under s. 66.0309(9), or development plan adopted by the county board or county planning agency under s. 59.69(3), and on the delivery of municipal services, and may comment on any other aspect of the plan. A county in the regional planning commission's jurisdiction may submit comments on the effect of the cooperative plan on the master plan adopted under s. 66.0309(9) and on the delivery of county services or on any other matter related to the plan.

(d) *Adoption of final plan.* 1. Subject to subd. 2., after the public hearing under par. (b) and consideration of comments made on the proposed cooperative plan, the plan participants may revise the plan in response to the comments and may, by resolution adopted by each participating municipality, adopt a final version of the plan.

2. If within 30 days after the public hearing under par. (b) a petition opposing the plan, signed by a number of qualified electors equal to at least 10 percent of the votes cast for governor in the municipality at the last gubernatorial election, is filed with the clerk of a participating municipality, the final version of the plan may be adopted in that municipality only by an affirmative vote of three-fourths of the members of the municipality's governing body who are present and voting. The petition shall conform to the requirements of s. 8.40.

(e) *Advisory referendum.* 1. Within 30 days after adoption of a final plan under par. (d), the governing body of a participating municipality may adopt a resolution calling for an advisory referendum on the plan. An advisory referendum shall be held if, within 30 days after adoption of the final plan under par. (d), a petition, signed by a number of qualified electors equal to at least 10 percent of the votes cast for governor in the municipality at the last gubernatorial election, is filed with the clerk of a participating municipality and as provided in s. 8.37, requesting an advisory referendum on the cooperative plan. The petition shall conform to the requirements of s. 8.40.

2. The advisory referendum shall be held not less than 70 days nor more than 100 days after adoption of the resolution under subd. 1. calling for the referendum or not less than 70 days nor more than 100 days after receipt of the petition by the municipal clerk. The municipal clerk shall give notice of the referendum by publishing a notice in a newspaper of general circulation in the municipality, both on the publication day next preceding the advisory referendum election and one week prior to that publication date.

3. The advisory referendum shall be conducted by the municipal election officials. The governing body of the municipality may specify the number of election officials for the referendum. The ballots shall contain the words “For the cooperative plan” and “Against the cooperative plan” and shall otherwise conform to the provisions of s. 5.64(2). The election shall be conducted as are other municipal elections in accordance with chs. 6 and 7, insofar as applicable.

4. The election inspectors shall report the results of the election, showing the total number of votes cast and the numbers cast for and against the cooperative plan. The election inspectors shall attach their affidavit to the report and immediately file the report in the office of the municipal clerk. The election inspector shall file a certified report of the results in the office of the clerk of each municipality that is a party to the cooperative plan.

5. The costs of the advisory referendum election shall be borne by the municipality that holds the election.

(f) *Submittal of final plan to department.* If no advisory referendum is held under par. (e), the plan participants may submit the final version of the cooperative plan to the department for approval under sub. (5) at least 60 days but not more than 180 days after the public hearing under par. (b). If an advisory referendum is held under par. (e), each participating municipality shall determine, by resolution, whether to submit the final version of the cooperative plan to the department for approval under sub. (5). The resolution shall be adopted within 60 days after the last advisory referendum is held. If any of the plan participants fails or refuses to approve submittal of the cooperative plan to the department, the plan may not be submitted. Any written comment received by a participating municipality on any version of the cooperative plan shall be submitted to the department at the time that the cooperative plan is submitted. If the cooperative plan is not submitted to and approved by the department, it may not be implemented under this section by any of the participating municipalities.

(4m) Mediated agreement procedure. (a)1. As an alternative to the parties mutually invoking the procedure under this section, a city, village, or town may petition the department for mediation of a cooperative plan under this paragraph.

2. A city or village may petition for mediation if all of the following apply:

a. The city or village adopts an authorizing resolution under sub. (4)(a)(intro.) and requests in writing an adjacent town to adopt an authorizing resolution under sub. (4)(a)(intro.) and the town fails to adopt the resolution within 60 days after the request is received by the town.

b. The city or village has adopted a comprehensive plan.

3. A town may petition for mediation if all of the following apply:

a. The town adopts an authorizing resolution under sub. (4)(a)(intro.) and requests in writing an adjacent city or village to adopt an authorizing resolution under sub. (4)(a)(intro.) and the city or village fails to adopt the resolution within 60 days after the request is received by the city or village.

b. The town has adopted a comprehensive plan.

(b) A municipality that is authorized under par. (a) to petition the department for mediation and elects to do so shall submit the petition within 90 days after the municipality has adopted the authorizing resolution described in par. (a)2. a. or 3. a. Upon receipt of a petition for mediation, the department shall notify the nonpetitioning adjacent municipality identified in the petition that the petition has been submitted. Within 45 days after receipt of notice from the department that a petition has been submitted, the nonpetitioning municipality shall notify the department whether it agrees to engage in mediation to develop a cooperative plan under this section. Failure of the nonpetitioning municipality to timely notify the department is considered notice that the municipality does not agree to engage in mediation. The department shall send written notice of the nonpetitioning municipality's decision, on whether it will participate, to the petitioning municipality. If the nonpetitioning municipality refuses to engage in mediation, the petitioning municipality may not submit a petition under this paragraph involving the same nonpetitioning municipality for a period of 3 years after the department sends notice of the refusal.

(c)1. If a nonpetitioning town refuses under par. (b) to engage in mediation, the town may not contest any annexation of its territory to the petitioning city or village that is commenced during the shorter of the following periods:

a. The period of 270 days beginning after the town refuses under par. (b) to engage in mediation.

b. The period beginning on the date the town refuses under par. (b) to engage in mediation and ending on the date the town agrees to engage in mediation.

2. If a nonpetitioning city or village refuses under par. (b) to engage in mediation, an annexation of territory of the petitioning town to the nonpetitioning city or village that is commenced during the shorter of the following periods shall be reviewed by the department in the manner described under s. 66.0217(6), regardless of the population of the county in which the annexation

proceeding is commenced, and, notwithstanding s. 66.0217(11)(c), may be contested by the town if the department determines that the annexation is not in the public interest:

a. The period of 270 days beginning after the city or village refuses under par. (b) to engage in mediation.

b. The period on the date the city or village refuses under par. (b) to engage in mediation and ending on the date the city or village agrees to engage in mediation.

(d)1. If both the petitioning municipality and nonpetitioning municipality agree to engage in mediation to develop a cooperative plan under this section, the municipalities shall select a mediator. The department may assist the municipalities in selecting a mediator. If the municipalities are unable to agree on the selection of a mediator, the department shall furnish a list of 5 mediators to the municipalities. The municipalities shall alternatively strike a name from the list until one name remains, who shall be the mediator.

2. The mediator shall assist the parties through recognized mediation techniques to develop and reach agreement on a cooperative plan under this section. Unless the participating municipalities agree to extend the mediation period, the mediation period expires after 270 days. Unless they agree otherwise, the participating municipalities are equally responsible for the costs of the mediation.

(e) Before the participating municipalities engage in mediation under this subsection, each shall adopt a resolution under sub. (4)(a)(intro.) and provide the required notice of the resolution. Notwithstanding sub. (4)(b), if the participating municipalities agree on a cooperative plan under this subsection, a public hearing on the plan shall be held under sub. (4)(b) no sooner than 45 days after agreement is reached and at least 45 days before submitting the plan to the department for review and approval under sub. (5).

(f) If any litigation contesting annexation of territory of the petitioning or nonpetitioning town to the city or village is commenced during the 3-year period after the department receives the petition for mediation under par. (b), the judge shall under s. 802.12(2), unless the nonpetitioning municipality objects, order the parties to select a settlement alternative under s. 802.12(1)(i) as a means to attempt settlement.

(5) Department review and approval of local or cooperative plan. (a) *Generally.* The department shall make a written determination of whether to approve a cooperative plan within 90 days after receiving the plan unless the department and the parties to the plan agree to a longer determination period. The department shall consider written comments on the plan received by a municipality under sub. (4)(c) that is submitted to the department under sub. (4)(f) or from any other source. The department may request information relating to the cooperative plan, including any comprehensive plan or land use plan currently being utilized by any participating municipality, from that municipality, and from any county or regional planning commission. The department may seek and consider comments from any state agency on whether the cooperative plan is consistent with state laws and administrative rules under the agency's jurisdiction. Any state agency requested to comment on a cooperative plan shall comply with the request. The department shall issue its determination of whether to approve the cooperative plan in writing, supported by specific findings based on the criteria under par. (c). The approval or disapproval of a cooperative plan by the department under this section is not a contested case, as defined in s. 227.01(3), for purposes of ch. 227.

(b) *Hearing.* Any person may request a public hearing before the department on a cooperative plan submitted to the department for approval. A request for a public hearing shall be in writing and shall be submitted to the department within 10 days after the cooperative plan is received by the department. If requested, the department shall, and on its own motion the department may, hold a public hearing on the cooperative plan. If requested to hold a public hearing, the department is required to hold only one hearing, regardless of the number of requests for a hearing. Any public hearing under this paragraph shall be held in a municipality that is a party to the cooperative plan.

(c) *Approval of cooperative plan.* A cooperative plan shall be approved by the department if the department determines that all of the following apply:

1. The content of the plan under sub. (3)(c) to (e) is sufficient to enable the department to make the determinations under subds. 2. to 5.

2. The cooperative plan is consistent with each participating municipality's comprehensive plan and with current state laws, municipal regulations, and administrative rules that apply to the territory affected by the plan.

3. Adequate provision is made in the cooperative plan for the delivery of necessary municipal services to the territory covered by the plan.

5. The shape of any boundary maintained or any boundary change under the cooperative plan is not the result of arbitrariness and reflects due consideration for compactness of area. Considerations relevant to the criteria under this subdivision include quantity of land affected by the boundary maintenance or boundary change and compatibility of the proposed boundary maintenance or boundary change with natural terrain including general topography, major watersheds, soil conditions and such features as rivers, lakes and major bluffs.

6. Any proposed planning period exceeding 10 years is consistent with the plan.

(d) *Return and resubmittal of plan.* The department may return a cooperative plan, with comments, if the department determines that the cooperative plan, if revised, may constitute a plan that can be approved by the department. If a cooperative plan is returned under this paragraph, each participating municipality may revise the plan, as directed by the department, adopt the revised plan by resolution and resubmit the plan to the department within 90 days after the plan is returned. After receiving a resubmitted cooperative plan, the department shall make a determination on approval within 30 days.

(6) Binding elements of cooperative plan. If a cooperative plan is approved by the department under sub. (5) or an amended plan is approved under sub. (8), provisions in the plan to maintain existing boundaries, the boundary changes in the plan, the schedule for those changes, the plan for delivery of services, including road maintenance, and the schedule for those services are binding on the parties to the plan and have the force and effect of a contract.

(7) Other boundary procedures. (a) *Other procedures after hearing.* After the joint hearing under sub. (4)(b) is held, no other procedure, except the procedure under s. 281.43(1m), for altering a municipality's boundaries may be used to alter a boundary included in the proposed cooperative plan under sub. (3)(d)1. until the boundary is no longer included in the proposed

cooperative plan, the municipality withdraws from the proposed cooperative plan or the proposed cooperative plan fails to receive approval from the department, whichever occurs first.

(b) *Other boundary procedures during the planning period.* During the planning period specified under sub. (3)(f), no other procedure for altering a municipality's boundaries may be used to alter a boundary that is included in the cooperative plan under sub. (3)(d)1., except if an annexation is conducted under s. 281.43(1m), regardless of whether the boundary is proposed to be maintained or changed or is allowed to be changed under the plan. After the planning period has expired, the boundary may be altered.

(7m) Zoning in town territory. (a) If a town is a party to a cooperative plan with a city or village, the town and city or village may agree, as part of the cooperative plan, to authorize the town, city, or village to enact a zoning ordinance under s. 60.61, 61.35, or 62.23 for all or a portion of the town territory covered by the plan. The exercise of zoning authority by a town under this paragraph is not subject to s. 60.61(3) or 60.62(3).

(b)1. If a county zoning ordinance applies to the town territory covered by a cooperative plan subject to an agreement under par. (a), that ordinance and any regulations, approvals, and conditions imposed under the ordinance continue in effect until the ordinance or the particular regulation, approval, or condition is specifically changed by official action of the town, city, or village with authority to enact a zoning ordinance under the agreement under par. (a). This subdivision does not expand or modify the authority of a town, city, or village to change a zoning ordinance, any regulation, approval, or condition imposed under a zoning ordinance, or any nonconforming use.

2. If a zoning ordinance is enacted under par. (a), that zoning ordinance and any regulations, approvals, and conditions imposed under the ordinance continue in effect after the planning period ceases until the ordinance or the particular regulation, approval, or condition is specifically changed under other applicable law.

(c) This subsection does not affect zoning ordinances adopted under s. 59.692 or 87.30 or ch. 91.

(8) Amendments to cooperative plan. (a) *Authority to amend plan.* A cooperative plan may be amended during the planning period if all the parties to the plan agree to the amendment and if the amendment is approved by the department.

(b) *When full procedure required.* An amendment to a cooperative plan that proposes to change a municipality's boundary or to change the approved planning period shall follow the same procedure as that required for an original plan.

(c) *When expedited procedure may occur.* An amendment to a cooperative plan that does not propose to change a boundary or the planning period shall follow the same procedure as that required for an original plan except that the hearing under sub. (4)(b) is not required unless objection to the amendment is made in writing by any person to the clerk of a participating municipality. An amendment under this paragraph shall be adopted by resolution of each of the participating municipalities. Notice of the amendment and adopting resolution shall follow the procedures specified in sub. (4)(a). Notice that the amendment will be submitted directly to the department unless objection is made in writing shall be given by each participating municipality by a class 3 notice under ch. 985. If no written objection to the amendment is received within 7 days after the last required notice is published, the amendment may be submitted directly to the department for approval. If written objection is timely made, the public hearing and other requirements under sub. (4)(b) and (c) apply.

(9) Court review of department decision. The decision of the department under sub. (5)(c) or (d) or (8) to approve or not to approve a cooperative plan or an amendment to a plan is subject to judicial review under ch. 227.

(10) Boundary change ordinance; filing and recording requirements. A boundary change under a cooperative plan shall be accomplished by the enactment of an ordinance by the governing body designated to do so in the plan. The filing and recording requirements under s. 66.0217(9)(a), as they apply to cities and villages under s. 66.0217(9)(a), apply to municipalities under this subsection. The requirements for the secretary of administration are the same as those required in s. 66.0217(9)(b).

(11) Time for bringing action. No action to contest the validity of a cooperative plan under this section or an amendment to a cooperative plan, regardless of the grounds for the action, may be commenced after 60 days from the date on which the department approves the cooperative plan under sub. (5) or the amendment under sub. (8), respectively. No action relating to compliance with a binding element of a cooperative plan may be commenced later than 180 days after the failure to comply.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (2)

W. S. A. 66.0307, WI ST 66.0307
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0309

66.0309. Creation, organization, powers and duties of regional planning commissions

Currentness

(1) Definitions. In this section:

(a) "Governing body" means the town, village or county board or the legislative body of a city.

(b) "Local governmental units" or "local units" means cities, villages, towns and counties.

(c) "Population" means the population of a local unit as shown by the last federal census or by any subsequent population estimate under s. 16.96.

(2) Creation of regional planning commissions. (a) A regional planning commission may be created by the governor, or a state agency or official as the governor designates, upon petition in the form of a resolution by the governing body of a local governmental unit and the holding of a public hearing on the petition. If the petition is joined in by the governing bodies of all the local units in the proposed region, including the county board of any county, part or all of which is in the proposed region, the governor may dispense with the hearing. Notice of any public hearing shall be given by the governor by mail at least 10 days in advance to the clerk of each local unit in the proposed region.

(b) If the governor finds that there is a need for a regional planning commission, and if the governing bodies of local units within the proposed region which include over 50 percent of the population and equalized assessed valuation of the region as determined by the last previous equalization of assessments, consent to the formation of such regional planning commission, the governor may create the regional planning commission by order and designate the area and boundaries of the commission's jurisdiction taking into account the elements of homogeneity based upon, but not limited to, such considerations as topographic and geographic conformations, extent of urban development, the existence of special or acute agricultural, forestry, conservation or other rural problems, uniformity of social or economic interests and values, park and recreational needs, civil defense, or the existence of physical, social and economic problems of a regional character.

(c) Territory included within a regional planning commission that consists of one county or less in area also may be included in the creation of a multicounty regional planning commission. The creation does not require that the existing regional planning commission consisting of one county or less in area be terminated or altered, but upon creation of the multicounty commission, the existing commission shall cease to have authority to make charges upon participating local governmental units under sub. (14) and shall adopt a name other than "regional planning commission".

(2m) Limitation on territory. No regional planning commission may be created to include territory located in 3 or more uniform state districts as established by 1970 executive order 22 dated August 24, 1970. Any existing regional planning commission which includes territory located in 3 or more uniform state districts shall be dissolved no later than December 31, 1972.

(3) Composition of regional planning commissions. (a) The membership composition of a regional planning commission which includes a city of the first class shall be as follows:

1. One member appointed by the county board of each county, part or all of which is initially within the region or is later added.

2. Two members from each participating county shall be appointed by the governor. At least one appointee shall be a person, selected from a list of 2 or more persons nominated by the county board, who has experience in local government in elective or appointive offices or who is professionally engaged in advising local governmental units in the fields of land-use planning, transportation, law, finance, engineering or recreation and natural resources development. The governor in making appointments under this subdivision shall give due weight to the place of residence of the appointees within the various counties encompassed by the region.

(b) For any region which does not include a 1st class city, the membership composition of a regional planning commission shall be in accordance with resolutions approved by the governing bodies of a majority of the local units in the region, and these units shall have in the aggregate at least half the population of the region. For the purposes of this determination a county, part or all of which is within the region, shall be counted as a local unit, but the population of an approving county shall not be counted. In the absence of the necessary approval by the local units, the membership composition of a commission shall be determined as follows:

1. For regions which include land in more than one county par. (a) shall apply.

2. For regions that include land in only one county, the commission shall consist of the following:

a. Three members appointed by the county board.

b. Three members appointed by the governing body of each city, village and town in the region having a population of 20,000 or more. If there is no city, village or town having a population of 20,000 or more, the governor shall appoint one member from each city, village or town with a population of 5,000 or more within the region. All governor appointees under this subd. 2.b. shall be persons who have experience in local government in elective or appointive offices or who are professionally engaged in advising local governmental units in the fields of land-use planning, transportation, law, finance or engineering.

c. Three members appointed at large by the governor. All governor appointees under this subd. 2.c. shall be persons who have experience in local government in elective or appointive offices or who are professionally engaged in advising local governmental units in the fields of land-use planning, transportation, law, finance or engineering.

(c) Terms of office for regional planning commission members shall be as follows:

1. If the composition of the commission is approved by local units under par. (b), the terms shall be as prescribed in the resolutions of approval.

2. For members of all other commissions the term is 6 years after the initial term. At the first meeting of the commission it shall be determined by lot which of the initial members shall have 2, 4 and 6-year terms, respectively, and each group shall be as nearly equal as may be.

(d) All regional planning commission members shall be electors of the state and reside within the region.

(4) Compensation; expenses. A per diem compensation may be paid members of regional planning commissions. This shall not affect in any way remuneration received by any state or local official who, in addition to serving as a state or local official, serves also as a member of the regional planning commission. All members may be reimbursed for actual expenses incurred as members of the commission in carrying out the work of the commission.

(5) Chairperson; rules of procedure; records. Each regional planning commission shall elect its own chairperson and executive committee and shall establish its own rules of procedure, and may create and fill other offices as it may determine necessary. The commission may authorize the executive committee to act for it on all matters under rules adopted by it. The commission shall meet at least once each year. It shall keep a record of its resolutions, transactions, findings and determinations, which shall be a public record.

(6) Director and employees. The regional planning commission shall appoint a director and such employees as it deems necessary for its work and may hire such experts and consultants for part-time or full-time service as may be necessary for the prosecution of its responsibilities.

(7) Advisory committees or councils; appointment. The regional planning commission may appoint advisory committees or councils whose membership may consist of individuals whose experience, training or interest in the program may qualify them to lend valuable assistance to the regional planning commission by acting in an advisory capacity in consulting with the regional planning commission on all phases of the commission's program. Members of advisory bodies shall receive no compensation for their services but may be reimbursed for actual expenses incurred in the performance of their duties.

(8) Functions, general and special. (a)1. The regional planning commission may take any of the following actions:

a. Conduct all types of research studies, collect and analyze data, prepare maps, charts and tables, and conduct all necessary studies for the accomplishment of its other duties.

b. Consistent with the elements specified in s. 66.1001, make plans for the physical, social and economic development of the region, and, consistent with the elements specified in s. 66.1001, adopt by resolution any plan or the portion of any plan so prepared as its official recommendation for the development of the region.

c. Publicize and advertise its purposes, objectives and findings, and distribute reports concerning these items.

d. Provide advisory services on regional planning problems to the local government units within the region and to other public and private agencies in matters relative to its functions and objectives, and may act as a coordinating agency for programs and activities of local units and agencies as they relate to its objectives.

2. All public officials shall, upon request, furnish to the regional planning commission, within a reasonable time, available information as it requires for its work. In general, the regional planning commission shall have all powers necessary to enable it to perform its functions and promote regional planning. The functions of the regional planning commission shall be solely advisory to the local governments and local government officials comprising the region.

(b) The regional planning commission shall make an annual report of its activities to the legislative bodies of the local governmental units within the region, and shall submit 2 copies of the report to the legislative reference bureau.

(9) Preparation of master plan for region. The regional planning commission shall have the function and duty of making and adopting a master plan for the physical development of the region. The master plan, with the accompanying maps, plats, charts, programs and descriptive and explanatory matter, shall show the commission's recommendations for physical development and shall contain at least the elements described in s. 66.1001. The regional planning commission may amend, extend or add to the master plan or carry any part or subject matter into greater detail.

(10) Adoption of master plan for region. The master plan shall be made with the general purpose of guiding and accomplishing a coordinated, adjusted and harmonious development of the region which will, in accordance with existing and future needs, best promote public health, safety, morals, order, convenience, prosperity or the general welfare, as well as efficiency and economy in the process of development. The regional planning commission may adopt the master plan as a whole by a single resolution, or, as the work of making the whole master plan progresses, may by resolution adopt a part or parts of the master plan, any part to correspond with one or more of the elements specified in s. 66.1001. The resolution shall refer expressly to the maps, plats, charts, programs and descriptive and explanatory matter, and other matters intended by the regional planning commission to form the whole or any part of the plan, and the action taken shall be recorded on the adopted plan or part of the adopted plan by the identifying signature of the chairperson of the regional planning commission and a copy of the plan or part of the adopted plan shall be certified to the legislative bodies of the local governmental units within the region. The purpose and effect of adoption of the master plan shall be solely to aid the regional planning commission and the local governments and local government officials comprising the region in the performance of their functions and duties.

(11) Matters referred to regional planning commission. The officer or public body of a local governmental unit within the region having final authority may refer to the regional planning commission, for its consideration and report, the location or acquisition of land for any of the items or facilities that are included in the adopted regional master plan. Within 20 days after the matter is referred to the regional planning commission or a longer period as may be stipulated by the referring officer or public body, the commission shall report its recommendations to the referring officer or public body. The report and recommendations of the commission shall be advisory only. A state agency may authorize the regional planning commission with the consent of the commission to act for the agency in approving, examining, or reviewing plats under s. 236.12(2)(ap). A regional planning commission authorized by a local unit on November 1, 1980, to act for the local unit in approving plats may continue to so act until the commission withdraws its consent or the local unit its approval. A local unit may authorize a regional planning commission, with the consent of the commission, to conduct an advisory review of plats.

(12) Local adoption of plans of regional commission; contracts. (a) Any local governmental unit within the region may adopt all or any portion of the plans and other programs prepared and adopted by the regional planning commission.

(b) In addition to the other powers specified in this section a regional planning commission may enter into a contract with any local unit within the region under s. 66.0301 to make studies and offer advice on any of the following topics:

1. Land use, thoroughfares, community facilities, and public improvements.

2. Encouragement of economic and other developments.

(13) Aid from governmental agencies; gifts and grants. Aid, in any form, for the purpose of accomplishing the objectives of the regional planning commission may be accepted from all governmental agencies whether local, state or federal, if the conditions under which aid is furnished are not incompatible with the other provisions of this section. The regional planning commission may accept gifts and grants from public or private individuals or agencies if the conditions under which the grants are made are in accordance with the accomplishment of the objectives of the regional planning commission.

(14) Budget and service charges. (a) For the purpose of providing funds to meet the expenses of a regional planning commission, the commission shall annually on or before October 1 prepare and approve a budget reflecting the cost of its operation and services to the local governmental units within the region. The amount of the budget charged to any local governmental unit shall be in the proportion of the equalized value for tax purposes of the land, buildings, and other improvements on the land of the local governmental unit, within the region, to the total equalized value within the region. The amount charged to a local governmental unit shall not exceed .003 percent of equalized value under its jurisdiction and within the region, unless the governing body of the unit expressly approves the amount in excess of that percentage. All tax or other revenues raised for a regional planning commission shall be forwarded by the treasurer of the local unit to the treasurer of the commission on written order of the treasurer of the commission.

(b) Where one-half or more of the land within a county is within a region, the chairperson of the regional planning commission shall certify to the county clerk, before August 1 of each year, the proportionate amount of the budget charged to the county for the services of the regional planning commission. Unless the county board finds the charges unreasonable, and institutes the procedures under par. (d), it shall take legislative action as necessary to provide the funds called for in the certified statement.

(c) Where less than one-half of the land within a county is within a region, the chairperson of the regional planning commission shall before August 1 of each year certify to the clerk of the local governmental unit involved a statement of the proportionate charges assessed to that local governmental unit. The clerk shall extend the amount shown in the statement as a charge on the tax roll under s. 281.43(2).

(d) If any local governmental unit makes a finding by resolution within 20 days of the certification to its clerk that the charges of the regional planning commission are unreasonable, it may take any of the following actions:

1. Submit the issue to arbitration by 3 arbitrators, one to be chosen by the local governmental unit, one to be chosen by the regional planning commission, and the third to be chosen by the first 2 arbitrators. If the arbitrators are unable to agree, the vote of 2 shall be the decision. The arbitrators may affirm or modify the report, and shall submit their decision in writing to the local governmental unit and the regional planning commission within 30 days of their appointment unless the time is extended by agreement of the commission and the local governmental unit. The decision is binding. An election to arbitrate is a waiver of

the right to proceed by action. Two-thirds of the expenses of arbitration shall be paid by the party requesting arbitration and the balance by the other.

2. If a local governmental unit does not elect to arbitrate, it may institute a proceeding for judicial review under ch. 227.

(e) By agreement between the regional planning commission and a local governmental unit, special compensation to the commission for unique and special services provided to the local governmental unit may be arranged.

(f) The regional planning commission may accept from any local governmental unit supplies, the use of equipment, facilities and office space and the services of personnel as part or all of the financial support assessed against the local governmental unit.

(15) Dissolution of regional planning commissions. Upon receipt of certified copies of resolutions recommending the dissolution of a regional planning commission adopted by the governing bodies of a majority of the local units in the region, including the county board of any county, part or all of which is within the region, and upon a finding that all outstanding indebtedness of the commission has been paid and all unexpended funds returned to the local units which supplied them, or that adequate provision has been made for the outstanding indebtedness or unexpended funds, the governor shall issue a certificate of dissolution of the commission which shall then cease to exist.

(16) Withdrawal. Within 90 days of the issuance by the governor of an order creating a regional planning commission, any local unit of government within the boundaries of the region may withdraw from the jurisdiction of the commission by a two-thirds vote of the members-elect of the governing body after a public hearing. Notice of withdrawal shall be given to the commission by registered mail not more than 3 nor less than 2 weeks before withdrawal and by publication of a class 2 notice, under ch. 985. A local unit may withdraw from a regional planning commission at the end of any fiscal year by a two-thirds vote of the members-elect of the governing body taken at least 6 months before the effective date of the withdrawal. However, the local unit shall be responsible for its allocated share of the contractual obligations of the regional planning commission continuing beyond the effective date of its withdrawal.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (25)

W. S. A. 66.0309, WI ST 66.0309
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.031

66.031. Renumbered 66.0401(1) and amended by 1999 Act 150, §§ 78, 79, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.031, WI ST 66.031
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter III. Intergovernmental Cooperation

W.S.A. 66.0311

66.0311. Intergovernmental cooperation in financing and undertaking housing projects

Currentness

(1) In this section, "municipality" has the meaning given in s. 66.0301(1)(a).

(2) Any municipality, housing authority, development authority or redevelopment authority authorized under ss. 66.1201 to 66.1211 and 66.1301 to 66.1337:

(a) To issue bonds or obtain other types of financing in furtherance of its statutory purposes may cooperate with any other municipality, housing authority, development authority or redevelopment authority similarly authorized under ss. 66.1201 to 66.1211 and 66.1301 to 66.1337 for the purpose of jointly issuing bonds or obtaining other types of financing.

(b) To plan, undertake, own, construct, operate and contract with respect to any housing project in accordance with its statutory purposes under ss. 66.1201 to 66.1211 and 66.1301 to 66.1337, may cooperate for the joint exercise of such functions with any other municipality, housing authority, development authority or redevelopment authority so authorized.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0311, WI ST 66.0311
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter III. Intergovernmental Cooperation

W.S.A. 66.0312

66.0312. Local health departments; mutual assistance

Currentness

(1) In this section "local health department" has the meaning given in s. 66.0314(1)(e).

(2)(a) Subject to sub. (3), upon the request of a local health department, the personnel of any other local health department may assist the requester within the requester's jurisdiction, notwithstanding any other jurisdictional provision.

(b) If a request for assistance is made under par. (a), payment for the requested services shall be made by one of the following methods:

1. If an agreement under s. 66.0301, or any other agreement between the parties, for the payment of such services exists, the terms of the agreement shall be followed.

2. If no agreement described under subd. 1. for the payment of such services exists, the governmental unit that receives the assistance is responsible for the personnel or equipment costs incurred by the responding agency if the responding agency requests payment of those costs.

(3) This section does not apply during a state of emergency declared by the governor under s. 323.10.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0312, WI ST 66.0312
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.03125

66.03125. Fire departments; mutual assistance

Currentness

(1) In this section "fire department" has the meaning given in s. 66.0314(1)(c).

(2)(a) Subject to sub. (3), upon the request of a fire department, the personnel of any other fire department may assist the requester within the requester's jurisdiction, notwithstanding any other jurisdictional provision.

(b) If a request for assistance is made under par. (a), payment for the requested services shall be made by one of the following methods:

1. If an agreement under s. 66.0301, or any other agreement between the parties, for the payment of such services exists, the terms of the agreement shall be followed.

2. If no agreement described under subd. 1. for the payment of such services exists, the governmental unit that receives the assistance is responsible for the personnel or equipment costs incurred by the responding agency if the responding agency requests payment of those costs.

(3) This section does not apply during a state of emergency declared by the governor under s. 323.10.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.03125, WI ST 66.03125
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0313

66.0313. Law enforcement; mutual assistance

Currentness

(1) In this section:

(a) "Law enforcement agency" has the meaning given in s. 165.83(1)(b) and includes a tribal law enforcement agency.

(b) "Tribal law enforcement agency" has the meaning given in s. 165.83(1)(e).

(2) Except as provided in sub. (4), upon the request of any law enforcement agency, including county law enforcement agencies as provided in s. 59.28(2), the law enforcement personnel of any other law enforcement agency may assist the requesting agency within the latter's jurisdiction, notwithstanding any other jurisdictional provision. For purposes of ss. 895.35 and 895.46, law enforcement personnel, while acting in response to a request for assistance, shall be deemed employees of the requesting agency and, to the extent that those sections apply to law enforcement personnel and a law enforcement agency acting under or affected by this section, ss. 895.35 and 895.46 shall apply to tribal law enforcement personnel and a tribal law enforcement agency acting under or affected by this section.

(3) The provisions of s. 66.0513 apply to this section and, to the extent that s. 66.0513 applies to law enforcement personnel and a law enforcement agency acting under or affected by this section, it applies to tribal law enforcement personnel and a tribal law enforcement agency acting under or affected by this section.

(4) A law enforcement agency, other than a tribal law enforcement agency, may not respond to a request for assistance from a tribal law enforcement agency at a location outside the law enforcement agency's territorial jurisdiction unless all of the following apply:

(a) One of the following applies:

1. The governing body of the tribe that created the tribal law enforcement agency adopts and has in effect a resolution that includes a statement that the tribe waives its sovereign immunity to the extent necessary to allow the enforcement in the courts of this state of its liability under sub. (2) and s. 66.0513 or another resolution that the department of justice determines will reasonably allow the enforcement in the courts of this state of the tribe's liability under sub. (2) and s. 66.0513.

2. The tribal law enforcement agency or the tribe that created the tribal law enforcement agency maintains liability insurance that does all of the following:

a. Covers the tribal law enforcement agency for its liability under sub. (2) and s. 66.0513.

b. Has a limit of coverage not less than $2,000,000 for any occurrence.

c. Provides that the insurer, in defending a claim against the policy, may not raise the defense of sovereign immunity of the insured up to the limits of the policy.

3. The law enforcement agency and the tribal law enforcement agency have in place an agreement under which the law enforcement agency accepts liability under sub. (2) and s. 66.0513 for instances in which it responds to a request for assistance from the tribal law enforcement agency.

(b) The tribal law enforcement agency requesting assistance has provided to the department of justice a copy of the resolution under par. (a)1., proof of insurance under par. (a)2., or a copy of the agreement under par. (a)3., and the department of justice has posted either a copy of the document or notice of the document on the Internet site it maintains for exchanging information with law enforcement agencies.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (10)

W. S. A. 66.0313, WI ST 66.0313
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0314

66.0314. State of emergency; mutual assistance

Currentness

(1) In this section:

(a) “Emergency management program” means the emergency management program of a city, village, town, or county, under s. 323.14(1).

(b) “Emergency medical services program” means a program established under s. 256.12.

(c) “Fire department” means any public organization engaged in fire fighting or a private sector employer fire company or fire department organized as a nonstock, nonprofit corporation under ch. 181 or ch. 213 without the input of a municipality.

(d) “Incident command system” means a functional management system established to control, direct, and manage the roles, responsibilities, and operations of all of the agencies involved in a multi-jurisdictional or multi-agency emergency response, which may include authorities designated by a participating tribe or band.

(e) “Local health department” has the meaning given in s. 250.01(4), and also includes an entity designated by a participating tribe or band as a local health department.

(fe) “Tribe or band” means a federally recognized American Indian tribe or band in this state.

(2)(a) If the governor declares a state of emergency under s. 323.10, upon the request of a city, village, town, or county, or a person acting under an incident command system, the personnel of any emergency management program, emergency medical services program, fire department, or local health department may assist the requester within the requester's jurisdiction, notwithstanding any other jurisdictional provision.

(b) If a request for assistance is made under par. (a), the governmental unit that receives the assistance is responsible for the personnel or equipment costs incurred by the responding agency to the extent that federal, state, and other 3rd-party reimbursement is available if all of the following apply:

1. The responding agency meets the personnel and equipment requirements in the state plan under s. 323.13(1)(b).

2. The responding agency requests payment of those costs.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0314, WI ST 66.0314
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0315

66.0315. Municipal cooperation; federal rivers, harbors or water resources projects

Currentness

A county, town, city or village acting under its powers and in conformity with state law may enter into an agreement with an agency of the federal government to cooperate in the construction, operation or maintenance of any federally authorized rivers, harbors or water resources management or control project or to assume any potential liability appurtenant to a project and may do all things necessary to consummate the agreement. If a project will affect more than one municipality, the municipalities affected may jointly enter into an agreement under this section with an agency of the federal government carrying any terms and provisions concerning the division of costs and responsibilities that are mutually agreed upon. The affected municipalities may by agreement submit any determinations of the division of construction costs, responsibilities, or any other liabilities among them to an arbitration board. The determination of the arbitration board shall be final. This section shall not be construed as a grant or delegation of power or authority to any county, town, city, village or other local municipality to do any work in or place any structures in or on any navigable water except as it is otherwise expressly authorized by state law to do.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0315, WI ST 66.0315
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0316

66.0316. Renew Wisconsin performance review

Currentness

(1) Definitions. In this section:

(a) "Analysis" means a performance analysis of the cost and benefit of a political subdivision providing a governmental service compared to a private person providing the same service.

(b) "Chief executive officer" has the meaning given in s. 66.1106(1)(a).

(c) "Department" means the department of revenue.

(d) "Extension" has the meaning given in s. 36.05(7).

(e) "Governmental service" means a service related to any of the following:

1. Law enforcement.

2. Fire protection.

3. Emergency services.

4. Public health.

5. Solid waste collection and disposal.

6. Recycling.

7. Public transportation.

8. Public housing.

9. Animal control.

10. Libraries.

11. Recreation and culture.

12. Human services.

13. Youth services.

(f) “Political subdivision” means any city, village, town, or county with a population greater than 2,500.

(2) Pilot program. The department shall establish a pilot program to study governmental services delivered by and to political subdivisions. The department shall solicit political subdivisions to participate in the program. Based on the department's solicitation, the department shall select 5 political subdivisions to form councils as provided under sub. (3) and shall include in that selection at least one county and at least one city, village, or town.

(3) Creation of council. (a) No later than January 1, 2002, each political subdivision selected under sub. (2) shall create a council consisting of 5 members, as follows:

1. The chief executive officer of the political subdivision, or his or her designee.

2. A member who is an employee of the political subdivision.

3. A member with cost accounting experience who is a resident of the political subdivision and who is not a political subdivision officer or employee.

4. Two members, not including the member under subd. 3., who are residents of the political subdivision and who are not political subdivision officers or employees.

(b) The political subdivision's chief executive officer shall appoint the council members under par. (a)2. to 4. The chief executive officer shall appoint 2 members to initial terms of 2 years and the remaining 2 members to initial terms of 4 years. The chief executive officer shall appoint the respective successors of the members under par. (a)2. to 4. to terms of 4 years. All members under par. (a)2. to 4. shall serve until their successors are appointed and qualified.

(c) The council shall organize annually at its first meeting to elect a chairperson. Four members of the council shall constitute a quorum.

(4) Duties of council. The council shall conduct an analysis of governmental services provided by the political subdivision with which the council is affiliated. In conducting such an analysis, the council shall do all of the following:

(a) Establish specific benchmarks for performance, including goals related to intergovernmental cooperation to provide governmental services.

(b) Conduct research and establish new methods to promote efficiency in the delivery of governmental services.

(c) Identify and recommend collaborative agreements to be developed with other political subdivisions to deliver governmental services.

(5) Data collection and analysis. (a) A council may conduct an analysis of a governmental service provided by the political subdivision with which the council is affiliated on its own or after receiving any of the following:

1. A written suggestion regarding delegating a governmental service to a private person.

2. A written complaint that a governmental service provided by the political subdivision is competing with the same or a similar service provided by a private person.

3. A written suggestion by a political subdivision employee or political subdivision employee labor organization to review a governmental service delegated to a private person.

(b) After receiving a suggestion or complaint under par. (a), the council shall meet to decide whether an analysis of the governmental service indicated in the suggestion or complaint is necessary. The council may hold hearings, conduct inquiries, and gather data to make its decision. If the council decides to analyze a governmental service under this paragraph, the council shall do all of the following:

1. Determine the costs of providing the governmental service, including the cost of personnel and capital assets used in providing the service.

2. Determine how often and to what extent the governmental service is provided and the quality of the governmental service provided.

3. Make a cost-benefit determination based on the findings under subds. 1. and 2.

4. Determine whether a private person can provide the governmental service at a cost savings to the political subdivision providing the service and at a quality at least equal to the quality of the service provided by the political subdivision.

5. If the council decides that a governmental service is not suitable for delegating to a private person, determine whether the governmental service should be retained in its present form, modified, or eliminated.

(c) After completing an analysis under par. (b), the council shall make a recommendation to the political subdivision providing the governmental service analyzed under par. (b) and publish the council's recommendation. The recommendation shall specify the recommendation's impact on the political subdivision and the political subdivision's employees.

(6) Training and assistance. The board of regents of the University of Wisconsin System shall direct the extension to assist councils created under this section in performing their duties under subs. (4) and (5). The board of regents shall ensure that council members are trained in how to do all of the following:

(a) Conduct an analysis of a governmental service.

(b) Determine ways to improve the efficiency of delivering a governmental service.

(c) Establish, quantify, and monitor performance standards.

(d) Prepare the reports required under sub. (7)(a) and (b).

(7) Reports. (a) On or before June 30, 2002, each council shall submit a report to the department describing the council's activities.

(b) On or before June 30, 2003, each council shall submit a final report to the department describing the council's activities and recommendations and the extent to which its recommendations have been adopted by the political subdivision with which the council is affiliated. A report submitted under this paragraph shall provide a detailed explanation of all analyses conducted under subs. (4) and (5).

(c) On or before July 31, 2003, the department shall submit a report concerning the activities and recommendations described in the reports submitted under pars. (a) and (b) to the legislature under s. 13.172(2) and to the governor. The department's report shall describe ways to implement such recommendations statewide.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0316, WI ST 66.0316
Current through 2023 Act 272, published April 10, 2024.

End of Document

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Subchapter III. Intergovernmental Cooperation

W.S.A. 66.0317

66.0317. Cooperation region

Currentness

(1) Definitions. In this section:

(a) "Cooperation region" means a federal standard metropolitan statistical area. For purposes of this section, if only a part of a county is located in a federal standard metropolitan statistical area the entire county is considered to be located in the federal standard metropolitan statistical area.

(b) "Governmental service" has the meaning given in s. 66.0316(1)(e).

(d) "Municipality" means any city, village, or town.

(2) Area cooperation compacts. (a)1. Except as provided in subd. 3., beginning in 2003, a municipality shall enter into an area cooperation compact with at least 2 municipalities or counties located in the same cooperation region as the municipality, or with any combination of at least 2 such entities, to perform at least 2 governmental services.

3. A municipality that is not adjacent to at least 2 other municipalities located in the same cooperation region as the municipality may enter into a cooperation compact with any adjacent municipality or with the county in which the municipality is located to perform the number of governmental services as specified under subd. 1.

(b) An area cooperation compact shall provide a plan for any municipalities or counties that enter into the compact to collaborate to provide governmental services. The compact shall provide benchmarks to measure the plan's progress and provide outcome-based performance measures to evaluate the plan's success. Municipalities and counties that enter into the compact shall structure the compact in a way that results in significant tax savings to taxpayers within those municipalities and counties.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0317, WI ST 66.0317
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.032

66.032. Renumbered 66.0403 and amended by 1999 Act 150, § 82, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.032, WI ST 66.032
Current through 2023 Act 272, published April 10, 2024.

End of Document


KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.033. Renumbered in part and repealed in part by 1999 Act 150, §§ 83, 84, eff. Jan. 1, 2001

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Subchapter III. Intergovernmental Cooperation

W.S.A. 66.033

66.033. Renumbered in part and repealed in part by 1999 Act 150, §§ 83, 84, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.033, WI ST 66.033
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.034

66.034. Renumbered 66.1027 by 1999 Act 150, § 85, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.034, WI ST 66.034
Current through 2023 Act 272, published April 10, 2024.

End of Document


KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.035. Repealed by 1999 Act 150, § 86, eff. Jan. 1, 2001

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W.S.A. 66.035

66.035. Repealed by 1999 Act 150, § 86, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.035, WI ST 66.035
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.036

66.036. Renumbered 145.195 by 1999 Act 150, § 87, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.036, WI ST 66.036
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.037

66.037. Renumbered 66.1111 by 1999 Act 150, § 88, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.037, WI ST 66.037
Current through 2023 Act 272, published April 10, 2024.

End of Document


KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.038. Repealed by 1997 Act 252, § 90, eff. June 19, 1998

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W.S.A. 66.038.

66.038. Repealed by 1997 Act 252, § 90, eff. June 19, 1998

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.038., WI ST 66.038.
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.04. Renumbered in part and repealed in part by 1999 Act 150, §§ 89 to 95, eff. Jan. 1, 2001; 1999 Act 186, § 43, eff. Jan. 1, 2001; 2001 Act 30, § 25, eff. Dec. 14, 2001

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
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Subchapter III. Intergovernmental Cooperation

W.S.A. 66.04

66.04. Renumbered in part and repealed in part by 1999 Act 150, §§ 89 to 95, eff. Jan. 1, 2001; 1999 Act 186, § 43, eff. Jan. 1, 2001; 2001 Act 30, § 25, eff. Dec. 14, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.04, WI ST 66.04
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IV. Regulation

W.S.A. 66.0401

66.0401. Regulation relating to solar and wind energy systems

Currentness

(1e) Definitions. In this section:

(a) "Application for approval" means an application for approval of a wind energy system under rules promulgated by the commission under s. 196.378(4g)(c)1.

(b) "Commission" means the public service commission.

(c) "Political subdivision" means a city, village, town, or county.

(d) "Wind energy system" has the meaning given in s. 66.0403(1)(m).

(1m) Authority to restrict systems limited. No political subdivision may place any restriction, either directly or in effect, on the installation or use of a wind energy system that is more restrictive than the rules promulgated by the commission under s. 196.378(4g)(b). No political subdivision may place any restriction, either directly or in effect, on the installation or use of a solar energy system, as defined in s. 13.48(2)(h)1.g., or a wind energy system, unless the restriction satisfies one of the following conditions:

(a) Serves to preserve or protect the public health or safety.

(b) Does not significantly increase the cost of the system or significantly decrease its efficiency.

(c) Allows for an alternative system of comparable cost and efficiency.

(2) Authority to require trimming of blocking vegetation. Subject to sub. (6)(a), a political subdivision may enact an ordinance relating to the trimming of vegetation that blocks solar energy, as defined in s. 66.0403(1)(k), from a collector surface, as defined under s. 700.41(2)(b), or that blocks wind from a wind energy system. The ordinance may include a designation of

responsibility for the costs of the trimming. The ordinance may not require the trimming of vegetation that was planted by the owner or occupant of the property on which the vegetation is located before the installation of the solar or wind energy system.

(3) Testing activities. A political subdivision may not prohibit or restrict any person from conducting testing activities to determine the suitability of a site for the placement of a wind energy system. A political subdivision objecting to such testing may petition the commission to impose reasonable restrictions on the testing activity.

(4) Local procedure. (a)1. Subject to subd. 2., a political subdivision that receives an application for approval shall determine whether it is complete and, no later than 45 days after the application is filed, notify the applicant about the determination. As soon as possible after receiving the application for approval, the political subdivision shall publish a class 1 notice, under ch. 985, stating that an application for approval has been filed with the political subdivision. If the political subdivision determines that the application is incomplete, the notice shall state the reason for the determination. An applicant may supplement and refile an application that the political subdivision has determined to be incomplete. There is no limit on the number of times that an applicant may refile an application for approval. If the political subdivision fails to determine whether an application for approval is complete within 45 days after the application is filed, the application shall be considered to be complete.

2. If a political subdivision that receives an application for approval under subd. 1. does not have in effect an ordinance described under par. (g), the 45-day time period for determining whether an application is complete, as described in subd. 1., does not begin until the first day of the 4th month beginning after the political subdivision receives the application. A political subdivision may notify an applicant at any time, after receipt of the application and before the first day of the 4th month after its receipt, that it does not intend to enact an ordinance described under par. (g).

3. On the same day that an applicant makes an application for approval under subd. 1. for a wind energy system, the applicant shall mail or deliver written notice of the application to the owners of land adjoining the site of the wind energy system.

4. A political subdivision may not consider an applicant's minor modification to the application to constitute a new application for the purposes of this subsection.

(b) A political subdivision shall make a record of its decision making on an application for approval, including a recording of any public hearing, copies of documents submitted at any public hearing, and copies of any other documents provided to the political subdivision in connection with the application for approval. The political subdivision's record shall conform to the commission's rules promulgated under s. 196.378(4g)(c)2.

(c) A political subdivision shall base its decision on an application for approval on written findings of fact that are supported by the evidence in the record under par. (b). A political subdivision's procedure for reviewing the application for approval shall conform to the commission's rules promulgated under s. 196.378(4g)(c)3.

(d) Except as provided in par. (e), a political subdivision shall approve or disapprove an application for approval no later than 90 days after the day on which it notifies the applicant that the application for approval is complete. If a political subdivision fails to act within the 90 days, or within any extended time period established under par. (e), the application is considered approved.

(e) A political subdivision may extend the time period in par. (d) if, within that 90-day period, the political subdivision authorizes the extension in writing. Any combination of the following extensions may be granted, except that the total amount of time for all extensions granted under this paragraph may not exceed 90 days:

1. An extension of up to 45 days if the political subdivision needs additional information to determine whether to approve or deny the application for approval.

2. An extension of up to 90 days if the applicant makes a material modification to the application for approval.

3. An extension of up to 90 days for other good cause specified in writing by the political subdivision.

(f)1. Except as provided in subd. 2., a political subdivision may not deny or impose a restriction on an application for approval unless the political subdivision enacts an ordinance that is no more restrictive than the rules the commission promulgates under s. 196.378(4g)(b).

2. A political subdivision may deny an application for approval if the proposed site of the wind energy system is in an area primarily designated for future residential or commercial development, as shown in a map that is adopted, as part of a comprehensive plan, under s. 66.1001(2)(b) and (f), before June 2, 2009, or as shown in such maps after December 31, 2015, as part of a comprehensive plan that is updated as required under s. 66.1001(2)(i). This subdivision applies to a wind energy system that has a nominal capacity of at least one megawatt.

(g) A political subdivision that chooses to regulate wind energy systems shall enact an ordinance, subject to sub. (6)(b), that is no more restrictive than the applicable standards established by the commission in rules promulgated under s. 196.378(4g).

(5) Public service commission review. (a) A decision of a political subdivision to determine that an application is incomplete under sub. (4)(a)1., or to approve, disapprove, or impose a restriction upon a wind energy system, or an action of a political subdivision to enforce a restriction on a wind energy system, may be appealed only as provided in this subsection.

(b)1. Any aggrieved person seeking to appeal a decision or enforcement action specified in par. (a) may begin the political subdivision's administrative review process. If the person is still aggrieved after the administrative review is completed, the person may file an appeal with the commission. No appeal to the commission under this subdivision may be filed later than 30 days after the political subdivision has completed its administrative review process. For purposes of this subdivision, if a political subdivision fails to complete its administrative review process within 90 days after an aggrieved person begins the review process, the political subdivision is considered to have completed the process on the 90th day after the person began the process.

2. Rather than beginning an administrative review under subd. 1., an aggrieved person seeking to appeal a decision or enforcement action of a political subdivision specified in par. (a) may file an appeal directly with the commission. No appeal to the commission under this subdivision may be filed later than 30 days after the decision or initiation of the enforcement action.

3. An applicant whose application for approval is denied under sub. (4)(f)2. may appeal the denial to the commission. The commission may grant the appeal notwithstanding the inconsistency of the application for approval with the political subdivision's planned residential or commercial development if the commission determines that granting the appeal is consistent with the public interest.

(c) Upon receiving an appeal under par. (b), the commission shall notify the political subdivision. The political subdivision shall provide a certified copy of the record upon which it based its decision or enforcement action within 30 days after receiving notice. The commission may request of the political subdivision any other relevant governmental records and, if requested, the political subdivision shall provide such records within 30 days after receiving the request.

(d) The commission may confine its review to the records it receives from the political subdivision or, if it finds that additional information would be relevant to its decision, expand the records it reviews. The commission shall issue a decision within 90 days after the date on which it receives all of the records it requests under par. (c), unless for good cause the commission extends this time period in writing. If the commission determines that the political subdivision's decision or enforcement action does not comply with the rules it promulgates under s. 196.378(4g) or is otherwise unreasonable, the political subdivision's decision shall be superseded by the commission's decision and the commission may order an appropriate remedy.

(e) In conducting a review under par. (d), the commission may treat a political subdivision's determination that an application under sub. (4)(a)1. is incomplete as a decision to disapprove the application if the commission determines that a political subdivision has unreasonably withheld its determination that an application is complete.

(f) Judicial review is not available until the commission issues its decision or order under par. (d). Judicial review shall be of the commission's decision or order, not of the political subdivision's decision or enforcement action. The commission's decision or order is subject to judicial review under ch. 227. Injunctive relief is available only as provided in s. 196.43.

(6) Applicability of a political subdivision or county ordinance. (a)1. A county ordinance enacted under sub. (2) applies only to the towns in the county that have not enacted an ordinance under sub. (2).

2. If a town enacts an ordinance under sub. (2) after a county has enacted an ordinance under sub. (2), the county ordinance does not apply, and may not be enforced, in the town, except that if the town later repeals its ordinance, the county ordinance applies in that town.

(b)1. Subject to subd. 2., a county ordinance enacted under sub. (4) applies only in the unincorporated parts of the county.

2. If a town enacts an ordinance under sub. (4), either before or after a county enacts an ordinance under sub. (4), the more restrictive terms of the 2 ordinances apply to the town, except that if the town later repeals its ordinance, the county ordinance applies in that town.

(c) If a political subdivision enacts an ordinance under sub. (4)(g) after the commission's rules promulgated under s. 196.378(4g) take effect, the political subdivision may not apply that ordinance to, or require approvals under that ordinance for, a wind energy system approved by the political subdivision under a previous ordinance or under a development agreement.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (4)

W. S. A. 66.0401, WI ST 66.0401
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0403

66.0403. Solar and wind access permits

Currentness

(1) Definitions. In this section:

(a) “Agency” means the governing body of a municipality which has provided for granting a permit or the agency which the governing body of a municipality creates or designates under sub. (2). “Agency” includes an officer or employee of the municipality.

(b) “Applicant” means an owner applying for a permit under this section.

(c) “Application” means an application for a permit under this section.

(d) “Collector surface” means any part of a solar collector that absorbs solar energy for use in the collector's energy transformation process. “Collector surface” does not include frames, supports and mounting hardware.

(e) “Collector use period” means 9 a.m. to 3 p.m. standard time daily.

(f) “Impermissible interference” means the blockage of wind from a wind energy system or solar energy from a collector surface or proposed collector surface for which a permit has been granted under this section during a collector use period if such blockage is by any structure or vegetation on property, an owner of which was notified under sub. (3)(b). “Impermissible interference” does not include:

1. Blockage by a narrow protrusion, including but not limited to a pole or wire, which does not substantially interfere with absorption of solar energy by a solar collector or does not substantially block wind from a wind energy system.

2. Blockage by any structure constructed, under construction or for which a building permit has been applied for before the date the last notice is mailed or delivered under sub. (3)(b).

3. Blockage by any vegetation planted before the date the last notice is mailed or delivered under sub. (3)(b) unless a municipality by ordinance under sub. (2) defines impermissible interference to include such vegetation.

(g) "Municipality" means any county with a zoning ordinance under s. 59.69, any town with a zoning ordinance under s. 60.61, any city with a zoning ordinance under s. 62.23(7), any 1st class city or any village with a zoning ordinance under s. 61.35.

(h) "Owner" means at least one owner, as defined under s. 66.0217(1)(d), of a property or the personal representative of at least one owner.

(i) "Permit" means a solar access permit or a wind access permit issued under this section.

(j) "Solar collector" means a device, structure or a part of a device or structure a substantial purpose of which is to transform solar energy into thermal, mechanical, chemical or electrical energy.

(k) "Solar energy" means direct radiant energy received from the sun.

(L) "Standard time" means the solar time of the ninetieth meridian west of Greenwich.

(m) "Wind energy system" means equipment and associated facilities that convert and then store or transfer energy from the wind into usable forms of energy.

(2) Permit procedure. The governing body of every municipality may provide for granting a permit. A permit may not affect any land except land which, at the time the permit is granted, is within the territorial limits of the municipality or is subject to an extraterritorial zoning ordinance adopted under s. 62.23(7a), except that a permit issued by a city or village may not affect extraterritorial land subject to a zoning ordinance adopted by a county or a town. The governing body may appoint itself as the agency to process applications or may create or designate another agency to grant permits. The governing body may provide by ordinance that a fee be charged to cover the costs of processing applications. The governing body may adopt an ordinance with any provision it deems necessary for granting a permit under this section, including but not limited to:

(a) Specifying standards for agency determinations under sub. (5)(a).

(b) Defining an impermissible interference to include vegetation planted before the date the last notice is mailed or delivered under sub. (3)(b), provided that the permit holder shall be responsible for the cost of trimming such vegetation.

(3) Permit applications. (a) In a municipality which provides for granting a permit under this section, an owner who has installed or intends to install a solar collector or wind energy system may apply to an agency for a permit.

(b) An agency shall determine if an application is satisfactorily completed and shall notify the applicant of its determination. If an applicant receives notice that an application has been satisfactorily completed, the applicant shall deliver by certified mail or by hand a notice to the owner of any property which the applicant proposes to be restricted by the permit under sub. (7). The applicant shall submit to the agency a copy of a signed receipt for every notice delivered under this paragraph. The agency shall supply the notice form. The information on the form may include, without limitation because of enumeration:

1. The name and address of the applicant, and the address of the land upon which the solar collector or wind energy system is or will be located.

2. That an application has been filed by the applicant.

3. That the permit, if granted, may affect the rights of the notified owner to develop his or her property and to plant vegetation.

4. The telephone number, address and office hours of the agency.

5. That any person may request a hearing under sub. (4) within 30 days after receipt of the notice, and the address and procedure for filing the request.

(4) Hearing. Within 30 days after receipt of the notice under sub. (3)(b), any person who has received a notice may file a request for a hearing on the granting of a permit or the agency may determine that a hearing is necessary even if no such request is filed. If a request is filed or if the agency determines that a hearing is necessary, the agency shall conduct a hearing on the application within 90 days after the last notice is delivered. At least 30 days prior to the hearing date, the agency shall notify the applicant, all owners notified under sub. (3)(b) and any other person filing a request of the time and place of the hearing.

(5) Permit grant. (a) The agency shall grant a permit if the agency determines that:

1. The granting of a permit will not unreasonably interfere with the orderly land use and development plans of the municipality;

2. No person has demonstrated that she or he has present plans to build a structure that would create an impermissible interference by showing that she or he has applied for a building permit prior to receipt of a notice under sub. (3)(b), has expended at least $500 on planning or designing such a structure or by submitting any other credible evidence that she or he has made substantial progress toward planning or constructing a structure that would create an impermissible interference; and

3. The benefits to the applicant and the public will exceed any burdens.

(b) An agency may grant a permit subject to any condition or exemption the agency deems necessary to minimize the possibility that the future development of nearby property will create an impermissible interference or to minimize any other burden on any person affected by granting the permit. Such conditions or exemptions may include but are not limited to restrictions on the location of the solar collector or wind energy system and requirements for the compensation of persons affected by the granting of the permit.

(6) Record of permit. If an agency grants a permit:

(a) The agency shall specify the property restricted by the permit under sub. (7) and shall prepare notice of the granting of the permit. The notice shall include the identification required under s. 706.05(2)(c) for the owner and the property upon which the solar collector or wind energy system is or will be located and for any owner and property restricted by the permit under

sub. (7), and shall indicate that the property may not be developed and vegetation may not be planted on the property so as to create an impermissible interference with the solar collector or wind energy system which is the subject of the permit unless the permit affecting the property is terminated under sub. (9) or unless an agreement affecting the property is filed under sub. (10).

(b) The applicant shall record with the register of deeds of the county in which the property is located the notice under par. (a) for each property specified under par. (a) and for the property upon which the solar collector or wind energy system is or will be located.

(7) Remedies for impermissible interference. (a) Any person who uses property which he or she owns or permits any other person to use the property in a way which creates an impermissible interference under a permit which has been granted or which is the subject of an application shall be liable to the permit holder or applicant for damages, except as provided under par. (b), for any loss due to the impermissible interference, court costs and reasonable attorney fees unless:

1. The building permit was applied for prior to receipt of a notice under sub. (3)(b) or the agency determines not to grant a permit after a hearing under sub. (4).

2. A permit affecting the property is terminated under sub. (9).

3. An agreement affecting the property is filed under sub. (10).

(b) A permit holder is entitled to an injunction to require the trimming of any vegetation which creates or would create an impermissible interference as defined under sub. (1)(f). If the court finds on behalf of the permit holder, the permit holder shall be entitled to a permanent injunction, damages, court costs and reasonable attorney fees.

(8) Appeals. Any person aggrieved by a determination by a municipality under this section may appeal the determination to the circuit court for a review.

(9) Termination of solar or wind access rights. (a) Any right protected by a permit under this section shall terminate if the agency determines that the solar collector or wind energy system which is the subject of the permit is:

1. Permanently removed or is not used for 2 consecutive years, excluding time spent on repairs or improvements.

2. Not installed and functioning within 2 years after the date of issuance of the permit.

(b) The agency shall give the permit holder written notice and an opportunity for a hearing on a proposed termination under par. (a).

(c) If the agency terminates a permit, the agency may charge the permit holder for the cost of recording and record a notice of termination with the register of deeds, who shall record the notice with the notice recorded under sub. (6)(b) or indicate on any notice recorded under sub. (6)(b) that the permit has been terminated.

(10) Waiver. A permit holder by written agreement may waive all or part of any right protected by a permit. A copy of such agreement shall be recorded with the register of deeds, who shall record such copy with the notice recorded under sub. (6)(b).

(11) Preservation of rights. The transfer of title to any property shall not change the rights and duties under this section or under an ordinance adopted under sub. (2).

(12) Construction. (a) This section may not be construed to require that an owner obtain a permit prior to installing a solar collector or wind energy system.

(b) This section may not be construed to mean that acquisition of a renewable energy resource easement under s. 700.35 is in any way contingent upon the granting of a permit under this section.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (3)

W. S. A. 66.0403, WI ST 66.0403
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0404

66.0404. Mobile tower siting regulations

Currentness

(1) Definitions. In this section:

(a) “Antenna” means communications equipment that transmits and receives electromagnetic radio signals and is used in the provision of mobile services.

(b) “Application” means an application for a permit under this section to engage in an activity specified in sub. (2)(a) or a class 2 collocation.

(c) “Building permit” means a permit issued by a political subdivision that authorizes an applicant to conduct construction activity that is consistent with the political subdivision's building code.

(d) “Class 1 collocation” means the placement of a new mobile service facility on an existing support structure such that the owner of the facility does not need to construct a free standing support structure for the facility but does need to engage in substantial modification.

(e) “Class 2 collocation” means the placement of a new mobile service facility on an existing support structure such that the owner of the facility does not need to construct a free standing support structure for the facility or engage in substantial modification.

(f) “Collocation” means class 1 or class 2 collocation or both.

(g) “Distributed antenna system” means a network of spatially separated antenna nodes that is connected to a common source via a transport medium and that provides mobile service within a geographic area or structure.

(h) “Equipment compound” means an area surrounding or adjacent to the base of an existing support structure within which is located mobile service facilities.

(i) “Existing structure” means a support structure that exists at the time a request for permission to place mobile service facilities on a support structure is filed with a political subdivision.

(j) “Fall zone” means the area over which a mobile support structure is designed to collapse.

(k) “Mobile service” has the meaning given in 47 USC 153 (33).

(L) “Mobile service facility” means the set of equipment and network components, including antennas, transmitters, receivers, base stations, power supplies, cabling, and associated equipment, that is necessary to provide mobile service to a discrete geographic area, but does not include the underlying support structure.

(m) “Mobile service provider” means a person who provides mobile service.

(n) “Mobile service support structure” means a freestanding structure that is designed to support a mobile service facility.

(o) “Permit” means a permit, other than a building permit, or approval issued by a political subdivision which authorizes any of the following activities by an applicant:

1. A class 1 collocation.

2. A class 2 collocation.

3. The construction of a mobile service support structure.

(p) “Political subdivision” means a city, village, town, or county.

(q) “Public utility” has the meaning given in s. 196.01 (5).

(r) “Search ring” means a shape drawn on a map to indicate the general area within which a mobile service support structure should be located to meet radio frequency engineering requirements, taking into account other factors including topography and the demographics of the service area.

(s) “Substantial modification” means the modification of a mobile service support structure, including the mounting of an antenna on such a structure, that does any of the following:

1. For structures with an overall height of 200 feet or less, increases the overall height of the structure by more than 20 feet.

2. For structures with an overall height of more than 200 feet, increases the overall height of the structure by 10 percent or more.

3. Measured at the level of the appurtenance added to the structure as a result of the modification, increases the width of the support structure by 20 feet or more, unless a larger area is necessary for collocation.

4. Increases the square footage of an existing equipment compound to a total area of more than 2,500 square feet.

(t) "Support structure" means an existing or new structure that supports or can support a mobile service facility, including a mobile service support structure, utility pole, water tower, building, or other structure.

(u) "Utility pole" means a structure owned or operated by an alternative telecommunications utility, as defined in s. 196.01(1d); public utility, as defined in s. 196.01(5); telecommunications utility, as defined in s. 196.01(10); political subdivision; or cooperative association organized under ch. 185; and that is designed specifically for and used to carry lines, cables, or wires for telecommunications service, as defined in s. 182.017(1g)(cq); for video service, as defined in s. 66.0420(2)(y); for electricity; or to provide light.

(2) New construction or substantial modification of facilities and support structures. (a) Subject to the provisions and limitations of this section, a political subdivision may enact a zoning ordinance under s. 59.69, 60.61, or 62.23 to regulate any of the following activities:

1. The siting and construction of a new mobile service support structure and facilities.

2. With regard to a class 1 collocation, the substantial modification of an existing support structure and mobile service facilities.

(b) If a political subdivision regulates an activity described under par. (a), the regulation shall prescribe the application process which a person must complete to engage in the siting, construction, or modification activities described in par. (a). The application shall be in writing and shall contain all of the following information:

1. The name and business address of, and the contact individual for, the applicant.

2. The location of the proposed or affected support structure.

3. The location of the proposed mobile service facility.

4. If the application is to substantially modify an existing support structure, a construction plan which describes the proposed modifications to the support structure and the equipment and network components, including antennas, transmitters, receivers, base stations, power supplies, cabling, and related equipment associated with the proposed modifications.

5. If the application is to construct a new mobile service support structure, a construction plan which describes the proposed mobile service support structure and the equipment and network components, including antennas, transmitters, receivers, base stations, power supplies, cabling, and related equipment to be placed on or around the new mobile service support structure.

6. If an application is to construct a new mobile service support structure, an explanation as to why the applicant chose the proposed location and why the applicant did not choose collocation, including a sworn statement from an individual who

has responsibility over the placement of the mobile service support structure attesting that collocation within the applicant's search ring would not result in the same mobile service functionality, coverage, and capacity; is technically infeasible; or is economically burdensome to the mobile service provider.

(c) If an applicant submits to a political subdivision an application for a permit to engage in an activity described under par. (a), which contains all of the information required under par. (b), the political subdivision shall consider the application complete. If the political subdivision does not believe that the application is complete, the political subdivision shall notify the applicant in writing, within 10 days of receiving the application, that the application is not complete. The written notification shall specify in detail the required information that was incomplete. An applicant may resubmit an application as often as necessary until it is complete.

(d) Within 90 days of its receipt of a complete application, a political subdivision shall complete all of the following or the applicant may consider the application approved, except that the applicant and the political subdivision may agree in writing to an extension of the 90 day period:

1. Review the application to determine whether it complies with all applicable aspects of the political subdivision's building code and, subject to the limitations in this section, zoning ordinances.

2. Make a final decision whether to approve or disapprove the application.

3. Notify the applicant, in writing, of its final decision.

4. If the decision is to disapprove the application, include with the written notification substantial evidence which supports the decision.

(e) A political subdivision may disapprove an application if an applicant refuses to evaluate the feasibility of collocation within the applicant's search ring and provide the sworn statement described under par. (b)6.

(f) A party who is aggrieved by the final decision of a political subdivision under par. (d)2. may bring an action in the circuit court of the county in which the proposed activity, which is the subject of the application, is to be located.

(g) If an applicant provides a political subdivision with an engineering certification showing that a mobile service support structure, or an existing structure, is designed to collapse within a smaller area than the setback or fall zone area required in a zoning ordinance, that zoning ordinance does not apply to such a structure unless the political subdivision provides the applicant with substantial evidence that the engineering certification is flawed.

(h) A political subdivision may regulate the activities described under par. (a) only as provided in this section.

(i) If a political subdivision has in effect on July 2, 2013, an ordinance that applies to the activities described under par. (a) and the ordinance is inconsistent with this section, the ordinance does not apply to, and may not be enforced against, the activity.

(3) Collocation on existing support structures. (a) 1. A class 2 collocation is a permitted use under ss. 59.69, 60.61, and 62.23.

2. If a political subdivision has in effect on July 2, 2013, an ordinance that applies to a class 2 collocation and the ordinance is inconsistent with this section, the ordinance does not apply to, and may not be enforced against, the class 2 collocation.

3. A political subdivision may regulate a class 2 collocation only as provided in this section.

4. A class 2 collocation is subject to the same requirements for the issuance of a building permit to which any other type of commercial development or land use development is subject.

(b) If an applicant submits to a political subdivision an application for a permit to engage in a class 2 collocation, the application shall contain all of the information required under sub. (2)(b)1. to 3., in which case the political subdivision shall consider the application complete. If any of the required information is not in the application, the political subdivision shall notify the applicant in writing, within 5 days of receiving the application, that the application is not complete. The written notification shall specify in detail the required information that was incomplete. An applicant may resubmit an application as often as necessary until it is complete.

(c) Within 45 days of its receipt of a complete application, a political subdivision shall complete all of the following or the applicant may consider the application approved, except that the applicant and the political subdivision may agree in writing to an extension of the 45 day period:

1. Make a final decision whether to approve or disapprove the application.

2. Notify the applicant, in writing, of its final decision.

3. If the application is approved, issue the applicant the relevant permit.

4. If the decision is to disapprove the application, include with the written notification substantial evidence which supports the decision.

(d) A party who is aggrieved by the final decision of a political subdivision under par. (c)1. may bring an action in the circuit court of the county in which the proposed activity, which is the subject of the application, is to be located.

(4) Limitations. With regard to an activity described in sub. (2)(a) or a class 2 collocation, a political subdivision may not do any of the following:

(a) Impose environmental testing, sampling, or monitoring requirements, or other compliance measures for radio frequency emissions, on mobile service facilities or mobile radio service providers.

(b) Enact an ordinance imposing a moratorium on the permitting, construction, or approval of any such activities.

(c) Enact an ordinance prohibiting the placement of a mobile service support structure in particular locations within the political subdivision.

(d) Charge a mobile radio service provider a fee in excess of one of the following amounts:

1. For a permit for a class 2 collocation, the lesser of $500 or the amount charged by a political subdivision for a building permit for any other type of commercial development or land use development.

2. For a permit for an activity described in sub. (2)(a), $3,000.

(e) Charge a mobile radio service provider any recurring fee for an activity described in sub. (2)(a) or a class 2 collocation.

(f) Permit 3rd party consultants to charge the applicant for any travel expenses incurred in the consultant's review of mobile service permits or applications.

(g) Disapprove an application to conduct an activity described under sub. (2)(a) based solely on aesthetic concerns.

(gm) Disapprove an application to conduct a class 2 collocation on aesthetic concerns.

(h) Enact or enforce an ordinance related to radio frequency signal strength or the adequacy of mobile service quality.

(i) Impose a surety requirement, unless the requirement is competitively neutral, nondiscriminatory, and commensurate with the historical record for surety requirements for other facilities and structures in the political subdivision which fall into disuse. There is a rebuttable presumption that a surety requirement of $20,000 or less complies with this paragraph.

(j) Prohibit the placement of emergency power systems.

(k) Require that a mobile service support structure be placed on property owned by the political subdivision.

(L) Disapprove an application based solely on the height of the mobile service support structure or on whether the structure requires lighting.

(m) Condition approval of such activities on the agreement of the structure or mobile service facility owner to provide space on or near the structure for the use of or by the political subdivision at less than the market rate, or to provide the political subdivision other services via the structure or facilities at less than the market rate.

(n) Limit the duration of any permit that is granted.

(o) Require an applicant to construct a distributed antenna system instead of either constructing a new mobile service support structure or engaging in collocation.

(p) Disapprove an application based on an assessment by the political subdivision of the suitability of other locations for conducting the activity.

(q) Require that a mobile service support structure, existing structure, or mobile service facilities have or be connected to backup battery power.

(r) Impose a setback or fall zone requirement for a mobile service support structure that is different from a requirement that is imposed on other types of commercial structures.

(s) Consider an activity a substantial modification under sub. (1)(s)1. or 2. if a greater height is necessary to avoid interference with an existing antenna.

(t) Consider an activity a substantial modification under sub. (1)(s)3. if a greater protrusion is necessary to shelter the antenna from inclement weather or to connect the antenna to the existing structure by cable.

(u) Limit the height of a mobile service support structure to under 200 feet.

(v) Condition the approval of an application on, or otherwise require, the applicant's agreement to indemnify or insure the political subdivision in connection with the political subdivision's exercise of its authority to approve the application.

(w) Condition the approval of an application on, or otherwise require, the applicant's agreement to permit the political subdivision to place at or collocate with the applicant's support structure any mobile service facilities provided or operated by, whether in whole or in part, a political subdivision or an entity in which a political subdivision has a governance, competitive, economic, financial or other interest.

(4e) Setback requirements. (a) Notwithstanding sub. (4)(r), and subject to the provisions of this subsection, a political subdivision may enact an ordinance imposing setback requirements related to the placement of a mobile service support structure that applies to new construction or the substantial modification of facilities and support structures, as described in sub. (2).

(b) A setback requirement may apply only to a mobile service support structure that is constructed on or adjacent to a parcel of land that is subject to a zoning ordinance that permits single-family residential use on that parcel. A setback requirement does not apply to an existing or new utility pole, or wireless support structure in a right-of-way that supports a small wireless facility, if the pole or facility meets the height limitations in s. 66.0414(2)(e)2. and 3.

(c) The setback requirement under par. (b) for a mobile service support structure on a parcel shall be measured from the lot lines of other adjacent and nonadjacent parcels for which single-family residential use is a permitted use under a zoning ordinance.

(d) A setback requirement must be based on the height of the proposed mobile service support structure, and the setback requirement may not be a distance that is greater than the height of the proposed structure.

(5) Applicability. If a county enacts an ordinance as described under sub. (2) the ordinance applies only in the unincorporated parts of the county, except that if a town enacts an ordinance as described under sub. (2) after a county has so acted, the county ordinance does not apply, and may not be enforced, in the town, except that if the town later repeals its ordinance, the county ordinance applies in that town.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (10)

W. S. A. 66.0404, WI ST 66.0404
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IV. Regulation

W.S.A. 66.0405

66.0405. Removal of rubbish

Currentness

Cities, villages and towns may remove ashes, garbage, and rubbish from such classes of places in the city, village or town as the board or council directs. The removal may be from all of the places or from those whose owners or occupants desire the service. Districts may be created and removal provided for certain districts only, and different regulations may be applied to each removal district or class of property. The cost of removal may be funded by special assessment against the property served, by general tax upon the property of the respective districts, or by general tax upon the property of the city, village or town. If a city, village or town contracts for ash, garbage or rubbish removal service, it may contract with one or more service providers.

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 119

Note: Amended to expressly authorize contracting with one or more service providers for removal of ash, garbage or rubbish. Express authority is extended in order to mitigate possible antitrust issues if the city, village or town determines that the service can best be provided by one service provider.

Notes of Decisions (8)

W. S. A. 66.0405, WI ST 66.0405
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IV. Regulation

W.S.A. 66.0406

66.0406. Radio broadcast service facility regulations

Currentness

(1) Definitions. In this section:

(a) "Political subdivision" means any city, village, town, or county.

(b) "Radio broadcast services" means the regular provision of a commercial or noncommercial service involving the transmission, emission, or reception of radio waves for the transmission of sound or images in which the transmissions are intended for direct reception by the general public.

(c) "Radio broadcast service facilities" means commercial or noncommercial facilities, including antennas and antenna support structures, intended for the provision of radio broadcast services.

(2) Limitations on local regulation. Beginning on May 1, 2013, if a political subdivision enacts an ordinance, adopts a resolution, or takes any other action that affects the placement, construction, or modification of radio broadcast service facilities, the ordinance, resolution, or other action may not take effect unless all of the following apply:

(a) The ordinance, resolution, or other action has a reasonable and clearly defined public health or safety objective, and reflects the minimum practical regulation that is necessary to accomplish that objective.

(b) The ordinance, resolution, or other action reasonably accommodates radio broadcast services and does not prohibit, or have the effect of prohibiting, the provision of such services in the political subdivision.

(3) Continued application of existing regulations. If a political subdivision has in effect on May 1, 2013, an ordinance or resolution that is inconsistent with the requirements that are specified in sub. (2) for an ordinance, resolution, or other action to take effect, the existing ordinance or resolution does not apply, and may not be enforced, to the extent that it is inconsistent with the requirements that are specified in sub. (2).

(4) Denial of placement, construction, or modification of facilities. If a political subdivision denies a request by any person to place, construct, or modify radio broadcast service facilities in the political subdivision, the denial may be based only on the political subdivision's public health or safety concerns. The political subdivision must provide the requester with a written

denial of the requester's request, and the political subdivision must provide the requester with substantial written evidence which supports the reasons for the political subdivision's action.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0406, WI ST 66.0406
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IV. Regulation

W.S.A. 66.0407

66.0407. Noxious weeds

Currentness

(1) In this section:

(a) “Destroy” means the complete killing of weeds or the killing of weed plants above the surface of the ground by the use of chemicals, cutting, tillage, cropping system, pasturing livestock, or any or all of these in effective combination, at a time and in a manner as will effectually prevent the weed plants from maturing to the bloom or flower stage.

(b) “Noxious weed” means Canada thistle, leafy spurge, field bindweed, any weed designated as a noxious weed by the department of natural resources by rule, and any other weed the governing body of any municipality or the county board of any county by ordinance or resolution declares to be noxious within its respective boundaries.

(3) A person owning, occupying or controlling land shall destroy all noxious weeds on the land. The person having immediate charge of any public lands shall destroy all noxious weeds on the lands. The highway patrolman on all federal, state or county trunk highways shall destroy all noxious weeds on that portion of the highway which that highway patrolman patrols. The town board is responsible for the destruction of all noxious weeds on the town highways.

(4) The chairperson of each town, the president of each village and the mayor or manager of each city may annually on or before May 15 publish a class 2 notice, under ch. 985, that every person is required by law to destroy all noxious weeds, as defined in this section, on lands in the municipality which the person owns, occupies or controls. A town, village or city which has designated as its official newspaper or which uses for its official notices the same newspaper as any other town, village or city may publish the notice under this subsection in combination with the other town, village or city.

(5) This section does not apply to Canada thistle or annual noxious weeds that are located on land that the department of natural resources owns, occupies or controls and that is maintained in whole or in part as habitat for wild birds by the department of natural resources.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (4)

W. S. A. 66.0407, WI ST 66.0407

Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IV. Regulation

W.S.A. 66.0408

66.0408. Regulation of occupations

Currentness

(1) Definitions. In this section, "political subdivision" means a city, village, town, or county.

(2) Limitations on new regulations. (a) Except as provided in sub. (3), beginning on November 13, 2015, a political subdivision may not impose any occupational fees or licensing requirements on any profession if that profession is not subject to occupational fees or licensing requirements of the political subdivision on that date, but the political subdivision may continue to so regulate any profession that is subject to its occupational fees or licensing requirements on that date.

(b) With regard to the areas in which the department of safety and professional services may impose requirements on a contractor under s. 101.654, a political subdivision may not impose any requirements on a contractor that are more stringent than the requirements imposed by the department of safety and professional services under s. 101.654.

(c) Beginning on November 13, 2015, if the department of safety and professional services or an examining board, affiliated credentialing board, or other board in the department of safety and professional services imposes any new occupational fees or licensing requirements on any profession that was previously unregulated by the state, and if a political subdivision regulates that occupation when the state regulations take effect, the political subdivision may not continue to regulate that profession on or after the day on which the state regulations take effect and the political subdivision's regulations do not apply and may not be enforced.

(d) With regard to the areas in which any department of state government may impose occupational licensing requirements on any profession, a political subdivision may not impose any occupational licensing requirements on an individual who works in that profession that are more stringent than the requirements imposed by the department that regulates that profession.

(3) Exception. If a political subdivision has in effect an occupational fee or licensing requirement on the profession of photographer on November 13, 2015, that regulation does not apply and may not be enforced.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0408, WI ST 66.0408
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IV. Regulation

W.S.A. 66.0409

66.0409. Local regulation of weapons

Currentness

(1) In this section:

(a) “Firearm” has the meaning given in s. 167.31(1)(c) and includes an airgun, as defined in s. 29.001(7).

(b) “Political subdivision” means a city, village, town or county.

(c) “Sport shooting range” means an area designed and operated for the practice of weapons used in hunting, skeet shooting and similar sport shooting.

(2) Except as provided in subs. (3) and (4), no political subdivision may enact or enforce an ordinance or adopt a resolution that regulates the sale, purchase, purchase delay, transfer, ownership, use, keeping, possession, bearing, transportation, licensing, permitting, registration, or taxation of any knife or any firearm or part of a firearm, including ammunition and reloader components, unless the ordinance or resolution is the same as or similar to, and no more stringent than, a state statute.

(3)(a) Nothing in this section prohibits a county from imposing a sales tax or use tax under subch. V of ch. 77 on any knife or any firearm or part of a firearm, including ammunition and reloader components, sold in the county.

(b)1. Nothing in this section prohibits a city, village or town that is authorized to exercise village powers under s. 60.22(3) from enacting an ordinance or adopting a resolution that restricts the discharge of a firearm.

2. Notwithstanding subd. 1., any ordinance or resolution that restricts the discharge of a firearm does not apply and may not be enforced if the actor's conduct is justified or, had it been subject to a criminal penalty, would have been subject to a defense described in s. 939.45.

3. Notwithstanding subd. 1., any ordinance or resolution that restricts the honorary discharge of a firearm that involves the use of only blanks and that is part of any of the following does not apply and may not be enforced:

a. An event, including a funeral, honoring a current or former member of the military, law enforcement officer, or professional fire fighter.

b. Military honors provided at a cemetery on Memorial Day or Veterans Day.

c. Military honors provided at a veterans memorial site.

(c) Nothing in this section prohibits a political subdivision from enacting or enforcing an ordinance or adopting a resolution that prohibits the possession of a knife in a building, or part of a building, that is owned, occupied, or controlled by the political subdivision.

(4)(a) Nothing in this section prohibits a political subdivision from continuing to enforce an ordinance or resolution that is in effect on November 18, 1995, and that regulates the sale, purchase, transfer, ownership, use, keeping, possession, bearing, transportation, licensing, permitting, registration or taxation of any firearm or part of a firearm, including ammunition and reloader components, if the ordinance or resolution is the same as or similar to, and no more stringent than, a state statute.

(am) Nothing in this section prohibits a political subdivision from continuing to enforce until November 30, 1998, an ordinance or resolution that is in effect on November 18, 1995, and that requires a waiting period of not more than 7 days for the purchase of a handgun.

(b) If a political subdivision has in effect on November 17, 1995, an ordinance or resolution that regulates the sale, purchase, transfer, ownership, use, keeping, possession, bearing, transportation, licensing, permitting, registration or taxation of any firearm or part of a firearm, including ammunition and reloader components, and the ordinance or resolution is not the same as or similar to a state statute, the ordinance or resolution shall have no legal effect and the political subdivision may not enforce the ordinance or resolution on or after November 18, 1995.

(c) Nothing in this section prohibits a political subdivision from enacting and enforcing a zoning ordinance that regulates the new construction of a sport shooting range or when the expansion of an existing sport shooting range would impact public health and safety.

(5) A county ordinance that is enacted or a county resolution that is adopted by a county under sub. (2) or a county ordinance or resolution that remains in effect under sub. (4)(a) or (am) applies only in those towns in the county that have not enacted an ordinance or adopted a resolution under sub. (2) or that continue to enforce an ordinance or resolution under sub. (4)(a) or (am), except that this subsection does not apply to a sales or use tax that is imposed under subch. V of ch. 77.

(6) Unless other facts and circumstances that indicate a criminal or malicious intent on the part of the person apply, no person may be in violation of, or be charged with a violation of, an ordinance of a political subdivision relating to disorderly conduct or other inappropriate behavior for loading a firearm, or for carrying or going armed with a firearm or a knife, without regard to whether the firearm is loaded or the firearm or the knife is concealed or openly carried. Any ordinance in violation of this subsection does not apply and may not be enforced.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (6)

W. S. A. 66.0409, WI ST 66.0409
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
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W.S.A. 66.041

66.041. Renumbered 66.0605 and amended by 1999 Act 150, § 97, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.041, WI ST 66.041
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0410

66.0410. Local regulation of ticket reselling

Currentness

(1) Definitions. In this section:

(a) "Political subdivision" means a city, village, town, or county.

(b) "Ticket" means a ticket that is sold to an entertainment or sporting event.

(2) Reselling of tickets. (a) A political subdivision may not enact an ordinance or adopt a resolution and the Board of Regents of the University of Wisconsin System may not promulgate a rule or adopt a resolution prohibiting the resale of any ticket for an amount that is equal to or less than the ticket's face value.

(b) If a political subdivision or the Board of Regents of the University of Wisconsin System has in effect on April 22, 2004 an ordinance, rule, or resolution that is inconsistent with par. (a), the ordinance, rule, or resolution does not apply and may not be enforced.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0410, WI ST 66.0410
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0411

66.0411. Sound-producing devices; impoundment; seizure and forfeiture

Currentness

(1) In this section, "sound-producing device" does not include a piece of equipment or machinery that is designed for agricultural purposes and that is being used in the conduct of agricultural operations.

(1m)(a) Any city, village, town or county may, by ordinance, authorize a law enforcement officer, at the time of issuing a citation for a violation of s. 346.94(16) or a local ordinance in strict conformity with s. 346.94(16) or any other local ordinance prohibiting excessive noise, to impound any radio, electric sound amplification device or other sound-producing device used in the commission of the violation if the person charged with such violation is the owner of the radio, electric sound amplification device or other sound-producing device and has 2 or more prior convictions within a 3-year period of s. 346.94(16) or a local ordinance in strict conformity with s. 346.94(16) or any other local ordinance prohibiting excessive noise. The ordinance may provide for impoundment of a vehicle for not more than 5 working days to permit the city, village, town or county or its authorized agent to remove the radio, electric sound amplification device or other sound-producing device if the vehicle is owned by the person charged with the violation and the sound-producing device may not be easily removed from the vehicle. Upon removal of the sound-producing device, an impounded vehicle shall be returned to its rightful owner.

(b) The ordinance under par. (a) may provide for recovery by the city, village, town or county of the cost of impounding the sound-producing device and, if a vehicle is impounded, the cost of impounding the vehicle and removing the sound-producing device. The ordinance under par. (a) shall provide that, upon disposition of the forfeiture action for the violation of s. 346.94(16) or a local ordinance in strict conformity with s. 346.94(16) or any other local ordinance prohibiting excessive noise and payment of any forfeiture imposed, the sound-producing device shall be returned to its rightful owner.

(c) The city, village, town or county may dispose of any impounded sound-producing device or, following the procedure for an abandoned vehicle under s. 342.40, any impounded vehicle which has remained unclaimed for a period of 90 days after disposition of the forfeiture action.

(d) This subsection does not apply to a radio, electric sound amplification device or other sound-producing device on a motorcycle.

(2)(a) Notwithstanding sub. (1m), any city, village, town or county may, by ordinance, authorize a law enforcement officer, at the time of issuing a citation for a violation of s. 346.94(16) or a local ordinance in strict conformity with s. 346.94(16) or any other local ordinance prohibiting excessive noise, to seize any radio, electric sound amplification device or other sound-producing device used in the commission of the violation if the person charged with such violation is the owner of the radio, electric sound amplification device or other sound-producing device and has 3 or more prior convictions within a 3-year period of s. 346.94(16) or a local ordinance in strict conformity with s. 346.94(16) or any other local ordinance prohibiting excessive noise.

(b) The ordinance under par. (a) may provide for impoundment of a vehicle for not more than 5 working days to permit the city, village, town or county or its authorized agent to remove the radio, electric sound amplification device or other sound-producing device if the vehicle is owned by the person charged with the violation and the sound-producing device may not be easily removed from the vehicle. Upon removal of the sound-producing device, an impounded vehicle shall be returned to its rightful owner upon payment of the reasonable costs of impounding the vehicle and removing the sound-producing device.

(c) The ordinance under par. (a) shall include provisions that treat any seized sound-producing device in substantially the manner provided in ss. 973.075(3), 973.076 and 973.077 for property realized through the commission of any crime, except that the sound-producing device shall remain in the custody of the applicable law enforcement agency; a district attorney or city, village or town attorney, whichever is applicable, shall institute the forfeiture proceedings; and, if the sound-producing device is sold by the law enforcement agency, all proceeds of the sale shall be retained by the applicable city, village, town or county.

(d) The city, village, town or county may, following the procedure for an abandoned vehicle under s. 342.40, dispose of any impounded vehicle which has remained unclaimed for a period of 90 days after disposition of the forfeiture action.

(e) This subsection does not apply to a radio, electric sound amplification device or other sound-producing device on a motorcycle.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0411, WI ST 66.0411
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IV. Regulation

W.S.A. 66.0412

66.0412. Local regulation of real estate brokers, brokerage services

Currentness

(1) Definitions. In this section:

(a) "Broker" means a real estate broker licensed under ch. 452.

(b) "Local governmental unit" has the meaning given in s. 66.0131(1)(a).

(c) "Political subdivision" means any city, village, town, or county.

(2) Regulation of brokers, brokerage services. (a) A local governmental unit may not enact an ordinance or adopt a resolution that does any of the following:

1. In relation to the provision of real estate services, imposes any fees on brokers or on real estate brokerage services.

2. Imposes any regulations on the professional services provided by a broker or by a person who provides real estate brokerage services.

(b) If a local governmental unit has in effect on July 2, 2013, an ordinance or resolution that is inconsistent with par. (a), the ordinance or resolution does not apply and may not be enforced.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0412, WI ST 66.0412
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0413

66.0413. Razing buildings

Currentness

(1) Authority and procedure. (a) *Definitions.* In this subsection:

1. “Building” includes any building or structure or any portion of a building or structure.

2. “Raze a building” means to demolish and remove the building and to restore the site to a dust-free and erosion-free condition.

(b) *Raze order.* The governing body, building inspector or other designated officer of a municipality may:

1. Except as provided in sub. (5), if a building is old, dilapidated, or out of repair and consequently dangerous, unsafe, unsanitary, or otherwise unfit for human habitation and unreasonable to repair, order the owner of the building to raze the building or, if the building can be made safe by reasonable repairs, order the owner to either make the building safe and sanitary or to raze the building, at the owner's option.

2. If there has been a cessation of normal construction of a building for a period of more than 2 years, order the owner of the building to raze the building.

(br) *Notice of unfitness for occupancy or use; penalty.* 1. If a building subject to an order under par. (b) is unsanitary and unfit for human habitation, occupancy or use and is not in danger of structural collapse, the building inspector or other designated officer shall post a placard on the premises containing the following notice: “This Building May Not Be Used For Human Habitation, Occupancy or Use.” The building inspector or other designated officer shall prohibit use of the building for human habitation, occupancy or use until necessary repairs have been made.

2. Any person who rents, leases or occupies a building which has been condemned for human habitation, occupancy or use under subd. 1. shall be fined not less than $5 nor more than $50 or imprisoned not more than 30 days for each week of the violation, or both.

(c) *Reasonableness of repair; presumption*. Except as provided in subs. (3) and (5), if a municipal governing body, building inspector, or designated officer determines that the cost of repairs of a building described in par. (b)1. would exceed 50 percent of the assessed value of the building divided by the ratio of the assessed value to the recommended value as last published

by the department of revenue for the municipality within which the building is located, the repairs are presumed unreasonable for purposes of par. (b)1.

(d) *Service of order.* An order under par. (b) shall be served on the owner of record of the building that is subject to the order or on the owner's agent if the agent is in charge of the building in the same manner as a summons is served in circuit court. An order under par. (b) shall be served on the holder of an encumbrance of record by 1st class mail at the holder's last-known address and by publication as a class 1 notice under ch. 985. If the owner and the owner's agent cannot be found or if the owner is deceased and an estate has not been opened, the order may be served by posting it on the main entrance of the building and by publishing it as a class 1 notice under ch. 985 before the time limited in the order begins to run. The time limited in the order begins to run from the date of service on the owner or owner's agent or, if the owner and agent cannot be found, from the date that the order was posted on the building.

(e) *Effect of recording order.* If a raze order issued under par. (b) is recorded with the register of deeds in the county in which the building is located, the order is considered to have been served, as of the date the raze order is recorded, on any person claiming an interest in the building or the real estate as a result of a conveyance from the owner of record unless the conveyance was recorded before the recording of the raze order.

(f) *Failure to comply with order; razing building.* An order under par. (b) shall specify the time within which the owner of the building is required to comply with the order and shall specify repairs, if any. If the owner fails or refuses to comply within the time prescribed, the building inspector or other designated officer may proceed to raze the building through any available public agency or by contract or arrangement with private persons, or to secure the building and, if necessary, the property on which the building is located if unfit for human habitation, occupancy or use. The cost of razing or securing the building may be charged in full or in part against the real estate upon which the building is located, and if that cost is so charged it is a lien upon the real estate and may be assessed and collected as a special charge, but may not be assessed and collected as a special tax. Any portion of the cost charged against the real estate that is not reimbursed under s. 632.103(2) from funds withheld from an insurance settlement may be assessed and collected as a special tax.

(g) *Court order to comply.* A municipality, building inspector or designated officer may commence and prosecute an action in circuit court for an order of the court requiring the owner to comply with an order to raze a building issued under this subsection if the owner fails or refuses to do so within the time prescribed in the order, or for an order of the court requiring any person occupying a building whose occupancy has been prohibited under this subsection to vacate the premises, or any combination of the court orders. A hearing on actions under this paragraph shall be given preference. Court costs are in the discretion of the court.

(h) *Restraining order.* A person affected by an order issued under par. (b) may within the time provided by s. 893.76 apply to the circuit court for an order restraining the building inspector or other designated officer from razing the building or forever be barred. The hearing shall be held within 20 days and shall be given preference. The court shall determine whether the raze order is reasonable. If the order is found reasonable the court shall dissolve the restraining order. If the order is found not reasonable the court shall continue the restraining order or modify it as the circumstances require. Costs are in the discretion of the court. If the court finds that the order is unreasonable, the building inspector or other designated officer shall issue no other order under this subsection in regard to the same building until its condition is substantially changed. The remedies provided in this paragraph are exclusive remedies and anyone affected by an order issued under par. (b) is not entitled to recover any damages for the razing of the building.

(i) *Removal of personal property.* If a building subject to an order under par. (b) contains personal property or fixtures which will unreasonably interfere with the razing or repair of the building or if the razing makes necessary the removal, sale or destruction

of the personal property or fixtures, the building inspector or other designated officer may order in writing the removal of the personal property or fixtures by a date certain. The order shall be served as provided in par. (d). If the personal property or fixtures are not removed by the time specified the inspector may store, sell or, if it has no appreciable value, destroy the personal property or fixture. If the property is stored the amount paid for storage is a lien against the property and against the real estate and, to the extent that the amount is not reimbursed under s. 632.103(2) from funds withheld from an insurance settlement, shall be assessed and collected as a special tax against the real estate if the real estate is owned by the owner of the personal property and fixtures. If the property is stored the owner of the property, if known, shall be notified of the place of storage and if the property is not claimed by the owner it may be sold at the expiration of 6 months after it has been stored. The handling of the sale and the distribution of the net proceeds after deducting the cost of storage and any other costs shall be as specified in par. (j) and a report made to the circuit court as specified in par. (j). A person affected by any order made under this paragraph may appeal as provided in par. (h).

(j) *Sale of salvage.* If an order to raze a building has been issued, the governing body or other designated officer under the contract or arrangement to raze the building may sell the salvage and valuable materials at the highest price obtainable. The net proceeds of the sale, after deducting the expenses of razing the building, shall be promptly remitted to the circuit court with a report of the sale or transaction, including the items of expense and the amounts deducted, for the use of any person entitled to the net proceeds, subject to the order of the court. If there remains no surplus to be turned over to the court, the report shall so state.

(k) *Public nuisance procedure.* A building which is determined under par. (b) 1. to be old, dilapidated or out of repair and consequently dangerous, unsafe, unsanitary or otherwise unfit for human habitation and unreasonable to repair may be proceeded against as a public nuisance under ch. 823.

(L) *Effect of subsection.* 1. Acts of municipal authorities under this subsection do not increase the liability of an insurer.

2. This section does not limit powers otherwise granted to municipalities by other laws of this state.

(2) Razing building that is a public nuisance; in rem procedure. (a) *Definitions.* In this subsection:

1. “Building” means a building, dwelling or structure.

2. “Public nuisance” means a building that, as a result of vandalism or any other reason, has deteriorated or is dilapidated or blighted to the extent that windows, doors or other openings, plumbing or heating fixtures, or facilities or appurtenances of the building are damaged, destroyed or removed so that the building offends the aesthetic character of the immediate neighborhood and produces blight or deterioration.

3. “Raze a building” means to demolish and remove the building and to restore the site to a dust-free and erosion-free condition.

(b) *Notification of nuisance.* If the owner of a building in a city, village or town permits the building to become a public nuisance, the building inspector or other designated officer of the city, village or town shall issue a written notice of the defect that makes the building a public nuisance. The written notice shall be served on the owner of the building as provided under sub. (1)(d) and shall direct the owner to remedy the defect within 30 days following service.

(c) *Failure to remedy; court order to remedy or raze.* 1. If an owner fails to remedy or improve the defect in accordance with the written notice under par. (b) within the 30-day period specified in the written notice, the building inspector or other designated

officer shall apply to the circuit court of the county in which the building is located for an order determining that the building constitutes a public nuisance. As a part of the application for the order from the circuit court the building inspector or other designated officer shall file a verified petition which recites the giving of written notice, the defect in the building, the owner's failure to comply with the notice and other pertinent facts. A copy of the petition shall be served upon the owner of record or the owner's agent if an agent is in charge of the building and upon the holder of any encumbrance of record under sub. (1)(d). The owner shall reply to the petition within 20 days following service upon the owner. Upon application by the building inspector or other designated officer the circuit court shall set promptly the petition for hearing. Testimony shall be taken by the circuit court with respect to the allegations of the petition and denials contained in the verified answer. If the circuit court after hearing the evidence on the petition and answer determines that the building constitutes a public nuisance, the court shall issue promptly an order directing the owner of the building to remedy the defect and to make such repairs and alterations as may be required. The court shall set a reasonable period of time in which the defect shall be remedied and the repairs or alterations completed. A copy of the order shall be served upon the owner as provided in sub. (1)(d). The order of the circuit court shall state in the alternative that if the order of the court is not complied with within the time fixed by the court, the court will appoint a receiver or authorize the building inspector or other designated officer to proceed to raze the building under par. (d).

2. In an action under this subsection, the circuit court before which the action is commenced shall exercise jurisdiction in rem or quasi in rem over the property that is the subject of the action. The owner of record of the property, if known, and all other persons of record holding or claiming any interest in the property shall be made parties defendant, and service of process may be made upon them.

3. It is not a defense to an action under this subsection that the owner of record of the property is a different person or entity than the owner of record of the property on or after the date the action was commenced if a lis pendens was filed before the change of ownership.

(d) *Failure to comply with court order.* If the order of the circuit court under par. (c) is not complied with within the time fixed by the court under par. (c), the court shall authorize the building inspector or other designated officer to raze the building or shall appoint a disinterested person to act as receiver of the property to do either of the following within a reasonable period of time set by the court:

1. Remedy the defect and make any repairs and alterations necessary to meet the standards required by the building code or any health order. A receiver appointed under this subdivision, with the approval of the circuit court, may borrow money against and mortgage the property held in receivership as security in any amount necessary to remedy the defect and make the repairs and alterations. For the expenses incurred to remedy the defect and make the repairs and alterations necessary under this subdivision, the receiver has a lien upon the property. At the request of and with the approval of the owner, the receiver may sell the property at a price equal to at least the appraised value of the property plus the cost of any repairs made under this subdivision. The selling owner is liable for those costs.

2. Secure and sell the building to a buyer who demonstrates to the circuit court an ability and intent to rehabilitate the building and to have the building reoccupied in a legal manner.

(e) *Receiver; order to raze.* 1. A receiver appointed under par. (d) shall collect all rents and profits accruing from the property held in receivership and pay all costs of management, including all general and special real estate taxes or assessments and interest payments on first mortgages on the property. A receiver under par. (d) shall apply moneys received from the sale of property held in receivership to pay all debts due on the property in the order set by law and shall pay any balance to the selling owner if the circuit court approves.

2. The circuit court shall set the fees and bond of a receiver appointed under par. (d) and may discharge the receiver as the court considers appropriate.

3. Nothing in this subsection relieves the owner of property for which a receiver has been appointed under par. (d) from any civil or criminal responsibility or liability except that the receiver has civil and criminal responsibility and liability for all matters and acts directly under the receiver's authority or performed at his or her discretion.

4. If a defect is not remedied and repairs and alterations are not made within the time limit set by the circuit court under par. (d), the court shall order that the building inspector or other designated officer proceed to raze the building.

5. All costs and disbursements to raze a building under this subsection shall be as provided under sub. (1)(f).

(3) Razing historic buildings. (a) In this subsection:

1. “Cost of repairs” includes the estimated cost of repairs that are necessary to comply with applicable building codes, or other ordinances or regulations, governing the repair or renovation of a historic building.

1m. “Historic building” means any building or object listed on, or any building or object within and contributing to a historic district listed on, the national register of historic places in Wisconsin, the state register of historic places or a list of historic places maintained by a municipality.

2. “Municipality” means a city, village, county or town.

(b) The state historical society shall notify a municipality of any historic building located in the municipality. If a historic district lies within a municipality, the historical society shall furnish to the municipality a map delineating the boundaries of the district.

(c) If an order is issued under this section to raze and remove a historic building and restore the site to a dust-free and erosion-free condition, an application is made for a permit to raze and remove a historic building and restore the site to a dust-free and erosion-free condition or a municipality intends to raze and remove a municipally owned historic building and restore the site to a dust-free and erosion-free condition, the municipality in which the historic building is located shall notify the state historical society of the order, application or intent. No historic building may be razed and removed nor the site restored to a dust-free and erosion-free condition for 30 days after the notice is given, unless a shorter period is authorized by the state historical society. If the state historical society authorizes a shorter period, however, such a period shall be subject to any applicable local ordinance. During the 30-day period, the state historical society shall have access to the historic building to create or preserve a historic record. If the state historical society completes its creation or preservation of a historic record, or decides not to create or preserve a historic record, before the end of the 30-day period, the society may waive its right to access the building and may authorize the person who intends to raze and remove the building, and restore the site to a dust-free and erosion-free condition, to proceed before the end of such period, except that such a person shall be subject to any applicable local ordinance.

(d) If a municipal governing body, inspector of buildings or designated officer determines that the cost of repairs to a historic building would be less than 85 percent of the assessed value of the building divided by the ratio of the assessed value to the recommended value as last published by the department of revenue for the municipality within which the historic building is located, the repairs are presumed reasonable.

(4) First class cities; other provisions. (a) First class cities may adopt by ordinance alternate or additional provisions governing the placarding, closing, razing and removal of a building and the restoration of the site to a dust-free and erosion-free condition.

(b) This subsection shall be liberally construed to provide 1st class cities with the largest possible power and leeway of action.

(5) Razing certain insured dwellings. (a) *Definitions*. In this subsection:

1. "Cost of repairs" includes the estimated cost of repairs that are necessary to comply with applicable building codes, or other ordinances or regulations, governing the repair or renovation of a dwelling.

2. "Covered damage" means damage that is covered by an insurance policy.

3. "Insured dwelling" means real property that is covered under an insurance policy and that is owned, occupied, and used primarily as a dwelling by the insured.

(b) *Insurer certification*. 1. No later than 14 days after real property has incurred damage, an insurer may provide a written certification through 1st class mail or electronic communication to a governing body, building inspector, or other designated officer of a municipality stating all of the following:

a. That the insurer reasonably believes the real property may qualify as an insured dwelling.

b. That the property owner or an insured has filed a claim for covered damage with the insurer or the insurer has reason to believe the property owner or an insured will file a claim for covered damage with the insurer.

c. That the insurer reasonably believes the claim may qualify as covered damage.

d. The date of damage to the insured dwelling, the insurance policy limits of the insured dwelling, the insurer's designated representative for the filed or anticipated claim, and the designated representative's mailing address, electronic mail address, and phone number.

2. A certification under this paragraph does not waive or limit any rights of the insurer under an insurance policy.

3. At any point prior to submitting a certification under subd. 1., an insurer may notify a governing body, building inspector, or other designated officer of a municipality that the insurer has determined the insured dwelling to be wholly destroyed. If at any point after submitting a certification under subd. 1. the insurer determines that the insured dwelling is wholly destroyed, the insurer shall notify the governing body, building inspector, or other designated officer of that determination.

(c) *Municipal assessment*. A governing body, building inspector, or other designated officer of a municipality may not issue a raze order under sub. (1)(b) for an insured dwelling for which an insurer has provided a certification under par. (b) unless the governing body, building inspector, or other designated officer does all of the following:

1. Provides notice of intent to issue a raze order to the owner of record of the insured dwelling, the holder of any encumbrance on the insured dwelling, and the insurer of the insured dwelling. The notice shall include a statement that materials may be submitted to the governing body, building inspector, or other designated officer under subd. 2. Notice under this subdivision shall be served in the manner provided under sub. (1)(d).

2. Accepts and considers materials that are submitted by any person entitled to notice under subd. 1., that assist in establishing the extent of the damage or the reasonable cost of repairs to the insured dwelling, and that are received within 30 days after provision of the notice under subd. 1. Materials that may be accepted and considered under this subdivision are limited to

damage estimates, evaluations of the cost of repairs, and the results of inspections of the property. When considering the materials submitted under this subdivision, the governing body, building inspector, or other designated officer shall consider the qualifications, expertise, and experience of the person that submitted the materials.

3. Conducts an on-site inspection of the insured dwelling to assess the extent of the damage.

4. Determines the estimated cost of repairs for the insured dwelling.

5. Determines that repair of the insured dwelling is not reasonable.

(d) *Cost of repair*. A municipal governing body, building inspector, or other designated officer of a municipality shall base its determination of the estimated cost of repairs for the insured dwelling under par. (c)4. on the materials accepted under par. (c)2. and similar materials produced by the municipal governing body, building inspector, or designated officer.

(e) *Reasonableness of repair*. If a municipal governing body, building inspector, or other designated officer of a municipality determines that the estimated cost of repairs of an insured dwelling does not exceed 70 percent of the insurance policy limits of the insured dwelling, the repairs are presumed reasonable.

(f) *Repair orders*. Nothing in this subsection shall preclude the governing body, building inspector, or other designated officer of a municipality from ordering the owner of an insured dwelling to make the building safe and sanitary under sub. (1)(b).

(g) *Application*. This subsection does not apply to any of the following:

1. A dwelling that the governing body, building inspector, or other designated officer of a municipality has determined to be in imminent danger of structural collapse and for which the property owner has failed to appropriately secure and limit access.

2. An insured dwelling that is the subject of a notification provided to the governing body, building inspector, or other designated officer of a municipality by an insurer pursuant to par. (b)3.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (71)

W. S. A. 66.0413, WI ST 66.0413
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0414

66.0414 Small wireless facilities

Currentness

(1) Definitions. In this section:

(a) "Antenna" means communications equipment that transmits and receives electromagnetic radio signals and is used in the provision of wireless services.

(b) "Antenna equipment" or "wireless equipment" means equipment, switches, wiring, cabling, power sources, shelters, or cabinets associated with an antenna, located at the same fixed location as the antenna, and, when collocated on a structure, is mounted or installed at the same time as such antenna.

(c) "Antenna facility" means an antenna and associated antenna equipment, including ground-mounted antenna equipment.

(d) "Applicable codes" means the state electrical wiring code, as defined in s. 101.80(4), the state plumbing code promulgated under s. 145.02(2)(a), the fire prevention code under ch. SPS 314, Wis. Adm. Code, the Wisconsin commercial building code under chs. SPS 361 to 366, Wis. Adm. Code, the Wisconsin uniform dwelling code under chs. SPS 320 to 325, Wis. Adm. Code, and local amendments to those codes enacted solely to address imminent threats of destruction of property or injury to persons.

(e) "Applicant" means a wireless provider that submits an application.

(f) "Application" means an application for a permit under this section to collocate a small wireless facility or to install, modify, or replace a utility pole.

(g) "Collocate," "collocate on," or "collocation" means the placement, mounting, replacement, modification, operation, or maintenance of a small wireless facility on, or of ground-mounted antenna equipment adjacent to, a structure.

(h) "Communications facilities" means the set of equipment and network components, including wires and cables and associated facilities, used by a communications service provider to provide communications service.

(i) "Communications network" means a network used to provide a communications service.

(j) “Communications service” means cable service, as defined in 47 USC 522(6), telecommunications service, as defined in 47 USC 153(53), information service, as defined in 47 USC 153(24), or wireless service.

(k) “Communications service provider” means a person that provides communications service.

(L) “Facility” means an antenna facility or a structure.

(m) “Fee” means a one-time charge.

(n) “Governmental pole” means a utility pole that is owned or operated by the state or by a political subdivision in a right-of-way.

(o) “Investor-owned electric utility” means a public utility whose purpose is the generation, transmission, delivery, or furnishing of electric power but does not include a public utility owned and operated wholly by a municipality or a cooperative association organized under ch. 185.

(p) “Micro wireless facility” means a small wireless facility that does not exceed 24 inches in length, 15 inches in width, and 12 inches in height and that has no exterior antenna longer than 11 inches.

(q) “Permit” means written authorization required by the state or a political subdivision to perform an action, or initiate, continue, or complete a project.

(r) “Political subdivision” means any city, village, town, or county.

(s) “Rate” means a recurring charge.

(t) “Right-of-way” means the area on, below, or above a highway, as defined in s. 340.01(22), other than a federal interstate highway; sidewalk; utility easement, other than a utility easement for a cooperative association organized under ch. 185 for purposes of providing or furnishing heat, light, power, or water to its members only; or other similar property, including property owned or controlled by the department of transportation.

(u) “Small wireless facility” means a wireless facility to which all of the following apply:

1. The wireless facility satisfies any of the following:

a. The wireless facility is mounted on a structure 50 feet or less in height including any antenna.

b. The wireless facility is mounted on a structure no more than 10 percent taller than any other adjacent structure.

c. The wireless facility does not increase the height of an existing structure on which the wireless facility is located to a height of more than 50 feet or by 10 percent, whichever is greater.

2. Each antenna associated with the deployment of the wireless facility, excluding associated antenna equipment, is no more than 3 cubic feet in volume.

3. All other wireless equipment associated with the wireless facility specified in subd. 1., including the wireless equipment associated with the antenna and any preexisting associated equipment on the structure, is no more than 28 cubic feet in volume.

4. The wireless facility does not require registration as an antenna structure under 47 CFR part 17.

5. The wireless facility is not located on tribal land, as defined in 36 CFR 800.16(x).

6. The wireless facility does not result in human exposure to radio frequency in excess of the applicable safety standards specified in 47 CFR 1.1307.

(v) Except in par. (zp), "structure" means a utility pole or wireless support structure, whether or not it has an existing antenna facility.

(w) "Technically feasible" means that by virtue of engineering or spectrum usage the proposed placement for a small wireless facility, or its design, concealment measures, or site location can be implemented without a reduction in the functionality of the small wireless facility.

(x) "Utility pole" means a pole that is used in whole or in part by a communications service provider; used for electric distribution, lighting, traffic control, signage, or a similar function; or used for the collocation of small wireless facilities. "Utility pole" does not include a wireless support structure or electric transmission structure.

(y) "Utility pole for designated services" means a utility pole owned or operated in a right-of-way by the state, a political subdivision, or a utility district that is designed to, or used to, carry electric distribution lines, or cables or wires for telecommunications, cable, or electric service.

(z)1. "Wireless facility" means an antenna facility at a fixed location that enables wireless services between user equipment and a communications network, and includes all of the following:

a. Equipment associated with wireless services.

b. Radio transceivers, antennas, or coaxial, metallic, or fiber-optic cable located on, in, under, or otherwise adjacent to a utility pole or wireless support structure.

c. Regular and backup power supplies.

d. Equipment that is comparable to equipment specified in this subdivision regardless of technical configuration.

2. “Wireless facility” does not include any of the following:

a. The structure or improvements on, under, or within which equipment specified in subd. 1. is collocated.

b. Wireline backhaul facilities.

c. Coaxial, metallic, or fiber-optic cable that is between utility poles or wireless support structures or that is not adjacent to a particular antenna.

(za) “Wireless infrastructure provider” means any person, other than a wireless services provider, that builds or installs wireless communication transmission equipment, antenna equipment, or wireless support structures.

(zc) “Wireless provider” means a wireless infrastructure provider or a wireless services provider.

(zg) “Wireless services” means any service using licensed or unlicensed wireless spectrum, including the use of a Wi-Fi network, whether at a fixed location or by means of a mobile device.

(zL) “Wireless services provider” means any person who provides wireless services.

(zp) “Wireless support structure” means an existing freestanding structure that is capable of supporting small wireless facilities, except that “wireless support structure” does not include any of the following:

1. A utility pole.

2. A structure designed solely for the collocation of small wireless facilities.

(zt) “Wireline backhaul facility” means a facility for providing wireline backhaul service.

(zx) “Wireline backhaul service” means the transport of communications services by wire from small wireless facilities to a communications network.

(2) Rights-of-way. (a) *Applicability*. This subsection applies only to the activities of a wireless provider within a right-of-way.

(b) *Exclusive use prohibited*. Neither the state nor a political subdivision may enter into an exclusive arrangement with any person for the use of a right-of-way for the construction, operation, marketing, maintenance, or collocation of small wireless facilities or wireless support structures.

(c) *Rates and fees*. Subject to sub. (3)(e)3., the state or a political subdivision may charge a wireless provider a nondiscriminatory rate or fee for the use of a right-of-way with respect to the collocation of a small wireless facility or the installation, modification, or replacement of a utility pole in the right-of-way only if the state or political subdivision charges other entities for the use of the right-of-way. If the state or a political subdivision charges a wireless provider a rate or fee as described in this paragraph, all of the following apply:

1. Subject to subd. 5., the fee or rate must be limited to no more than the direct and actual cost of managing the right-of-way.

2. Except as provided in par. (d), the fee or rate must be competitively neutral with regard to other users of the right-of-way.

3. The fee or rate may not result in a double recovery by the state or political subdivision if existing fees, rates, or taxes imposed by a political subdivision on the wireless provider already recover the direct and actual cost of managing the right-of-way.

4. The fee or rate may not be in the form of a franchise or other fee based on revenue or customer counts.

5. The fee or rate may not exceed an annual amount equal to $20 multiplied by the number of small wireless facilities in the right-of-way in the state's or political subdivision's geographic jurisdiction.

6. Beginning on July 12, 2019, the state or a political subdivision may adjust a rate or fee allowed under this paragraph by 10 percent every 5 years, rounded to the nearest dollar. During each 5-year period, the adjustment may be applied incrementally or as a single adjustment.

(d) *Rate or fee adjustment*. 1. Except as provided in subd. 2., by the later of October 1, 2019, or 3 months after receiving its first request for access to the right-of-way by a wireless provider, the state or a political subdivision shall implement rates, fees, and terms for such access that comply with this subsection.

2. Agreements between a wireless provider and the state or a political subdivision that are in effect on July 12, 2019, and that relate to access to the right-of-way, remain in effect, subject to applicable termination provisions, except that by August 1, 2021, the state or political subdivision shall amend any such agreement to comply with the rates, fees, and terms required under this subsection.

(e) *Right of access*. 1. Except as otherwise provided in this subsection and subs. (3)(c)4. and 5. and (4), and notwithstanding ss. 182.017 and 196.58 and any zoning ordinance enacted by a political subdivision under s. 59.69, 60.61, 60.62, or 62.23, a wireless provider shall have the right to collocate small wireless facilities and construct, modify, maintain, and replace its own utility poles, or, with the permission of the owner, a 3rd party's utility pole, that supports small wireless facilities along, across, upon, and under a right-of-way. Such small wireless facilities and utility poles, and activities related to the installation and maintenance of the small wireless facilities and utility poles, may not obstruct or hinder travel, drainage, maintenance, or

the public health, safety, and general welfare on or around the right-of-way, or obstruct the legal use of the right-of-way for other communications providers, public utilities, cooperative associations organized under ch. 185 for the purpose of producing or furnishing heat, light, power, or water to their members only, or pipes or pipelines transmitting liquid manure. A political subdivision may enact an ordinance consistent with this subdivision.

2. Except as provided in subd. 4., the height of a utility pole installed, or modified, in a right-of-way may not exceed the greater of:

a. A height that is 10 percent taller than the tallest existing utility pole as of July 12, 2019, that is located within 500 feet of the new or modified utility pole in the same right-of-way.

b. Fifty feet above ground level.

3. The height of a small wireless facility installed, or modified, in a right-of-way may not exceed the greater of:

a. A height that is 10 percent taller than the existing utility pole or wireless support structure on which the small wireless facility is located.

b. Fifty feet above ground level.

4. A wireless provider may construct, modify, and maintain a utility pole, wireless support structure, or small wireless facility along, across, upon, and under a right-of-way that exceeds the height limits in this paragraph if the wireless provider complies with height limits under the zoning ordinances enacted by a political subdivision under s. 59.69, 60.61, 60.62, or 62.23.

5. With regard to the rights of a wireless provider to construct or modify a utility pole as described in subd. 1., a political subdivision may propose an alternate location for collocation, which the wireless provider shall use if it has the right to use the alternate structure on reasonable terms and conditions and the alternate location is technically feasible and does not impose material additional costs.

(f) *Damage and repair*. The state or a political subdivision may require a wireless provider to repair all damage that is directly caused by the activities of the wireless provider in a right-of-way involving its small wireless facilities or structures, and to return the right-of-way to its former condition before it was so damaged. If the wireless provider fails to make the required repairs within a reasonable amount of time after receiving a written request to do so from the state or a political subdivision, the state or political subdivision may make the necessary repairs and charge the liable party for the cost of the repairs. This paragraph does not prohibit a political subdivision from recovering damages under s. 86.02.

(g) *Nondiscrimination*. The state and political subdivisions must administer and regulate a right-of-way in a competitively neutral manner with regard to all users of the right-of-way.

(3) Permitting process. (a) *Applicability*. This subsection applies to the permitting for the collocation of small wireless facilities by a wireless provider within and outside a right-of-way and to the permitting for the installation, modification, and replacement

of associated utility poles by a wireless provider inside a right-of-way. Except as provided in this subsection and in subs. (2) and (4), neither the state nor a political subdivision may prohibit, regulate, or charge any person for the collocation of small wireless facilities.

(b) *Zoning*. Notwithstanding an ordinance enacted under s. 59.69, 60.61, 60.62, or 62.23, and except as provided in par. (c)4. and 5., small wireless facilities shall be classified as permitted uses and are not subject to a political subdivision's zoning ordinances if they are collocated in a right-of-way or outside a right-of-way if the property is not zoned exclusively for single-family residential use. For purposes of this paragraph and notwithstanding sub. (1)(u)3., the volume of a small wireless facility does not include preexisting associated wireless equipment on a structure outside the right-of-way.

(c) *Permits*. 1. Subject to subds. 4. and 5., the state or a political subdivision may require an application for a permit to collocate a small wireless facility and to construct, modify, maintain, or operate a new or replacement utility pole, provided such permit is of general applicability and does not apply exclusively to small wireless facilities. All of the following apply to such permit applications filed by an applicant:

a. Neither the state nor a political subdivision may require an applicant to perform services unrelated to the approval sought.

b. Neither the state nor a political subdivision may require an applicant that is a wireless provider to provide more information in its permit application than such a governmental unit requires from a communications service provider that is not a wireless provider and that applies for the same type of permit. The state or a political subdivision may require the types of information specified in subd. 2. in an application.

c. The state or a political subdivision shall notify an applicant in writing, within 10 days of receiving an application, whether it is complete. If an application is incomplete, the state or political subdivision shall specify why the application is incomplete. The processing deadlines under subd. 1. d., e., and f. restart at zero on the date that the applicant submits to the state or a political subdivision an application that includes information identified by the state or political subdivision to render the application complete.

d. Except as provided in subd. 1. g., if a permit application involves a new or replacement utility pole, and the state or a political subdivision fails to approve or deny the permit application under this section not later than 90 days after its receipt, the applicant may consider its permit application approved.

e. Except as provided in subd. 1. g., if a permit application proposes to collocate small wireless facilities on an existing structure and the state or a political subdivision fails to approve or deny the permit application under this section not later than 60 days after its receipt, the applicant may consider its permit application approved.

f. Except as provided in subd. 1. g., if there is any type of construction, building, or encroachment permit required by a political subdivision that relates to a permit under subd. 1. d. or e., and the political subdivision fails to approve or deny that permit application within the specified 60-day or 90-day time frame, the applicant may consider its permit application approved.

g. The applicant and the state or political subdivision may mutually agree to extend the deadline for the state or political subdivision to approve or deny a permit application under subd. 1. d., e., or f.

h. Subject to subd. 1. i., the state or a political subdivision shall approve a permit application unless it does not meet the applicable codes, sub. (2)(e)1., or the standards of an ordinance enacted pursuant to sub. (2)(e)1. If the permit application is denied for any of these reasons, the state or political subdivision shall provide the applicant with written documentation explaining the basis for the denial no later than the date that the permit application is denied. An applicant may cure the deficiencies identified in the documentation and resubmit the permit application no later than 30 days after receipt of the documentation without being required to pay an additional application fee. The state or a political subdivision shall approve or deny the revised permit application not later than 30 days after its receipt.

i. The state or a political subdivision may condition approval of a permit on compliance with reasonable and nondiscriminatory relocation, abandonment, or bonding requirements that are consistent with state law applicable to other occupiers of rights-of-way.

j. An applicant may file a consolidated permit application to collocate up to 30 small wireless facilities, or a greater number if agreed to by a political subdivision, provided that all the small wireless facilities in the application consist of substantially similar equipment and are to be placed on similar types of structures. In rendering a decision on a consolidated permit application, a political subdivision may approve a permit for some small wireless facilities and deny a permit for others, but the political subdivision may not use the denial of one or more permits as a basis to deny permits for all of the small wireless facilities in the application.

k. If an applicant's permit application is approved, the applicant shall commence the activity authorized by the permit no later than 365 days after its receipt and shall pursue work on the activity until completion. Neither the state nor a political subdivision may place any time limitation on an applicant that is related to the permit. An applicant may request that the state or a political subdivision terminate the applicant's permit.

2. The state or a political subdivision may require any of the following types of information in an application for a permit specified in subd. 1. (intro.):

a. The applicant's name, address, telephone number, e-mail address, and emergency contact information.

b. The names, addresses, telephone numbers, and e-mail addresses of all duly authorized representatives and consultants, if any, acting on behalf of the applicant with respect to the filing of the application.

c. A general description of the proposed small wireless facility and associated utility pole, if applicable. The scope and detail of such description shall be appropriate to the nature and character of the work to be performed, with special emphasis on those matters likely to be affected or impacted by the physical work proposed.

d. Site plans and detailed construction drawings to scale that identify the proposed small wireless facility and the proposed use of the right-of-way.

e. To the extent the proposed facility involves collocation on a new utility pole, existing utility pole, or existing wireless support structure, a structural report performed by a duly licensed engineer evidencing that the utility pole or wireless support structure

will structurally support the collocation, or that the utility pole or wireless support structure may and will be modified to meet structural requirements, in accordance with applicable codes.

f. If the small wireless facility will be collocated on a utility pole or wireless support structure owned by a 3rd party, other than a governmental pole or a utility pole for designated services, a certification that the wireless provider has permission from the owner to collocate on the utility pole or wireless support structure.

g. Certification by the wireless provider that the small wireless facility will comply with relevant federal communications commission regulations concerning 1) radio frequency emissions from radio transmitters and 2) unacceptable interference with public safety spectrum, including compliance with the abatement and resolution procedures for interference with public safety spectrum established by the federal communications commission set forth in 47 CFR 22.970 to 22.973 and 47 CFR 90.672 to 90.675.

h. Certification by the wireless provider that the small wireless facility will not materially interfere with any of the following: 1) the safe operation of traffic control equipment; 2) sight lines or clear zones for transportation or pedestrians; and 3) the federal Americans with Disabilities Act or similar federal or state standards regarding pedestrian access or movement.

i. A statement that the small wireless facility shall comply with all applicable codes.

3. Neither the state nor a political subdivision may institute an express or de facto moratorium on any of the following:

a. The filing, receiving, or processing of applications.

b. The issuance of permits or other approvals, if any, for the collocation of small wireless facilities or the installation, modification, or replacement of utility poles to support small wireless facilities.

4. A political subdivision may adopt aesthetic requirements governing the deployment of small wireless facilities and associated antenna equipment and utility poles in the right-of-way, subject to the following conditions:

a. The aesthetic requirements must be 1) reasonable in that they are technically feasible and reasonably directed to avoiding or remedying unsightly or out-of-character deployments; 2) no more burdensome than those applied to other types of infrastructure deployments; and 3) objective and published in advance.

b. Any design or concealment measures are not considered a part of the small wireless facility for purpose of the size parameters in the definition of a small wireless facility under sub. (1)(u).

c. A political subdivision may deny an application for not complying with aesthetic requirements only if the denial does not prohibit or have the effect of prohibiting the provision of wireless service.

5. A political subdivision may enact an ordinance to prohibit, in a nondiscriminatory way, a communications service provider from installing structures in the right-of-way of a historic district or an underground district, except that the ordinance may not

prohibit collocations or the replacement of existing structures. In this subdivision, a historic district is an area designated as historic by the political subdivision, listed on the national register of historic places in Wisconsin, or listed on the state register of historic places. In this subdivision, an underground district is an area designated by the political subdivision in which all pipes, pipelines, ducts, wires, lines, conduits, or other equipment, which are used for the transmission, distribution, or delivery of electrical power, heat, water, gas, sewer, or telecommunications equipment, are located underground. A political subdivision may require any collocation on or replacement of an existing structure to reasonably conform to the design aesthetics of the original structure in a historic or underground district. Any design or concealment measures are not considered a part of the small wireless facility for purposes of the size restrictions in the definition of "small wireless facility" under sub. (1)(u). The requirements of an ordinance enacted under this subdivision must be objective, technically feasible, no more burdensome than requirements applied to other types of infrastructure deployment, and reasonably directed at avoiding or remedying the intangible public harm of unsightly or out-of-character deployments. A political subdivision may not apply any requirements under an ordinance enacted under this subdivision in a manner that results in an effective prohibition of wireless service.

(d) *Application fees*. 1. Except as provided in subd. 2., the state or a political subdivision may only charge an application fee that is reasonable, nondiscriminatory, and recovers no more than a governmental unit's direct cost for processing an application, except that no application fee may exceed any of the following:

a. For an application that includes 5 or fewer small wireless facilities, $500.

b. For an application that includes more than 5 small wireless facilities, $500 plus $100 for each small wireless facility in excess of 5.

c. One thousand dollars for the installation or replacement of a utility pole together with the collocation of an associated small wireless facility.

2. Beginning on July 12, 2019, the state or a political subdivision may adjust a fee allowed under subd. 1. by 10 percent every 5 years, rounded to the nearest multiple of $5. During each 5-year period, the adjustment may be applied incrementally or as a single adjustment.

3. If the federal communications commission adjusts its levels for fees that are presumptively lawful under 47 USC 253 or 332(c)(7), the state or a political subdivision may adjust any impacted fee under subd. 1. on a pro rata basis, consistent with the federal communications commission's action.

(e) *Approvals not required*. Neither the state nor a political subdivision may require applications, permits, fees, or any other approval for any of the following:

1. Routine maintenance.

2. The replacement of a small wireless facility with a small wireless facility that is substantially similar to, or the same size or smaller than, the existing small wireless facility, except that the governmental unit may require the person seeking to replace the small wireless facility to obtain a permit to work within a right-of-way to complete such a replacement. For purposes of this subdivision, a small wireless facility does not include the structure on which it is collocated.

3. The installation, placement, maintenance, operation, or replacement of micro wireless facilities that are strung on cables between existing utility poles in compliance with the National Electrical Safety Code.

(f) *Traffic work permits*. Nothing in this section prohibits a political subdivision from requiring a work permit for work that will unreasonably affect traffic patterns or obstruct vehicular traffic in a right-of-way, provided that such permits are issued to any applicant on a nondiscriminatory basis upon terms and conditions that apply to the activities of any other person performing work in the right-of-way that requires excavation or the closing of sidewalks or traffic lanes.

(4) Collocation of small wireless facilities on governmental poles and utility poles for designated services. (a) A person owning or controlling a governmental pole or a utility pole for designated services may not enter into an exclusive arrangement with any person for the right to attach to, or use, such poles.

(b) The fees or rates charged by the owner of a pole described under par. (a), and the terms and conditions for such attachment or use, may not be discriminatory.

(c) The rate a political subdivision may charge a wireless provider to collocate a small wireless facility on a utility pole for designated services shall be governed by an agreement between the political subdivision and the wireless provider. If there is a failure to agree on the rate, the public service commission shall determine the compensation pursuant to the procedures in s. 196.04 and the determination shall be reviewable under s. 196.41.

(d)1. The rate an owner of a governmental pole other than a utility pole for designated services charges another person to collocate on the owner's pole shall be sufficient to recover the actual, direct, and reasonable costs related to the applicant's application for, and use of, space on the pole, except that subject to subd. 2., the total annual rate for a collocation and any related activities may not exceed the lesser of the actual, direct, and reasonable costs related to the collocation or $250 per year per small wireless facility. If a dispute arises concerning the appropriateness of a rate charged by the state or political subdivision under this subdivision, the governmental unit bears the burden of proving that the rate is reasonably related to the actual, direct, and reasonable costs incurred by the governmental unit.

2. Beginning on July 12, 2019, the owner of a governmental pole other than a utility pole for designated services may adjust a rate allowed under subd. 1. by 10 percent every 5 years, rounded to the nearest multiple of $5. During each 5-year period, the adjustment may be applied incrementally or as a single adjustment.

3. If the federal communications commission adjusts its levels for rates that are presumptively lawful under 47 USC 253 or 332(c)(7), the state or a political subdivision may adjust any impacted rate under subd. 1. on a pro rata basis, consistent with the federal communications commission's action.

(e)1. Except as provided in subd. 2., by the later of October 1, 2019, or 3 months after receiving its first request to collocate a small wireless facility on a governmental pole, other than a utility pole for designated services, the state or a political subdivision shall implement rates, fees, and terms for the collocation of small wireless facilities on governmental poles that comply with this subsection.

2. Agreements between a wireless provider and the state or a political subdivision that are in effect on July 12, 2019, and that relate to the collocation of small wireless facilities in the right-of-way, including the collocation of small wireless facilities on governmental poles, remain in effect, subject to applicable termination provisions, except that by August 1, 2021, the state or political subdivision shall amend any such agreement to comply with the rates, fees, and terms required under this subsection.

(f) With regard to a governmental pole that supports aerial cables used for video, communications, or electric service, and with regard to utility poles for designated services, the parties shall comply with the process for make-ready work under 47 USC 224 and its implementing regulations, including 47 CFR 1.1420 and 1.1422. The good faith estimate of the person owning or controlling such poles for any make-ready work necessary to enable the pole to support the requested collocation must include pole replacement if necessary.

(g) With regard to a governmental pole that does not support aerial cables used for video, communications, or electric service, the state or political subdivision shall provide a good faith estimate for any make-ready work necessary to enable the pole to support the requested collocation, including pole replacement if necessary, not later than 60 days beginning after receipt of a complete application, except that the governmental unit may provide the applicant with access to the governmental pole that is necessary for the applicant to make that estimate. Make-ready work, including any pole replacement, must be completed within 60 days after the applicant's written acceptance of a good faith estimate provided by the governmental unit or within 60 days after the applicant makes the estimate.

(h) A person owning or controlling a governmental pole other than a utility pole for designated services may not require more make-ready work than required to meet applicable codes or industry standards. Fees for make-ready work may not include any costs that are related to preexisting conditions, prior damage, or noncompliance with currently applicable standards. Fees for make-ready work, including any pole replacement, may not exceed actual costs or the amount charged to other communications service providers for similar work, and may not include any consultant fees or expenses.

(5) Dispute resolution. Except as provided in sub. (4)(c), and notwithstanding ss. 182.017(8)(a) and 196.58(4)(a), a court of competent jurisdiction shall determine all disputes arising under this section. Unless otherwise agreed to by the parties to a dispute, and pending resolution of a right-of-way access rate dispute, a political subdivision controlling access to and use of a right-of-way shall allow the placement of a small wireless facility or utility pole at a temporary rate of one-half of the political subdivision's proposed annual rate, or $20, whichever is less. Rates shall be reconciled and adjusted upon final resolution of the dispute. Pending the resolution of a dispute concerning rates for collocation of small wireless facilities on governmental poles or utility poles for designated services, the person owning or controlling the pole shall allow the collocating person to collocate on its poles, at annual rates of no more than $20 per year per pole, with rates to be reconciled and adjusted upon final resolution of the dispute.

(6) Indemnification. A wireless provider shall indemnify and hold harmless a political subdivision against any and all liability and loss from personal injury or property damage resulting from or arising out of, in whole or in part, the use or occupancy of rights-of-way by the wireless provider or its employees, agents, or contractors arising out of the rights and privileges granted under this section. A wireless provider has no obligation to indemnify or hold harmless against any liabilities and losses as may be due to or caused by the sole negligence of the political subdivision or its employees or agents.

(7) Federal law; contracts. Nothing in this section adds to, replaces, or supersedes federal laws regarding utility poles owned by investor-owned electric utilities nor shall this section impose or otherwise affect any rights, controls, or contractual obligations investor-owned electric utilities may establish with respect to their utility poles.

(8) Private property owners. Nothing in this section is intended to authorize a person to place, maintain, modify, operate, or replace a privately owned utility pole or wireless support structure or to collocate small wireless facilities on a privately owned utility pole, a privately owned wireless support structure, or other private property without the consent of the property owner.

(9) Communications services. (a) This section may not be construed or interpreted to authorize any entity to provide communications service without compliance with all applicable laws or to authorize the collocation, installation, placement, operation, or maintenance of any communications facilities, including wireline backhaul facilities, other than small wireless facilities and associated utility poles.

(b) Except as it relates to small wireless facilities subject to the permit and fee requirements established under this section and except as otherwise authorized by federal or state law, a political subdivision may not do any of the following:

1. Adopt or enforce any regulation or requirement on the placement or operation of communications facilities in rights-of-way by a communications service provider authorized under federal, state, or local law to operate in rights-of-way.

2. Regulate any communications service.

3. Impose or collect any tax, fee, or other charge for the provision of additional communications services over a communications service provider's communications facilities in a right-of-way.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0414, WI ST 66.0414
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0415

66.0415. Offensive industry

Currentness

(1) Except as provided under s. 62.23 (7a)(am), the common council of a city or village board may direct the location, management and construction of, and license, regulate or prohibit, any industry, thing or place where any nauseous, offensive or unwholesome business is carried on, that is within the city or village or within 4 miles of the boundaries of the city or village, except that the Milwaukee, Menominee and Kinnickinnic rivers with their branches to the outer limits of the county of Milwaukee, and all canals connecting with these rivers, together with the lands adjacent to these rivers and canals or within 100 yards of them, are within the jurisdiction of the city of Milwaukee. A town board has the same powers as are provided in this section for cities and villages as to the area within the town that is not licensed, regulated or prohibited by a city or village under this section. A business that is conducted in violation of a city, village or town ordinance that is authorized under this section is a public nuisance. An action for the abatement or removal of the business or an injunction to prevent operation of the business may be brought and maintained by the common council or village or town board in the name of this state on the relation of the city, village or town as provided in ss. 823.01, 823.02 and 823.07, or as provided in s. 254.58. Section 97.42 does not limit the powers granted by this section. Section 95.72 does not limit the powers granted by this section to cities or villages but powers granted to towns by this section are limited by s. 95.72 and by any orders and rules promulgated under s. 95.72.

(2) To prevent nuisance, a city or village may, subject to the approval of the appropriate town board, by ordinance enact reasonable regulations governing areas where refuse, rubbish, ashes or garbage are dumped or accumulated in a town within one mile of the corporate limits of the city or village.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (12)

W. S. A. 66.0415, WI ST 66.0415
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W.S.A. 66.0416

66.0416. Certain businesses operated by minors

Currentness

(1) In this section:

(a) "Political subdivision" means a city, village, town, or county.

(b) "Stand operated by a minor" means a stand or other location at which goods other than potentially hazardous food, as defined in s. 97.30(1)(bm), are sold in occasional sales, as defined in s. 77.51(9), directly to consumers; that operates on a temporary, occasional basis; and that is operated solely by a person or persons under the age of 18 on private property with the permission of the property owner.

(2) No political subdivision may do any of the following:

(a) Enact an ordinance or adopt a resolution that prohibits a stand operated by a minor.

(b) Require a license or permit for, or impose a fee, charge, or surcharge on, any stand operated by a minor.

(c) Require a license or permit for a business that is operated by a person under the age of 18 and that is operated only occasionally. This paragraph does not apply to a business at which potentially hazardous food, as defined in s. 97.30(1)(bm), is sold.

(3) If a political subdivision has enacted an ordinance or adopted a resolution before November 27, 2019, that is inconsistent with sub. (2)(a), the ordinance or resolution does not apply and may not be enforced.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0416, WI ST 66.0416
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0417

66.0417. Local enforcement of certain food and health regulations

Currentness

(1) An employee or agent of a local health department designated by the department of agriculture, trade and consumer protection under s. 97.41 or 97.615(2) may enter, at reasonable hours, any premises for which the local health department issues a license under s. 97.41 or 97.615(2) to inspect the premises, secure samples or specimens, examine and copy relevant documents and records, or obtain photographic or other evidence needed to enforce ch. 97, relating to those premises. If samples of food are taken, the local health department shall pay or offer to pay the market value of those samples. The local health department or department of agriculture, trade and consumer protection shall examine the samples and specimens secured and shall conduct other inspections and examinations needed to determine whether there is a violation of ch. 97, rules adopted by the department under those statutes, ordinances adopted by the village, city or county or regulations adopted by the local board of health under s. 97.41(7) or 97.615.

(2)(a) Whenever, as a result of an examination, a village, city or county has reasonable cause to believe that any examined food constitutes, or that any construction, sanitary condition, operation or method of operation of the premises or equipment used on the premises creates an immediate danger to health, the administrator of the village, city or county agency responsible for the village's, city's or county's agent functions under s. 97.41 or 97.615(2) may issue a temporary order and cause it to be delivered to the licensee, or to the owner or custodian of the food, or to both. The order may prohibit the sale or movement of the food for any purpose, prohibit the continued operation or method of operation of specific equipment, require the premises to cease any other operation or method of operation which creates the immediate danger to health, or set forth any combination of these requirements. The administrator may order the cessation of all operations authorized by the license only if a more limited order does not remove the immediate danger to health. Except as provided in par. (c), no temporary order is effective for longer than 14 days from the time of its delivery, but a temporary order may be reissued for one additional 14-day period, if necessary to complete the analysis or examination of samples, specimens or other evidence.

(b) No food described in a temporary order issued and delivered under par. (a) may be sold or moved and no operation or method of operation prohibited by the temporary order may be resumed without the approval of the village, city or county, until the order has terminated or the time period specified in par. (a) has run out, whichever occurs first. If the village, city or county, upon completed analysis and examination, determines that the food, construction, sanitary condition, operation or method of operation of the premises or equipment does not constitute an immediate danger to health, the licensee, owner, or custodian of the food or premises shall be promptly notified in writing and the temporary order shall terminate upon his or her receipt of the written notice.

(c) If the analysis or examination shows that the food, construction, sanitary condition, operation or method of operation of the premises or equipment constitutes an immediate danger to health, the licensee, owner, or custodian shall be notified within the effective period of the temporary order issued under par. (a). Upon receipt of the notice, the temporary order remains in

effect until a final decision is issued under sub. (3), and no food described in the temporary order may be sold or moved and no operation or method of operation prohibited by the order may be resumed without the approval of the village, city or county.

(3) A notice issued under sub. (2)(c) shall be accompanied by notice of a hearing as provided in s. 68.11(1). The village, city or county shall hold a hearing no later than 15 days after the service of the notice, unless both parties agree to a later date. Notwithstanding s. 68.12, a final decision shall be issued under s. 68.12 within 10 days of the hearing. The decision may order the destruction of food, the diversion of food to uses which do not pose a danger to health, the modification of food so that it does not create a danger to health, changes to or replacement of equipment or construction, other changes in or cessations of any operation or method of operation of the equipment or premises, or any combination of these actions necessary to remove the danger to health. The decision may order the cessation of all operations authorized by the license only if a more limited order will not remove the immediate danger to health.

(4) A proceeding under this section, or the issuance of a license for the premises after notification of procedures under this section, does not constitute a waiver by the village, city or county of its authority to rely on a violation of ch. 97 or any rule adopted under those statutes as the basis for any subsequent suspension or revocation of the license or any other enforcement action arising out of the violation.

(5)(a) Except as provided in par. (b), any person who violates this section or an order issued under this section may be fined not more than $10,000 plus the retail value of any food moved, sold or disposed of in violation of this section or the order, or imprisoned not more than one year in the county jail, or both.

(b) Any person who does either of the following may be fined not more than $5,000 or imprisoned not more than one year in a county jail, or both:

1. Assaults, restrains, threatens, intimidates, impedes, interferes with or otherwise obstructs a village, city or county inspector, employee or agent in the performance of his or her duties under this section.

2. Gives false information to a village, city or county inspector, employee or agent engaged in the performance of his or her duties under this section, with the intent to mislead the inspector, employee or agent.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0417, WI ST 66.0417
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0418

66.0418. Prohibition of local regulation of certain foods, beverages

Currentness

(1) In this section "political subdivision" means a city, village, town, or county.

(2) (a) No political subdivision may enact an ordinance or adopt a resolution that prohibits or restricts the sale of food or nonalcoholic beverages based on the number of calories, portion size, or other nutritional criteria of the food or nonalcoholic beverage.

(b) If a political subdivision has enacted an ordinance or adopted a resolution before July 2, 2013, that is inconsistent with par. (a), the ordinance or resolution does not apply and may not be enforced.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0418, WI ST 66.0418
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0419

66.0419. Local regulation of auxiliary containers

Currentness

(1) In this section:

(a) "Auxiliary container" means a bag, cup, bottle, can, or other packaging that is designed to be reusable or single-use; that is made of cloth, paper, plastic, cardboard, corrugated material, aluminum, glass, postconsumer recycled material, or similar material or substrates, including coated, laminated, or multi-layer substrates; and that is designed for transporting or protecting merchandise, food, or beverages from a food service or retail facility.

(b) "Political subdivision" means a city, village, town, or county.

(2) No political subdivision may do any of the following:

(a) Enact or enforce an ordinance or adopt or enforce a resolution regulating the use, disposition, or sale of auxiliary containers.

(b) Prohibit or restrict auxiliary containers.

(c) Impose a fee, charge, or surcharge on auxiliary containers.

(3)(a) This section does not limit the authority of a political subdivision in operating a curbside recycling or commercial recycling program or an effective recycling program under s. 287.11 or in designating a recycling location.

(b) Subsection (2)(b) and (c) does not apply to the use of auxiliary containers on a property owned by the political subdivision.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0419, WI ST 66.0419

Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0420

66.0420. Video service

Currentness

(1) Legislative findings. The legislature finds all of the following:

(a) Video service brings important daily benefits to state residents by providing news, education, and entertainment.

(b) Uniform regulation of all video service providers by this state is necessary to ensure that state residents receive adequate and efficient video service and to protect and promote the public health, safety, and welfare.

(c) Fair competition in the provision of video service will result in new and more video programming choices for consumers in this state, and a number of providers have stated their desire to provide that service.

(d) Timely entry into the market is critical for new entrants seeking to compete with existing providers.

(e) This state's economy would be enhanced by additional investment in communications and video programming infrastructure by existing and new providers of video service.

(f) Minimal regulation of all providers of video service within a uniform framework will promote the investment described in par. (e).

(g) Ensuring that existing providers of video service are subject to the same regulatory requirements and procedures as new entrants will ensure fair competition among all providers.

(h) This section is an enactment of statewide concern for the purpose of providing uniform regulation of video service that promotes investment in communications and video infrastructures and the continued development of this state's video service marketplace within a framework that is fair and equitable to all providers.

(2) Definitions. In this section:

(a) “Affiliate,” when used in relation to any person, means another person who owns or controls, is owned or controlled by, or is under common ownership or control with such person.

(b) “Basic local exchange service area” means the area on file with the public service commission in which a telecommunications video service provider provides basic local exchange service, as defined in s. 196.01(1g).

(c) “Cable franchise” means a franchise granted under s. 66.0419(3)(b), 2005 stats.

(d) “Cable operator” has the meaning given in 47 USC 522(5).

(e) “Cable service” has the meaning given in 47 USC 522(6).

(f) “Cable system” has the meaning given in 47 USC 522(7).

(g) Except as provided in sub. (8)(ag), “department” means the department of financial institutions.

(h) “FCC” means the federal communications commission.

(i) “Franchise fee” has the meaning given in 47 USC 542(g), and includes any compensation required under s. 66.0425.

(j)1. “Gross receipts” means all revenues received by and paid to a video service provider by subscribers residing within a municipality for video service, or received from advertisers, including all of the following:

a. Recurring charges for video service.

b. Event-based charges for video service, including pay-per-view and video-on-demand charges.

c. Rental of set top boxes and other video service equipment.

d. Service charges related to the provision of video service, including activation, installation, repair, and maintenance charges.

e. Administrative charges related to the provision of video service, including service order and service termination charges.

f. Revenues received from the provision of home shopping or similar programming.

g. All revenue, except for refunds, rebates, and discounts, derived by the video service provider for advertising over its video service network to subscribers within a municipality. If such revenue is derived under a regional or national compensation contract or arrangement between the video service provider and one or more advertisers or advertising representatives, the amount of revenue derived for a municipality shall be determined by multiplying the total revenue derived under the contract

or arrangement by the percentage resulting from dividing the number of subscribers in the municipality by the total number of regional or national subscribers that potentially receive the advertising under the contract or arrangement.

2. Notwithstanding subd. 1., "gross receipts" does not include any of the following:

a. Discounts, refunds, and other price adjustments that reduce the amount of compensation received by a video service provider.

b. Uncollectible fees, except that any uncollectible fees that are written off as bad debt but subsequently collected shall be included as gross receipts in the period collected, less the expenses of collection.

c. Late payment charges.

e. Amounts billed to video service subscribers to recover taxes, fees, surcharges or assessments of general applicability or otherwise collected by a video service provider from video service subscribers for pass through to any federal, state, or local government agency, including video service provider fees and regulatory fees paid to the FCC under 47 USC 159.

f. Revenue from the sale of capital assets or surplus equipment not used by the purchaser to receive video service from the seller of those assets or surplus equipment.

g. Charges, other than those described in subd. 1., that are aggregated or bundled with amounts described in subd. 1., including but not limited to any revenues received by a video service provider or its affiliates for telecommunications services, information services, or the provision of directory or Internet advertising, including yellow pages, white pages, banner advertisement, and electronic publishing, if a video service provider can reasonably identify such charges on books and records kept in the regular course of business or by other reasonable means.

h. Reimbursement by programmers of marketing costs actually incurred by a video service provider.

(k) "Household" means a house, apartment, mobile home, group of rooms, or single room that is intended for occupancy as separate living quarters. For purposes of this paragraph, "separate living quarters" are those in which the occupants live and eat separately from any other persons in the building and which have direct access from the outside of the building or through a common hall.

(L) "Incumbent cable operator" means a person who, immediately before January 9, 2008, was providing cable service under a cable franchise, expired cable franchise, or cable franchise extension, or under an ordinance or resolution adopted or enacted by a municipality.

(m) "Institutional network" means a network that connects governmental, educational, and community institutions.

(n) "Interim cable operator" means an incumbent cable operator that elects to continue to provide cable service under a cable franchise as specified in sub. (3)(b)2. a.

(p) “Large telecommunications video service provider” means a telecommunications video service provider that, on January 1, 2007, had more than 500,000 basic local exchange access lines in this state or an affiliate of such a telecommunication video service provider.

(r) “Municipality” means a city, village, or town.

(s) “PEG channel” means a channel designated for public, educational, or governmental use.

(sm) “Qualified cable operator” means any of the following:

1. A cable operator that has been providing cable service in this state for at least 3 years prior to applying for a video service franchise and that has never had a cable franchise revoked by a municipality.

2. An affiliate of a cable operator specified in subd. 1.

3. A cable operator that, on the date that it applies for a video service franchise, individually or together with its affiliates or parent company, is one of the 10 largest cable operators in the United States as determined by data collected and reported by the FCC or determined by information available to the public through a national trade association representing cable operators.

(t) “Service tier” means a category of video service for which a separate rate is charged.

(u) “State agency” means any board, commission, department, or office in the state government.

(um) “Telecommunications utility” has the meaning given in s. 196.01(10).

(v) “Telecommunications video service provider” means a video service provider that uses facilities for providing telecommunications service, as defined in s. 196.01(9m), also to provide video service.

(w) “Video franchise area” means the area or areas described in an application for a video service franchise under sub. (3)(d)2.

(x) “Video programming” means programming provided by, or generally considered comparable to programming provided by, a television broadcast station.

(y) “Video service” means any video programming service, cable service, or service provided via an open video system that complies with 47 USC 573, that is provided through facilities located at least in part in public rights-of-way, without regard to delivery technology, including Internet protocol technology or any other technology. “Video service” does not include any of the following:

1. Video programming provided by a commercial mobile radio service provider, as defined in s. 196.01(2g).

2. Video programming provided solely as part of and via a service that enables users to access content, information, electronic mail, or any other service offered over the public Internet.

(z) "Video service franchise" means a franchise issued under sub. (3)(f)2.

(zb) "Video service network" means wireline facilities, or any component thereof, located at least in part in the public right-of-way that deliver video service, without regard to delivery technology, including Internet protocol technology or any other technology. "Video service network" includes a cable system.

(zg) "Video service provider" means a person, including an incumbent cable operator, who is issued a video service franchise or a successor or assign of such a person.

(zm) "Video service provider fee" means the fee paid by a video service provider under sub. (7).

(3) Authority to provide video service. (a) *In general.* Except for an interim cable operator, and except as provided in par. (c) and sub. (11), no person may provide video service in this state unless the department has issued a video service franchise to the person and the person has provided the notice required under par. (h).

(b) *Incumbent cable operators.* 1. A municipality may not renew or extend the cable franchise of an incumbent cable operator that expires after January 9, 2008.

2. An incumbent cable operator may do one of the following:

a. Continue to provide cable service as an interim cable operator until the cable franchise expires.

b. Apply for a video service franchise. If an incumbent cable operator applies for a video service franchise, the cable franchise shall terminate and have no effect upon issuance of the video service franchise. Upon termination of the cable franchise, the municipality that granted the franchise shall, at the request of the incumbent cable operator, surrender, return, or take such other action as may be necessary to nullify any bond, letter of credit, or similar instrument intended to secure the performance of the incumbent cable operator under the cable franchise.

3. An incumbent cable operator whose cable franchise expires after January 9, 2008, may not, after expiration of the cable franchise, provide video service in this state unless the incumbent cable operator applies for a video service franchise under subd. 2. b. and, upon issuance of the video service franchise, provides the notice required under par. (h). An incumbent cable operator whose cable franchise expired before January 9, 2008, and who was providing cable service immediately before January 9, 2008, may continue to provide cable service if, no later than March 1, 2008, the incumbent cable operator applies for a video service franchise under subd. 2.b.

(c) *Other providers.* A person, other than an incumbent cable operator, who was providing video service immediately before January 9, 2008, may provide video service without a video service franchise issued by the department. This paragraph ceases to apply to such a person if the person does not apply for a video service franchise no later than March 1, 2008.

(d) *Application.* An applicant for a video service franchise shall submit an application to the department that consists of all of the following:

1. The location and telephone number of the applicant's principal place of business, the names of the principal executive officers of the applicant, and the names of any persons authorized to represent the applicant before the department.

2. A description of the area or areas of the state in which the applicant intends to provide video service.

3. The date on which the applicant intends to begin providing video service in the video franchise area.

4. An affidavit signed by an officer or general partner of the applicant that affirms all of the following:

a. That the applicant has filed or will timely file with the FCC all forms required by the FCC in advance of offering video service.

b. That the applicant agrees to comply with this section and all applicable federal statutes and regulations.

c. That the applicant is legally, financially, and technically qualified to provide video service.

5. A description of the services that the applicant proposes to provide.

(e) *Service upon municipalities.* 1. At the time that an applicant submits an application under par. (d), or a video service provider submits a notification regarding a modification to an application under par. (j), to the department, the applicant or video service provider shall serve a copy of the application or notification on each municipality in the video franchise area.

2. a. This subdivision applies only to a municipality that, under subd. 1., is served a copy of an application or that, under subd. 1., is served a copy of a notification relating to an expansion of the area or areas of the state in which a video service provider intends to provide video service, if the municipality has not previously been served a copy of an application under subd. 1. by that video service provider.

b. If a municipality specified in subd. 2.a. has granted any cable franchise that is in effect immediately before January 9, 2008, the municipality shall, no later than 10 business days after receipt of the copy, notify the applicant in writing of the number of PEG channels for which incumbent cable operators are required to provide channel capacity in the municipality, the amount and type of monetary support for access facilities for PEG channels required of incumbent cable operators as described in sub. (7)(em), and the percentage of revenues that incumbent cable operators are required to pay the municipality as franchise fees.

(f) *Department duties.* 1. After the filing of an application, the department shall notify the applicant in writing as to whether the application is complete and, if the department has determined that the application is not complete, the department shall state the reasons for the determination.

2. After the filing of an application that the department has determined is complete, the department shall determine whether an applicant is legally, financially, and technically qualified to provide video service. If the department determines that an applicant is legally, financially, and technically qualified to provide video service, the department shall issue a video service franchise to the applicant. If the department determines that an applicant is not legally, financially, and technically qualified to provide video service, the department shall reject the application and shall state the reasons for the determination.

4. The department shall promulgate rules for determining whether an applicant is legally, financially, and technically qualified to provide video service.

(g) *Effect of video service franchise.* A video service franchise issued by the department authorizes a video service provider to occupy the public rights-of-way and to construct, operate, maintain, and repair a video service network to provide video service in the video franchise area.

(h) *Notice before providing service*. No later than 10 business days before providing video service in a municipality in a video franchise area, a video service provider shall provide notice to the department and the municipality.

(i) *Expiration and revocation of video service franchise.* The department may revoke a video service franchise issued to a video service provider if the department determines that the video service provider has failed to substantially meet a material requirement imposed upon it by the department. Before commencing a revocation proceeding, the department shall provide the video service provider written notice of the department's intention to revoke the franchise and the department's reasons for the revocation and afford the video service provider a reasonable opportunity to cure any alleged violation. The department must, before revoking any video service franchise, afford a video service provider full due process that, at a minimum, must include a proceeding before a hearing officer during which the video service provider must be afforded the opportunity for full participation, including the right to be represented by counsel, to introduce evidence, to require the production of evidence, and to question or cross-examine witnesses under oath. A transcript shall be made of any such hearing. A video service provider may bring an action to appeal the decision of the department.

(j) *Modifications.* If there is any change in the information included in an application filed by a video service provider under this subsection, the video service provider shall notify the department and update the information within 10 business days after the change, except that if the video service provider determines to expand the area or areas of the state in which the video service provider intends to provide video service, the video service provider shall apply to the department for a modified video service franchise under par. (d). A video service provider that makes a notification regarding a change in the information specified in par. (d)3., 4., or 5., shall include with the notification a fee of $100. No fee is required for a notification regarding a change in the information specified in par. (d)1.

(k) *Annual fee.* 1. A video service provider shall pay an annual fee.

2. If a video service provider has 10,000 or less subscribers, the first annual fee required under subd. 1. shall be $2,000 and each subsequent annual fee shall be $100.

(4) Franchising authority. For purposes of 47 USC 521 to 573, the state is the exclusive franchising authority for video service providers in this state. No municipality may require a video service provider to obtain a franchise to provide video service.

(5) PEG channels. (a) *Maximum number of PEG channels.* 1. If an incumbent cable operator is providing channel capacity for PEG channels to a municipality under a cable franchise in effect immediately before January 9, 2008, the municipality shall require each interim cable operator or video service provider that provides video service in the municipality to provide channel capacity for the same number of PEG channels for which channel capacity is provided immediately before January 9, 2008.

2. a. Except as provided in subd. 2. b. and c., if no incumbent cable operator is providing channel capacity for PEG channels to a municipality under a cable franchise that is in effect immediately before January 9, 2008, then, if the municipality has a population of 50,000 or more, the municipality may require each interim cable operator and video service provider that provides video service in the municipality to provide channel capacity for up to 3 PEG channels, and, if the municipality has a population of less than 50,000, the municipality may require each interim cable operator and video service provider that provides video service in the municipality to provide channel capacity for no more than 2 PEG channels.

b. If an interim cable operator or video service provider distributes video programming to more than one municipality through a single headend or video hub office and the aggregate population of the municipalities is 50,000 or more, the municipalities may not require the interim cable operator or video service provider to provide, in the aggregate, channel capacity for more than 3 PEG channels under subd. 2.a.

c. If an interim cable operator or video service provider distributes video programming to more than one municipality through a single headend or video hub office and the aggregate population of the municipalities is less than 50,000, the municipalities may not require the interim cable operator or video service provider to provide, in the aggregate, channel capacity for more than 2 PEG channels under subd. 2.a.

3. An interim cable operator or video service provider shall provide any channel capacity for PEG channels required under this paragraph on any service tier that is viewed by more than 50 percent of the interim cable operator's or video service provider's customers.

4. If a municipality is not required to provide notice to a video service provider under sub. (3)(e)2., the video service provider's duty to provide any additional channel capacity for PEG channels that is required by the municipality under this paragraph first applies on the date that the video service provider begins to provide service in the municipality, and, if the municipality is required to provide notice under sub. (3)(e)2., the video service provider's duty to provide any such additional channel capacity first applies on the date that the video service provider begins to provide video service in the municipality or on the 90th day after the video service provider receives the municipality's notice, whichever is later.

(b) *Exceptions.* 1. a. Notwithstanding par. (a), an interim cable operator or video service provider may reprogram for any other purpose any channel capacity provided for a PEG channel required by a municipality under par. (a) if the PEG channel is not substantially utilized by the municipality. If the municipality certifies to the interim cable operator or video service provider that reprogrammed channel capacity for a PEG channel will be substantially utilized by the municipality, the interim cable operator or video service provider shall, no later than 120 days after receipt of the certification, restore the channel capacity for the PEG

channel. Notwithstanding par. (a)3., an interim cable operator or video service provider may provide restored channel capacity for a PEG channel on any service tier.

b. For purposes of this subdivision, a PEG channel is substantially utilized by a municipality if the municipality provides 40 hours or more of programming on the PEG channel each week and at least 60 percent of that programming is locally produced.

2. Notwithstanding par. (a), if a municipality fails to provide the notice specified in sub. (3)(e)2. before the deadline specified in sub. (3)(e)2., no interim cable operator or video service provider is required to provide channel capacity for any PEG channel, or monetary support for access facilities for PEG channels pursuant to sub. (7)(em), until the 90th day after the municipality provides such notice.

(c) *Powers and duties of municipalities.* 1. Except as otherwise required under pars. (a) and (d) and sub. (7)(em), a municipality may not require an interim cable operator or video service provider to provide any funds, services, programming, facilities, or equipment related to public, educational, or governmental use of channel capacity.

2. The operation of any PEG channel for which a municipality requires an interim cable operator or video service provider to provide channel capacity under par. (a), and the production of any programming appearing on such a PEG channel, shall be the sole responsibility of the municipality and, except as provided in par. (d)1., the interim cable operator or video service provider shall bear only the responsibility to transmit programming appearing on the PEG channel.

3. A municipality that requires an interim cable operator or video service provider to provide channel capacity for a PEG channel under par. (a) shall do all of the following:

a. Ensure that all content and programming that the municipality provides or arranges to provide for transmission on the PEG channel is submitted to the interim cable operator or video service provider in a manner and form that is capable of being accepted and transmitted by the interim cable operator or video service provider over its video service network without changing the content or transmission signal and that is compatible with the technology or protocol, including Internet protocol television, utilized by the interim cable operator or video service provider to deliver video service.

b. Make the content and programming that the municipality provides or arranges to provide for transmission on a PEG channel available in a nondiscriminatory manner to all interim cable operators and video service providers that provide video service in the municipality.

(d) *Duties of interim cable providers and video service providers.* 1. If a municipality requires an interim cable operator or video service provider to provide capacity for PEG channels under par. (a), the interim cable operator or video service provider shall be required to provide transmission capacity sufficient to connect the interim cable operator's or video service provider's headend or video hub office to the municipality's PEG access channel origination points existing as of January 9, 2008. A municipality shall permit the interim cable operator or video service provider to determine the most economically and technologically efficient means of providing such transmission capacity. If a municipality requests that such a PEG access channel origination point be relocated, the interim cable operator or video service provider shall be required to provide only the first 200 feet of transmission line that is necessary to connect the interim cable operator or video service provider's headend or video hub office to such origination point. A municipality shall be liable for the costs of construction of such a transmission line beyond the first 200 feet and for any construction costs associated with additional origination points, but not for the costs associated with the transmission

of PEG programming over such line. The interim cable operator or video service provider may recover its costs to provide transmission capacity under this subdivision by identifying and collecting a "PEG Transport Fee" as a separate line item on customer bills.

2. If the interconnection of the video service networks of interim cable operators or video service providers is technically necessary and feasible for the transmission of programming for any PEG channel for which channel capacity is required by a municipality under par. (a), the interim cable operators and video service providers shall negotiate in good faith for interconnection on mutually acceptable rates, terms, and conditions, except that an interim cable operator or video service provider who requests interconnection is responsible for interconnection costs, including the cost of transmitting programming from its origination point to the interconnection point. Interconnection may be accomplished by direct cable, microwave link, satellite, or any other reasonable method.

(5m) Contracts with University of Wisconsin campuses. If an incumbent cable operator has entered into an agreement with an institution or college campus within the University of Wisconsin System that is in effect on January 9, 2008, and that requires the incumbent cable operator to broadcast University of Wisconsin events on one of its channels, any video service provider that provides video service in the area in which the events are broadcast by the incumbent cable operator shall, upon the request of the institution or college campus, enter into an agreement with the institution or college campus that requires the video service provider to provide the same service on the same terms and conditions as the agreement between the institution or college campus and the incumbent cable operator.

(6) Institutional networks. Notwithstanding any franchise, ordinance, or resolution in effect on January 9, 2008, no state agency or municipality may require an interim cable operator or video service provider to provide any institutional network or equivalent capacity on its video service network.

(7) Video service provider fee. (a) *Duty to pay fee.* 1. Notwithstanding s. 66.0611 and except as provided in subds. 2. and 2m., a video service provider shall, on a quarterly calendar basis, calculate and pay to each municipality in which the video service provider provides video service a video service provider fee equal to the percentage of the video service provider's gross receipts that is specified in par. (b) and the monetary support for access facilities for PEG channels described in par. (em). A video service provider shall remit the fee to the municipality no later than 45 days after the end of each quarter. Except as provided in subd. 2. or par. (b)1., if the municipality is not required to provide notice under sub. (3)(e)2., the duty to remit the fee first applies to the quarter in which the video service provider begins to provide service in the municipality, and, if the municipality is required to provide notice under sub. (3)(e)2., the duty to remit the fee first applies to the quarter in which the video service provider begins to provide service in the municipality or to the quarter that includes the 45th day after the video service provider receives the municipality's notice, whichever quarter is later.

2. If a municipality fails to provide the notice specified in sub. (3)(e)2. before the deadline specified in sub. (3)(e)2., no video service provider is required to pay a video service provider fee, and no interim cable operator is required to pay a franchise fee, to the municipality until the 45th day after the end of the quarter in which the municipality provides the notice specified in sub. (3)(e)2.

2m. If a municipality requires a video service provider to pay a cost-based permit fee under a regulation under s. 182.017(1r), the video service provider may deduct the amount of the fee from any other compensation that is due to the municipality including the video service provider fee under subd. 1.

(b) *Amount of fee.* 1. Except as provided in subd. 2m., the percentage applied to a video service provider's gross receipts under par. (a)1. for each municipality shall be 5 percent or one of the following percentages, whichever is less:

a. If no incumbent cable operator was required to pay a franchise fee equal to a percentage of gross revenues to the municipality immediately before January 9, 2008, the municipality may specify a percentage of no more than 5 percent. The duty of a video service provider to pay the municipality a video service fee equal to such percentage shall first apply to the quarter that includes the 45th day after the municipality provides notice of the percentage to the video service provider.

b. If an incumbent cable operator was required to pay a franchise fee equal to a percentage of gross revenues to the municipality immediately before January 9, 2008, that percentage.

c. If more than one incumbent cable operator was required to pay a franchise fee equal to a percentage of gross revenues to the municipality immediately before January 9, 2008, the lowest such percentage.

2m. The percentage applied to a video service provider's gross receipts under par. (a)1. for a municipality shall be the percentage that applied under subd. 1. on December 31, 2018, less one of the following:

a. Beginning on January 1, 2020, 0.5 percent.

b. Beginning on January 1, 2021, 1.0 percent.

(c) *Generally accepted accounting principles.* All determinations and computations made under this subsection shall be made pursuant to generally accepted accounting principles.

(d) *Record review.* A municipality may, upon reasonable written request, for the purpose of ensuring proper and accurate payment of a video service provider fee, review the business records of a video service provider that is required to pay the municipality a video service provider fee.

(e) *Actions to enforce payment.* 1. A municipality or a video service provider may not bring an action concerning the amount of a video service provider fee allegedly due to the municipality unless the parties have first participated in and completed good faith settlement discussions. For purposes of any future litigation, all negotiations pursuant to this paragraph shall be treated as compromise negotiations under s. 904.08.

2. An action regarding a dispute over the amount of a video service provider fee paid or allegedly due under this subsection shall be commenced within 4 years following the end of the calendar quarter to which the disputed amount relates or be barred, unless the parties agree in writing to an extension of time. Notwithstanding ss. 814.01, 814.02, 814.03, and 814.035, no costs may be allowed in the action to either party.

(em) *PEG channel monetary support.* 1. This subdivision applies to an incumbent cable operator whose cable franchise is terminated under sub. (3)(b)2.b. The obligation that is actually imposed by a municipality prior to April 18, 2007, on such an

incumbent cable operator to provide monetary support for access facilities for PEG channels and that is contained in a cable franchise existing on January 9, 2008, shall continue until January 1, 2011.

2. The duty of an interim cable operator to provide monetary support for access facilities for PEG channels that is contained in a cable franchise existing on January 9, 2008, shall continue until January 1, 2011.

3. Each video service provider providing video service in a municipality shall have the same obligation to provide monetary support for access facilities for PEG channels as the incumbent cable operator with the most subscribers in the municipality as of January 9, 2008. To the extent that such incumbent cable operator provides such support in the form of a percentage of gross revenues or a per subscriber fee, any other video service provider shall pay the same percentage of gross revenues or per subscriber fee to the municipality as the incumbent cable operator. To the extent that such incumbent cable operator provides such support in the form of a lump sum payment without an offset to its franchise fee or video service provider fee, any other video service provider that commences service in the municipality shall pay the municipality a sum equal to the pro rata amount of such lump sum payment based on its proportion of video service customers in such municipality. The obligation to provide monetary support required under this subdivision shall continue until January 1, 2011.

4. For purposes of this paragraph, the proportion of video service customers of a video service provider shall be determined based on the relative number of subscribers as of the end of the prior calendar year as reported by all incumbent cable operators and holders of video service authorizations.

(f) *Itemization.* A video service provider may identify and collect the amount related to a video service provider fee and any fee imposed for monetary support for access facilities for PEG channels as described in par. (em) as a separate line item on customer bills.

(g) *Other fees.* A municipality may require the video service provider to pay any compensation under s. 66.0425, or, except as provided in a regulation under s. 182.017(1r), any permit fee, encroachment fee, degradation fee, or any other fee, for the occupation of or work within public rights-of-way.

(8) Discrimination; access to services. (ag) *Definition.* In this subsection, "department" means the department of agriculture, trade and consumer protection.

(am) *Discrimination prohibited.* 1. No video service provider may deny access to video service to any group of potential residential customers in the video service provider's video franchise area because of the race or income of the residents in the local area in which the group resides.

2. It is a defense to an alleged violation of subd. 1. based on income if, no later than 3 years after the date on which the video service provider began providing video service under this section, at least 30 percent of the households with access to the video service provider's video service are low-income households.

(b) *Access.* 1. A large telecommunications video service provider shall provide access to its video service to the following percentages of households within the large telecommunications video service provider's basic local exchange service area:

a. Not less than 35 percent no later than 3 years after the date on which the large telecommunications video service provider began providing video service under this section.

b. Not less than 50 percent no later than 5 years after the date on which the large telecommunications video service provider began providing video service under this section, or no later than 2 years after at least 30 percent of households with access to the large telecommunications video service provider's video service subscribe to the service for 6 consecutive months, whichever occurs later.

2. A large telecommunications video service provider shall file an annual report with the department regarding the large telecommunications video service provider's progress in complying with subd. 1.

(c) *Extensions and waivers.* A video service provider may apply to the department for an extension of any time limit specified in par. (am)2. or (b) or a waiver of a requirement to comply with par. (b). The department shall grant the extension or waiver if the video service provider demonstrates to the satisfaction of the department that the video service provider has made substantial and continuous efforts to comply with the requirements of this subsection and that the extension or waiver is necessary due to one or more of the following factors:

1. The video service provider's inability to obtain access to public and private rights-of-way under reasonable terms and conditions.

2. Developments and buildings that are not subject to competition because of exclusive service arrangements.

3. Developments and buildings that are not accessible using reasonable technical solutions under commercially reasonable terms and conditions.

4. Natural disasters.

5. Other factors beyond the control of the video service provider.

(d) *Alternative technologies.* A video service provider may satisfy the requirements of this subsection through the use of an alternative technology, other than satellite service, that does all of the following:

1. Offers service, functionality, and content demonstrably similar to the service, functionality, and content provided through the video service provider's video service network.

2. Provides access to PEG channels and messages broadcast over the emergency alert system.

(e) *Limitations.* Notwithstanding any other provision of this section, a telecommunications video service provider is not required to provide video service outside the provider's basic local exchange service area, and a video service provider that is an

incumbent cable operator is not required to provide video service outside the area in which the incumbent cable operator provided cable service at the time the department of financial institutions issued a video service franchise to the incumbent cable operator.

(9) Customer service standards. (a) Except as provided in par. (b), upon 90 days' advance notice, a municipality may require a video service provider to comply with the customer service standards specified in 47 CFR 76.309(c) in its provision of video service. Neither the department nor any municipality shall have the authority to impose additional or different customer service standards that are specific to the provision of video service.

(b) Except as provided in s. 100.209, no video service provider that provides video service in a municipality may be subject to any customer service standards if there is at least one other person offering cable or video service in the municipality or if the video service provider is subject to effective competition, as determined under 47 CFR 76.905, in the municipality. This paragraph does not apply to any customer service standards promulgated by rule by the department of agriculture, trade and consumer protection.

(9m) Local broadcast stations. (a) In this subsection, a "noncable video service provider" means a video service provider that is not a cable operator.

(b) If a local broadcast station is authorized to exercise against a cable operator the right to require mandatory carriage under 47 USC 534, or the right to grant or withhold retransmission consent under 47 USC 325(b), the local broadcast station may exercise the same right against a noncable video service provider to the same extent as the local broadcast station may exercise such right against a cable operator under federal law.

(c) A noncable video service provider shall transmit, without degradation, the signals that a local broadcast station delivers to the noncable video service provider, but is not required to utilize the same or similar reception technology as the local broadcast station or the programming providers of the local broadcast station.

(d) A noncable video service provider may not do any of the following:

1. Discriminate among or between local broadcast stations, or programming providers of local broadcast stations, with respect to the transmission of their signals.

2. Delete, change, or alter a copyright identification transmitted as part of a local broadcast station's signal.

(10) Limitation on rate regulation. The department or a municipality may not regulate the rates charged for any video service by an interim cable operator or video service provider that provides video service in a municipality if at least one other interim cable operator or video service provider is providing video service in the municipality and the other interim cable operator or video service provider is not an affiliate of the interim cable operator or video service provider. This subsection applies regardless of whether any affected interim cable operator or video service provider has sought a determination from the FCC regarding effective competition under 47 CFR 76.905.

(11) Transfer of video service franchise. A person who is issued a video service franchise may transfer the video service franchise to any successor-in-interest, including a successor-in-interest that arises through merger, sale, assignment,

restructuring, change of control, or any other transaction. No later than 15 days after the transfer is complete, the successor-in-interest shall apply for a video service franchise under sub. (3)(d) and comply with sub. (3)(e)1. The successor-in-interest may provide video service in the video franchise area during the period that the department reviews the application.

(12) Municipal cable system costs. (a) Except for costs for any of the following, a municipality that owns and operates a cable system, or an entity owned or operated, in whole or in part, by such a municipality, may not require nonsubscribers of the cable system to pay any of the costs of the cable system:

1. PEG channels.

2. Debt service on bonds issued under s. 66.0619 to finance the construction, renovation, or expansion of a cable system.

3. The provision of broadband service by the cable system, if the requirements of s. 66.0422(3d)(a), (b), or (c) are satisfied.

(am) Paragraph (a) does not apply to a municipality that, on March 1, 2004, was providing cable service to the public.

(b) Paragraph (a) does not apply to a municipality if all of the following conditions apply:

1. On November 1, 2003, the public service commission has determined that the municipality is an alternative telecommunications utility under s. 196.203.

2. A majority of the governing board of the municipality votes to submit the question of supporting the operation of a cable system by the municipality to the electors in an advisory referendum and a majority of the voters in the municipality voting at the advisory referendum vote to support the operation of a cable system by the municipality.

(13) Rule-making; enforcement. (a) The department of financial institutions may promulgate rules interpreting or establishing procedures for this section and the department of agriculture, trade and consumer protection may promulgate rules interpreting or establishing procedures for sub. (8).

(b) Except as provided in sub. (7)(e), a municipality, interim cable operator, or video service provider that is affected by a failure to comply with this section may bring an action to enforce this section. If a court finds that a municipality, interim cable operator, or video service provider has not complied with this section, the court shall order the municipality, interim cable operator, or video service provider to comply with this section. Notwithstanding ss. 814.01, 814.02, 814.03, and 814.035, no costs may be allowed in an action under this paragraph to any party.

(c) The department shall enforce this section, except sub. (8). The department may bring an action to recover any fees that are due and owing under this section or to enjoin a violation of this section, except sub. (8), or any rule promulgated under sub. (3)(f)4. An action shall be commenced under this paragraph within 3 years after the occurrence of the unlawful act or practice or be barred.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (1)

W. S. A. 66.0420, WI ST 66.0420
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.042

66.042. Renumbered 66.0607 and amended by 1999 Act 150, § 109, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.042, WI ST 66.042
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W.S.A. 66.0421

66.0421. Access to video service

Currentness

(1) Definitions. In this section:

(c) "Video service" has the meaning given in s. 66.0420(2)(y).

(d) "Video service provider" has the meaning given in s. 66.0420(2)(zg), and also includes an interim cable operator, as defined in s. 66.0420(2)(n).

(2) Interference prohibited. The owner or manager of a multiunit dwelling under common ownership, control or management or of a mobile home park or the association or board of directors of a condominium may not prevent a video service provider from providing video service to a subscriber who is a resident of the multiunit dwelling, mobile home park or of the condominium or interfere with a video service provider providing video service to a subscriber who is a resident of the multiunit dwelling, mobile home park or of the condominium.

(3) Installation in multiunit building. Before installation, a video service provider shall consult with the owner or manager of a multiunit dwelling or with the association or board of directors of a condominium to establish the points of attachment to the building and the methods of wiring. A video service provider shall install facilities to provide video service in a safe and orderly manner and in a manner designed to minimize adverse effects to the aesthetics of the multiunit dwelling or condominium. Facilities installed to provide video service may not impair public safety, damage fire protection systems or impair fire-resistive construction or components of a multiunit dwelling or condominium.

(4) Repair responsibility. A video service provider is responsible for any repairs to a building required because of the construction, installation, disconnection or servicing of facilities to provide video service.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0421, WI ST 66.0421
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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W.S.A. 66.0422

66.0422. Video service, telecommunications, and broadband facilities

Currentness

(1) In this section:

(b) “Local government” means a city, village, or town.

(c) “Telecommunications service” has the meaning given in s. 196.01(9m).

(d) “Video service” has the meaning given in s. 66.0420(2)(y).

(2) Except as provided in subs. (3), (3d), (3m), and (3n), no local government may enact an ordinance or adopt a resolution authorizing the local government to construct, own, or operate any facility for providing video service, telecommunications service, or broadband service, directly or indirectly, to the public, unless all of the following are satisfied:

(a) The local government holds a public hearing on the proposed ordinance or resolution.

(b) Notice of the public hearing is given by publication of a class 3 notice under ch. 985 in the area affected by the proposed ordinance or resolution.

(c) No less than 30 days before the public hearing, the local government prepares and makes available for public inspection a report estimating the total costs of, and revenues derived from, constructing, owning, or operating the facility and including a cost-benefit analysis of the facility for a period of at least 3 years. The costs that are subject to this paragraph include personnel costs and costs of acquiring, installing, maintaining, repairing, or operating any plant or equipment, and include an appropriate allocated portion of costs of personnel, plant, or equipment that are used to provide jointly both telecommunications services and other services.

(3) Subsection (2) does not apply to a local government if all of the following conditions apply:

(a) On November 1, 2003, the public service commission has determined that the local government is an alternative telecommunications utility under s. 196.203.

(b) A majority of the governing board of the local government votes to submit the question of supporting the operation of the facility for providing video service, telecommunications service, or Internet access service, directly or indirectly to the public, by the local government to the electors in an advisory referendum and a majority of the voters in the local government voting at the advisory referendum vote to support operation of such a facility by the local government.

(3d) Subsection (2) does not apply to a facility for providing broadband service to an area within the boundaries of a local government if any of the following are satisfied:

(a) The local government asks, in writing, each person that provides broadband service within the boundaries of the local government whether the person currently provides broadband service to the area or intends to provide broadband service within 9 months to the area and within 60 days after receiving the written request no person responds in writing to the local government that the person currently provides broadband service to the area or intends to provide broadband service to the area within 9 months.

(b) The local government determines that a person who responded to a written request under par. (a) that the person currently provides broadband service to the area did not actually provide broadband service to the area and no other person makes the response to the local government described in par. (a).

(c) The local government determines that a person who responded to a written request under par. (a) that the person intended to provide broadband service to the area within 9 months did not actually provide broadband service to the area within 9 months and no other person makes the response to the local government described in par. (a).

(3m) Subsection (2) does not apply to a facility for providing broadband service if all of the following apply:

(a) The municipality offers use of the facility on a nondiscriminatory basis to persons who provide broadband service to end users of the service.

(b) The municipality itself does not use the facility to provide broadband service to end users.

(c) The municipality determines that, at the time that the municipality authorizes the construction, ownership, or operation of the facility, whichever occurs first, the facility does not compete with more than one provider of broadband service.

(3n) Subsection (2) does not apply to a local government that, on March 1, 2004, was providing video service to the public.

(4) Notwithstanding sub. (2), a local government may enact an ordinance or adopt a resolution authorizing the local government to prepare a report specified in sub. (2)(c).

(5) If a local government enacts an ordinance or adopts a resolution that complies with the requirements of sub. (2), the local government must determine the cost incurred in preparing the report specified in sub. (2)(c). As soon as practicable after the local government generates revenue from a facility specified in sub. (2)(intro.), the local government shall use the revenues to reimburse the treasury of the local government for the cost determined under this subsection.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0422, WI ST 66.0422
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0423

66.0423. Transient merchants

Currentness

(1) In this section:

(a) “Sale of merchandise” includes a sale in which the personal services rendered upon or in connection with the merchandise constitutes the greatest part of value for the price received, but does not include a farm auction sale conducted by or for a resident farmer of personal property used on the farm or the sale of produce or other perishable products at retail or wholesale by a resident of this state.

(b) “Transient merchant” means a person who engages in the sale of merchandise at any place in this state temporarily and who does not intend to become and does not become a permanent merchant of that place.

(2) Cities and villages, and towns not subject to an ordinance enacted under s. 59.55(4), may, by ordinance, regulate the retail sales, other than auction sales, made by transient merchants and provide penalties for violations of those ordinances.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0423, WI ST 66.0423
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0425

66.0425. Privileges in streets

Currentness

(1) In this section, “privilege” means the authority to place an obstruction or excavation beyond a lot line, or within a highway in a town, village, or city, other than by general ordinance affecting the whole public.

(2) A person may apply to a town or village board or the common council of a city for a privilege. A privilege may be granted if the applicant assumes primary liability for damages to person or property by reason of the granting of the privilege, is obligated to remove an obstruction or excavation upon 10 days' notice by the state or the municipality and waives the right to contest in any manner the validity of this section or the amount of compensation charged. The grantor of the privilege may require the applicant to file a bond that does not exceed $10,000; that runs to the town, village, or city and to 3rd parties that may be injured; and that secures the performance of the conditions specified in this subsection. If there is no established lot line and the application is accompanied by a blue print, the town or village board or the common council of the city may impose any conditions on the privilege that it considers advisable.

(3) Compensation for a privilege shall be paid into the general fund and shall be fixed by the governing body of a city, village or town or by the designee of the governing body.

(4) The holder of a privilege is not entitled to damages for removal of an obstruction or excavation, and if the holder does not remove the obstruction or excavation upon due notice, it shall be removed at the holder's expense.

(5) Third parties whose rights are interfered with by the granting of a privilege have a right of action against the holder of the privilege only.

(6) Subsections (1) to (5) do not apply to telecommunications carriers, as defined in s. 196.01(8m), telecommunications utilities, as defined in s. 196.01(10), alternative telecommunications utilities, as defined in s. 196.01(1d), public service corporations, or cooperatives organized under ch. 185 to render or furnish gas, light, heat, or power, or to cooperatives organized under ch. 185 or 193 to render or furnish telecommunications service, but the carriers, utilities, corporations and associations shall secure a permit from the proper official for temporary obstructions or excavations in a highway and are liable for all injuries to person or property caused by the obstructions or excavations.

(7) This section does not apply to an obstruction or excavation that is in place for less than 90 days, and for which a permit has been granted by the proper official. This section does not apply if a permit has been issued under s. 86.07(2) with respect to a manure hose, or written consent has been given under s. 86.16(1) with respect to a pipe or pipeline, transmitting liquid manure within or across the right-of-way of a highway.

(8) This section applies to an obstruction or excavation by a city, village or town in any street, alley, or public place belonging to any other municipality.

(9) Any person who violates this section may be fined not less than $25 nor more than $500 or imprisoned for not less than 10 days nor more than 6 months or both.

(10) A privilege may be granted only as provided in this section.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (12)

W. S. A. 66.0425, WI ST 66.0425
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W.S.A. 66.0427

66.0427. Open excavations in populous counties

Currentness

In a town, city or village in a county with a population of 750,000 or more no excavation for building purposes, whether or not completed, may be left open for more than 6 months without proceeding with the erection of a building on the excavation. If an excavation remains open for more than 6 months, the building inspector or other designated officer of the town, village or city shall order that the erection of a building on the excavation begin forthwith or that the excavation be filled to grade. The order shall be served upon the owner of the land or the owner's agent and upon the holder of any encumbrance of record as provided in s. 66.0413(1)(d). If the owner of the land fails to comply with the order within 15 days after service of the order upon the owner, the building inspector or other designated officer shall fill the excavation to grade and the cost shall be charged against the real estate as provided in s. 66.0413(1)(f). Section 66.0413(1)(h) applies to orders issued under this section. This section does not impair the authority of a city or village to enact ordinances in this field.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0427, WI ST 66.0427
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0429

66.0429. Street barriers; neighborhood watch signs

Currentness

(1) The governing body of a city, village or town may set aside streets or roads that are not a part of any federal, state or county trunk highway system for the safety of children in coasting or other play activities, and may obstruct or barricade the streets or roads to safeguard the children from accidents. The governing body of the city, village or town may erect and maintain on the streets or roads barriers or barricades, lights, or warning signs and is not liable for any damage caused by the erection or maintenance.

(2) A city or village which has a neighborhood watch program authorized by the law enforcement agency of the city or village and in which the residents of the city or village participate may, in a manner approved by the city council or village board, place within the right-of-way of a street or highway within its limits a neighborhood watch sign of a uniform design approved by the department of transportation. No sign under this subsection may be placed within the right-of-way of a highway designated as part of the national system of interstate and defense highways.

(3)(a) The governing body of a city may monitor or limit access to streets that are not part of any federal, state or county trunk highway system or connecting highway, as described in s. 84.02(11), for the purposes of security or public safety. The governing body of a city may authorize gates or security stations, or both, to be erected and maintained to monitor traffic or limit access on these streets. The restriction of access to streets that is authorized under this subsection does not affect a city's eligibility for state transportation aids.

(b) This subsection applies only to the city of Arcadia.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (3)

W. S. A. 66.0429, WI ST 66.0429
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0431

66.0431. Prohibiting operators from leaving keys in parked motor vehicles

Currentness

The governing body of a city, village or town may by ordinance require every passenger motor vehicle to be equipped with a lock suitable to lock either the starting lever, throttle, steering apparatus, gear shift lever or ignition system; prohibit any person from permitting a motor vehicle in the person's custody from standing or remaining unattended on any street, road, or alley or in any other public place, except an attended parking area, unless either the starting lever, throttle, steering apparatus, gear shift or ignition of the vehicle is locked and the key for that lock is removed from the vehicle; and provide forfeitures for violations of the ordinance. This section does not apply to motor vehicles operated by common carriers of passengers under ch. 194.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (3)

W. S. A. 66.0431, WI ST 66.0431
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0433

66.0433. Licenses for nonintoxicating beverages

Currentness

(1) A town board, village board or common council may grant licenses to persons it considers proper for the sale of beverages containing less than 0.5 percent of alcohol by volume to be consumed on the premises where sold and to manufacturers, wholesalers, retailers and distributors of these beverages. The fee for a license shall be not less than $5 nor more than $50, to be fixed by the board or council, except that where these beverages are sold for consumption off the premises the license fee shall be $5. The license shall be issued by the town, village or city clerk, shall designate the specific premises for which granted and shall expire the next June 30 after issuance. The full license fee shall be charged for the whole or a fraction of the year. No beverages described in this paragraph may be manufactured, sold at wholesale or retail or sold for consumption on the premises, or kept for sale at wholesale or retail or for consumption on the premises where sold, without a license issued under this paragraph.

(1m) If a place of business moves from the premises designated in the license to another location in the town, village or city within the license period, the licensee shall give notice of the change of location, and the license shall be amended accordingly without payment of an additional fee. A license is not transferable from one person to another.

(2) No license or permit may be granted to any person, unless to a domestic corporation or domestic limited liability company, not a resident of this state and of the town, village or city in which the license is applied for, nor, subject to ss. 111.321, 111.322 and 111.335, to any person who has been convicted of a felony, unless the person has been restored to civil rights.

(3) A town board, village board or common council may by resolution or ordinance adopt reasonable and necessary regulations regarding the location of licensed premises, the conduct of the licensed premises, the sale of beverages containing less than 0.5 percent of alcohol by volume and the revocation of any license.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (16)

W. S. A. 66.0433, WI ST 66.0433
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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W.S.A. 66.0435

66.0435. Manufactured and mobile home communities

Currentness

(1) Definitions. In this section:

(am) "Community" means a manufactured and mobile home community.

(b) "Licensee" means any person licensed to operate and maintain a manufactured and mobile home community under this section.

(c) "Licensing authority" means the city, town or village wherein a manufactured and mobile home community is located.

(cg) "Manufactured and mobile home community" means any plot or plots of ground upon which 3 or more manufactured homes or mobile homes, occupied for dwelling or sleeping purposes, are located, regardless of whether a charge is made for the accommodation.

(cm) "Manufactured home" has the meaning given in s. 101.91(2) and includes any additions, attachments, annexes, foundations, and appurtenances.

(d) "Mobile home" has the meaning given in s. 101.91(10) and includes any additions, attachments, annexes, foundations and appurtenances.

(h) "Person" means any natural individual, firm, trust, partnership, association, corporation or limited liability company.

(hm) "Recreational mobile home" means a prefabricated structure that is no larger than 400 square feet, or that is certified by the manufacturer as complying with the code promulgated by the American National Standards Institute as ANSI A119.5, and that is designed to be towed and used primarily as temporary living quarters for recreational, camping, travel, or seasonal purposes.

(i) "Space" means a plot of ground within a manufactured and mobile home community, designed for the accommodation of one manufactured or mobile home.

(j) “Unit” means a single manufactured or mobile home.

(2) Granting, revoking or suspending license. (a) It is unlawful for any person to maintain or operate a community within the limits of a city, town or village, unless the person has received a license from the city, town or village.

(b) In order to protect and promote the public health, morals and welfare and to equitably defray the cost of municipal and educational services required by persons and families using communities for living, dwelling or sleeping purposes, a city council, village board and town board may do any of the following:

1. Establish and enforce by ordinance reasonable standards and regulations for every community.

2. Require an annual license fee to operate a community and levy and collect special assessments to defray the cost of municipal and educational services furnished to a community.

3. Limit the number of units that may be located in any one community.

4. Limit the number of licenses for communities in any common school district, if the development of a community would cause the school costs to increase above the state average or if an exceedingly difficult or impossible situation exists with regard to providing adequate and proper sewage disposal in the particular area.

(c) In a town in which the town board enacts an ordinance regulating manufactured and mobile homes under this section and has also enacted and approved a county zoning ordinance under the provisions of s. 59.69, the provisions of the ordinance which is most restrictive apply with respect to the establishment and operation of a community in the town.

(d) A license granted under this section is subject to revocation or suspension for cause by the licensing authority that issued the license upon complaint filed with the clerk of the licensing authority, if the complaint is signed by a law enforcement officer, local health officer, as defined in s. 250.01(5), or building inspector, after a public hearing upon the complaint. The holder of the license shall be given 10 days' written notice of the hearing, and is entitled to appear and be heard as to why the license should not be revoked. A holder of a license that is revoked or suspended by the licensing authority may within 20 days of the date of the revocation or suspension appeal the decision to the circuit court of the county in which the community is located by filing a written notice of appeal with the clerk of the licensing authority, together with a bond executed to the licensing authority, in the sum of $500 with 2 sureties or a bonding company approved by the clerk, conditioned for the faithful prosecution of the appeal and the payment of costs adjudged against the license holder.

(3) License and monthly municipal permit fee.

(a) The licensing authority shall collect from the licensee an annual license fee of not less than $25 nor more than $100 for each 50 spaces or fraction of 50 spaces within each community within its limits. If the community lies in more than one municipality the amount of the license fee shall be determined by multiplying the gross fee by a fraction the numerator of which is the number of spaces in the community in a municipality and the denominator of which is the entire number of spaces in the community.

(b) The licensing authority may collect a fee of $10 for each transfer of a license.

(c) 1. In addition to the license fee provided in pars. (a) and (b), each licensing authority shall collect from each unit occupying space or lots in a community in the licensing authority, except from recreational mobile homes as provided under par. (cm), from manufactured and mobile homes that constitute improvements to real property, from recreational vehicles as defined in s. 340.01(48r), and from camping trailers as defined in s. 340.01(6m), a monthly municipal permit fee computed as follows:

a. On January 1, the assessor shall determine the total fair market value of each unit in the taxation district subject to the monthly municipal permit fee.

b. The fair market value, determined under subd. 1.a., minus the tax-exempt household furnishings thus established, shall be equated to the general level of assessment for the prior year on other real and personal property in the district.

c. The value of each unit, determined under subd. 1. b., shall be multiplied by the general property gross tax rate, less any credit rate for the property tax relief credit, established on the preceding year's assessment of general property.

d. The total annual permit fee, computed under subd. 1. c., shall be divided by 12 and shall represent the monthly municipal permit fee.

2. The monthly municipal permit fee is applicable to units moving into the tax district any time during the year. The community operator shall furnish information to the tax district clerk and the assessor on units added to the community within 5 days after their arrival, on forms prescribed by the department of revenue. As soon as the assessor receives the notice of an addition of a unit to a community, the assessor shall determine its fair market value and notify the clerk of that determination. The clerk shall equate the fair market value established by the assessor and shall apply the appropriate tax rate, divide the annual permit fee thus determined by 12 and notify the unit owner of the monthly fee to be collected from the unit owner. Liability for payment of the fee begins on the first day of the next succeeding month and continues for the months in which the unit remains in the tax district.

3. A new monthly municipal permit fee and a new valuation shall be established each January and shall continue for that calendar year.

4. The valuation established is subject to review as are other values established under ch. 70. If the board of review reduces a valuation on which previous monthly payments have been made the tax district shall refund past excess fee payments.

5. The monthly municipal permit fee shall be paid by the unit owner to the local taxing authority on or before the 10th of the month following the month for which the monthly municipal permit fee is due.

6. The licensee of a community is liable for the monthly municipal permit fee for any unit occupying space in the community as well as the owner and occupant of each such unit, except that the licensee is not liable until the licensing authority has failed, in an action under ch. 799, to collect the fee from the owner and occupant of the unit. A municipality, by ordinance, may require the community operator to collect the monthly municipal permit fee from the unit owner.

8. The credit under s. 79.10(9)(bm), as it applies to the principal dwelling on a parcel of taxable property, applies to the estimated fair market value of a unit that is the principal dwelling of the owner. The owner of the unit shall file a claim for the credit with the treasurer of the municipality in which the property is located. To obtain the credit under s. 79.10(9)(bm), the owner shall attest on the claim that the unit is the owner's principal dwelling. The treasurer shall reduce the owner's monthly municipal permit fee by the amount of any allowable credit. The treasurer shall furnish notice of all claims for credits filed under this subdivision to the department of revenue as provided under s. 79.10(1m).

9. No monthly municipal permit fee may be imposed on a financial institution, as defined in s. 69.30(1)(b), that relates to a vacant unit that has been repossessed by the financial institution.

(cm) Recreational mobile homes and recreational vehicles, as defined in s. 340.01(48r), are exempt from the monthly municipal permit fee under par. (c). The exemption under this paragraph also applies to steps and a platform, not exceeding 50 square feet, that lead to a recreational mobile home or recreational vehicle, but does not apply to any other addition, attachment, patio, or deck.

(d) This section does not apply to a community that is owned and operated by any county under the provisions of s. 59.52(16)(b).

(e) If a unit is permitted by local ordinance to be located outside of a licensed community, the monthly municipal permit fee shall be paid by the owner of the land on which it stands, and the owner of the land shall comply with the reporting requirements of par. (c). The owner of the land may collect the fee from the owner of the unit and, on or before January 10 and on or before July 10, shall transmit to the taxation district all fees owed for the 6 months ending on the last day of the month preceding the month when the transmission is required.

(f) Nothing in this subsection prohibits the regulation by local ordinance of a community.

(g) Failure to timely pay the tax prescribed in this subsection shall be treated as a default in payment of property tax and is subject to all procedures and penalties applicable under chs. 70 and 74.

(h) Each local governing body may enact an ordinance providing a forfeiture of up to $25 for failure to comply with the reporting requirements of par. (c) or (e). Each failure to report is a separate offense.

(3m) Community operator reimbursement. A community operator who collects a monthly municipal permit fee from a unit owner may deduct, for administrative expenses, 2 percent of the monthly fees collected.

(4) Application for license. Original application for a community license shall be filed with the clerk of the licensing authority. Applications shall be in writing, signed by the applicant and shall contain the following:

(a) The name and address of the applicant.

(b) The location and legal description of the community.

(c) The complete plan of the community.

(6) Renewal of license. Upon application by any licensee, after approval by the licensing authority and upon payment of the annual license fee, the clerk of the licensing authority shall issue a certificate renewing the license for another year, unless sooner revoked. The application for renewal shall be in writing, signed by the applicant on forms furnished by the licensing authority.

(7) Transfer of license; fee. Upon application for a transfer of license the clerk of the licensing authority, after approval of the application by the licensing authority, shall issue a transfer upon payment of the required $10 fee.

(8) Distribution of fees. The licensing authority may retain 10 percent of the monthly municipal permit fees collected in each month, without reduction for any amounts deducted under sub. (3m), to cover the cost of administration. The licensing authority shall pay to the school district in which the community is located, within 20 days after the end of each month, such proportion of the remainder of the fees collected in the preceding month as the ratio of the most recent property tax levy for school purposes bears to the total tax levy for all purposes in the licensing authority. If the community is located in more than one school district, each district shall receive a share in the proportion that its property tax levy for school purposes bears to the total school tax levy.

(9) Municipalities; monthly municipal permit fees on recreational mobile homes and recreational vehicles. A licensing authority may assess monthly municipal permit fees at the rates under this section on recreational mobile homes and recreational vehicles, as defined in s. 340.01(48r), except recreational mobile homes and recreational vehicles that are located in campgrounds licensed under s. 97.67, recreational mobile homes that constitute improvements to real property, and recreational mobile homes or recreational vehicles that are located on land where the principal residence of the owner of the recreational mobile home or recreational vehicle is located, regardless of whether the recreational mobile home or recreational vehicle is occupied during all or part of any calendar year.

(10) Powers of municipalities. The powers conferred on licensing authorities by this section are in addition to all other grants of authority and are limited only by the express language of this section.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (28)

W. S. A. 66.0435, WI ST 66.0435
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0436

66.0436. Certificates of food protection practices for restaurants

Currentness

(1) In this section, "restaurant" has the meaning given in s. 97.01(14g).

(2) No city, village, town, or county may enact an ordinance requiring a restaurant, a person who holds a license for a restaurant, or a person who conducts, maintains, manages, or operates a restaurant to satisfy a requirement related to the issuance or possession of a certificate of food protection practices that is not found under s. 97.33.

(3)(a) Except as provided in par. (b), if a city, village, town, or county has in effect on January 1, 2015, an ordinance that the city, village, town, or county is prohibited from enacting under sub. (2), the ordinance does not apply and may not be enforced.

(b) Paragraph (a) does not apply to an ordinance of a 1st class city that was in effect on March 20, 2014.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0436, WI ST 66.0436
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0437

66.0437. Drug disposal programs

Currentness

(1) In this section, "political subdivision" has the meaning given in s. 165.65(1)(e).

(2) A political subdivision may operate or authorize a person to operate a drug disposal program as provided under s. 165.65(3).

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0437, WI ST 66.0437
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0438

66.0438. Limitations on locally issued identification cards

Currentness

(1) Definition. In this section, "public assistance benefits" means services, benefits, payments, or other assistance provided under a program administered by the department of health services or the department of children and families under s. 253.06 or ch. 49.

(2) Towns and counties. (a) Except as provided in par. (b), no town or county may issue, or expend any funds for the issuance of, a photo identification card for any resident of the town or county.

(b) Notwithstanding par. (a), a town or county may issue, or expend funds for the issuance of, a photo identification card to any of the following individuals or for any of the following purposes:

1. An employee or elected official of the town or county, if the photo identification card relates to the employee's or official's job duties.

2. An employee of a vendor or contractor that contracts with the town or county, or an employee of a subcontractor that contracts with such a vendor or contractor, if the photo identification card relates to the employee's job duties for the town or county.

3. To use a transit system owned or operated by the town or county.

4. To use or access services or facilities owned by the town or county.

5. An employee of, or a student who is attending, an institution of higher education that contracts with the town or county, if the photo identification card relates to the employee's or student's job duties for the town or county.

(c) If a town or county has issued an identification card, other than a card described in par. (b), that has been used before April 27, 2016, as an identification document to establish proof of residence under s. 6.34(3)(a)3., that card is not valid for such purposes on or after April 27, 2016.

(3) Cities and villages. (a) If a city or village issues, or expends funds for the issuance of, a photo identification card for any resident of the city or village, the card must state clearly on its face, in 12 point type, "Not authorized for voting purposes."

(b) A photo identification card issued by, or at the direction of, a city or village, as described under par. (a), may not be used for any of the following purposes:

1. As an identification document to establish proof of residence under s. 6.34(3)(a)3.

2. As proof of identification under s. 6.79(2), 6.82(1)(a), 6.86, 6.87, or 6.875.

3. To obtain public assistance benefits.

(c) If a city or village has issued an identification card that has been used before April 27, 2016, as an identification document to establish proof of residence under s. 6.34(3)(a)3., that card is not valid for such purposes on or after April 27, 2016.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0438, WI ST 66.0438
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0439

66.0439. Environmental, occupational health, and safety credentials

Currentness

(1) No city, village, town, or county may enact an ordinance or adopt a resolution that restricts the use of a title or a representation described in s. 100.70(1)(a) to (h).

(2) If a city, village, town, or county has in effect on November 29, 2017, an ordinance that the city, village, town, or county is prohibited from enacting under sub. (1), the ordinance does not apply and may not be enforced.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0439, WI ST 66.0439
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0440

66.0440. Battery-powered, alarmed electric security fences

Currentness

(1) In this section:

(a) “Battery-powered, alarmed electric security fence” means an electric fence that satisfies all of the following:

1. Is equipped with an energizer that produces direct current and is powered by a commercial storage battery with a voltage of not greater than 12 volts.

2. Produces an electric charge on contact that satisfies standards provided by the International Electrotechnical Commission, as published in the latest version of the commission's standards for electric fence energizers.

3. Is connected to a system that is capable of signaling law enforcement.

4. Includes warning signage that a battery-powered, alarmed electric security fence is in operation.

5. Is surrounded by a perimeter fence or wall that is at least 5 feet in height.

6. Is no more than 10 feet in height, or 2 feet higher than the perimeter fence or wall, whichever is higher.

(b) “Political subdivision” means a city, village, town, or county.

(2) No political subdivision may do any of the following:

(a) Prohibit the installation or use of a battery-powered, alarmed electric security fence, except on property designated exclusively for residential use.

(b) Require a permit, other than an alarm system permit, for the installation or use of a battery-powered, alarmed electric security fence.

(c) Impose installation or operation requirements that are inconsistent with the standards set by the International Electrotechnical Commission for installation or operation of an electrified fence that is a component of a battery-powered, alarmed electric security fence.

(3) No person may locate a battery-powered, alarmed electric security fence on property designated exclusively for residential use.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0440, WI ST 66.0440
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0441

66.0441. Quarries extracting certain nonmetallic minerals

Currentness

(1) Construction. (a) Nothing in this section may be construed to affect the authority of a political subdivision to regulate land use for a purpose other than quarry operations.

(b) Subject to pars. (c) and (d), nothing in this section may be construed to exempt a quarry from a regulation of general applicability placed by a political subdivision that applies to other property in the political subdivision that is not a quarry unless the regulation is inconsistent with this section.

(c) Nothing in this section may be construed to exempt a quarry from the application, outside of a nonmetallic mining licensing permit, of a requirement imposed by a political subdivision under ch. 349, a regulation of general applicability placed by a political subdivision that regulates access to property from roads for which the political subdivision is the maintaining authority, or a restriction on the use of roads for which the political subdivision is the maintaining authority.

(d) Nothing in this section may be construed to exempt a quarry from a restriction placed by a political subdivision regulating a nonconforming use under s. 59.69(10), 60.61(5), or 62.23(7).

(2) Definitions. In this section:

(a) “Active quarry” means a quarry that has operated during the preceding 12-month period.

(am) “Conditional use permit” means a form of approval, including a special exception or other special zoning permission, granted by a political subdivision pursuant to a zoning ordinance for the operation of a quarry.

(b) “Nonmetallic mining licensing ordinance” means an ordinance that is enacted by a political subdivision specifically regulating the operation of a quarry and that is not enacted pursuant to zoning authority.

(c) “Nonmetallic mining licensing permit” means a form of approval that is granted by a political subdivision pursuant to a nonmetallic mining licensing ordinance and that is specifically related to the operation of a quarry.

(d) “Permit” means a form of approval granted by a political subdivision for the operation of a quarry.

(e) “Political subdivision” means a city, village, town, or county.

(f) “Public works project” means a federal, state, county, or municipal project that involves the construction, maintenance, or repair of a public transportation facility or other public infrastructure and in which nonmetallic minerals are used.

(g) “Quarry” means the surface area from which nonmetallic minerals, including soil, clay, sand, gravel, and construction aggregate, that are used primarily for a public works project or a private construction or transportation project are extracted and processed.

(h) “Quarry operations” means the extraction and processing of minerals at a quarry and all related activities, including blasting, vehicle and equipment access to the quarry, and loading and hauling of material to and from the quarry.

(2m) Effective dates of certain ordinances. For purposes of sub. (3)(a)3., the date on which a town or county enacts a zoning ordinance that requires a conditional use permit for a quarry operator to conduct quarry operations is the date the ordinance becomes effective, except as follows:

(a) If a town that previously did not have a general zoning ordinance enacts a general zoning ordinance requiring a conditional use permit to conduct quarry operations and the town ceases to be covered by a county general zoning ordinance that required a conditional use permit to conduct quarry operations, a conditional use permit for a quarry in effect at the time of the transition from county zoning to town zoning shall continue in effect and the conditional use permit shall be treated as if it was originally issued by the town. For purposes of a conditional use permit subject to this paragraph, the date of the adoption of the town ordinance shall be deemed to be the date the conditional use permit was issued by the county but only with respect to requirements that were included in the county ordinance on the date the conditional use permit was issued and that were adopted in the town ordinance.

(b) If a town that has a general zoning ordinance requiring a conditional use permit to conduct quarry operations repeals its zoning ordinance and becomes subject to a county general zoning ordinance under s. 59.69(5)(c) and the county zoning ordinance requires a conditional use permit to conduct quarry operations, a conditional use permit for a quarry in effect at the time of the transition from town zoning to county zoning shall continue in effect and the conditional use permit shall be treated as if it was originally issued by the county. For purposes of a conditional use permit subject to this paragraph, the date of the adoption of the county ordinance shall be deemed to be the date the conditional use permit was issued by the town but only with respect to requirements that were included in the town ordinance on the date the conditional use permit was issued and that were adopted in the county ordinance.

(3) Limitations on local regulation. (a) *Permits*. 1. In this paragraph, “substantial evidence” means facts and information, other than merely personal preference or speculation, directly pertaining to the requirements that an applicant must meet to obtain a nonmetallic mining licensing permit and that a reasonable person would accept in support of a conclusion.

2. Consistent with the requirements and limitations in this subsection, except as provided in subd. 3., a political subdivision may require a quarry operator to obtain a conditional use permit or nonmetallic mining licensing permit to conduct quarry operations.

3. A political subdivision may not require a quarry operator of an active quarry to obtain a conditional use permit or nonmetallic mining licensing permit to conduct quarry operations unless prior to the establishment of quarry operations the political subdivision enacts an ordinance that requires the permit. A political subdivision that requires a quarry operator to obtain a nonmetallic mining licensing permit under this subdivision may not impose a requirement in the nonmetallic mining licensing permit pertaining to any matter regulated by an applicable zoning ordinance or addressed through conditions imposed or agreed to in a previously issued and effective conditional use permit. Any requirement imposed in a nonmetallic mining licensing permit shall be related to the purpose of the ordinance requiring the nonmetallic mining licensing permit and shall be based on substantial evidence. The duration of a nonmetallic mining licensing permit may not be shorter than 5 years.

(b) *Applicability of local limit*. If a political subdivision enacts a nonmetallic mining licensing ordinance requirement regulating the operation of a quarry that was not in effect when quarry operations began at an active quarry, the ordinance requirement does not apply to that quarry or to land that is contiguous to the land on which the quarry is located, if the contiguous land has remained continuously under common ownership, leasehold, or control with land on which the quarry is located from the time the ordinance was enacted; can be shown to have been intended for quarry operations prior to the enactment of the ordinance; and is located in the same political subdivision.

(c) *Hours of operation*. A political subdivision may not limit the times, including days of the week, that quarry operations may occur if the materials produced by the quarry will be used in a public works project that requires construction work to be performed during the night or an emergency repair.

(d) *Blasting*. 1. In this paragraph, "affected area" means an area within a certain radius of a blasting site that may be affected by a blasting operation, as determined using a formula established by the department of safety and professional services by rule that takes into account a scaled-distance factor and the weight of explosives to be used.

2. Except as provided under subds. 3. and 4. and s. 101.02(7y), a political subdivision may not limit blasting at a quarry.

3. A political subdivision may require the operator of a quarry to do any of the following:

a. Before beginning a blasting operation at the quarry, provide notice of the blasting operation to each political subdivision in which any part of the quarry is located and to owners of dwellings or other structures within the affected area.

b. Before beginning a blasting operation at the quarry, cause a 3rd party to conduct a building survey of any dwellings or other structures within the affected area.

c. Before beginning a blasting operation at the quarry, cause a 3rd party to conduct a survey of and test any wells within the affected area.

d. Provide evidence of insurance to each political subdivision in which any part of the quarry is located.

e. Provide copies of blasting logs to each political subdivision in which any part of the quarry is located.

f. Provide maps of the affected area to each political subdivision in which any part of the quarry is located.

g. Provide copies of any reports submitted to the department of safety and professional services relating to blasting at the quarry.

4. A political subdivision may suspend a permit for a violation of the requirements under s. 101.15 relating to blasting and rules promulgated by the department of safety and professional services under s. 101.15(2)(e) relating to blasting only if the department of safety and professional services determines that a violation of the requirements or rules has occurred and only for the duration of the violation as determined by the department of safety and professional services.

5. Nothing in this section exempts a quarry operator from applicable limitations on the time of day during which blasting activities may be conducted that are imposed by rules promulgated by the department of safety and professional services.

(e) *Quarry permit requirements*. 1. A political subdivision may not add a condition to a permit during the duration of the permit unless the permit holder consents.

2. If a political subdivision requires a quarry to comply with another political subdivision's ordinance as a condition for obtaining a permit, the political subdivision that grants the permit may not require the quarry operator to comply with a provision of the other political subdivision's ordinance that is enacted after the permit is granted and while the permit is in effect.

3. a. A town may not require, as a condition for granting a permit to a quarry operator, that the quarry operator satisfy a condition that a county requires in order to grant a permit that is imposed by a county ordinance enacted after the county grants a permit to the quarry operator.

b. A county may not require, as a condition for granting a permit to a quarry operator, that the quarry operator satisfy a condition that a town requires in order to grant a permit that is imposed by a town ordinance enacted after the town grants a permit to the quarry operator.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0441, WI ST 66.0441
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0442

66.0442. Electric vehicle charging stations

Currentness

(1) In this section:

(a) "Level 1 charger" means a device with one or more charging ports and connectors for charging electric vehicles that operates on a circuit up to 120 volts and transfers alternating current electricity to a device in an electric vehicle that converts alternating current to direct current to recharge an electric vehicle battery.

(b) "Level 2 charger" has the meaning given for "AC Level 2" under 23 CFR 680.104.

(c) "Level 3 charger" means a direct current fast charger, as defined under 23 CFR 680.104, and analogous successor technologies.

(d) "Local governmental unit" means any of the following:

1. A city, village, town, or county.

2. A school district.

3. A special purpose district in this state.

4. An agency or corporation of an entity described in subd. 1. or 3.

5. A combination or subunit of an entity described in this paragraph.

(e) "Municipal utility" has the meaning given in s. 16.957(1)(q).

(2)(a) Except as provided in pars. (b) and (c), no local governmental unit may own, operate, manage, or lease an electric vehicle charging station containing a Level 1, Level 2, or Level 3 charger unless the charger is not available to the public and is used solely to charge vehicles owned or leased by the local governmental unit.

(b) A local governmental unit may own, operate, manage, or lease an electric vehicle charging station at which a Level 1 charger or Level 2 charger is available to the public if the local governmental unit makes all Level 1 chargers or Level 2 chargers installed before March 22, 2024, available for public use free of any charge.

(c) A local governmental unit may own, operate, manage, or lease an electric vehicle charging station at which a Level 1 charger or a Level 2 charger installed on or after March 22, 2024, is available to the public if the local governmental unit charges a reasonable fee for the electricity delivered or placed by all such Level 1 chargers and Level 2 chargers.

(3) Notwithstanding sub. (2) and subject to sub. (4), a local governmental unit may authorize an electric provider, as defined in s. 16.957(1)(f), or a person described in s. 196.01(5)(b)8. to own and operate an electric vehicle charging station at which a Level 1 charger, Level 2 charger, or Level 3 charger is available to the public on property owned by the local governmental unit.

(3m) An electric provider, as defined in s. 16.957(1)(f), or a person described in s. 196.01(5)(b)8. who is authorized under sub. (3) to own and operate an electric vehicle charging station at which a Level 1 charger, Level 2 charger, or Level 3 charger is available to the public on property owned by a local governmental unit, shall charge a reasonable fee for the electricity delivered or placed by all such chargers.

(4) Notwithstanding sub. (2), a municipal utility existing on March 22, 2024, may own and operate an electric vehicle charging station that is available to the public and may charge a fee for using the electric vehicle charging station that is based on the amount of kilowatt-hours of electricity that users consume if all of the following apply:

(a) The electric vehicle charging station receives any approvals from the public service commission required under ch. 196.

(b) No tax revenue subsidizes, directly or indirectly, any costs associated with the electric vehicle charging station. This paragraph does not prohibit a municipal utility from using grant money from this state that is distributed after approval by the joint committee on finance under s. 13.10 or the federal government to pay costs associated with constructing an electric vehicle charging station if the purpose of the grant is to expand the availability of electric vehicle charging infrastructure.

(c) Notwithstanding s. 66.0811(2), no revenue generated by the electric vehicle charging station is transferred to the general fund of the municipality that owns the municipal utility or otherwise directly or indirectly supplements any portion of the municipality's budget.

(5) No local governmental unit may require a private developer to install an electric vehicle charging station or allow the installation of an electric vehicle charging station on the developer's property as a condition of granting a building permit, conditional use permit, or other approval. This subsection does not apply to the enforcement of a voluntary contractual agreement between a developer and local governmental unit.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0442, WI ST 66.0442
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.044

66.044. Renumbered 66.0609 and amended by 1999 Act 150, § 113, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.044, WI ST 66.044
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.045

66.045. Renumbered 66.0425 and amended by 1999 Act 150, § 114, eff. Jan. 1, 2001

Currentness

Credits
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W. S. A. 66.045, WI ST 66.045
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W.S.A. 66.046

66.046. Renumbered 66.0429 and amended by 1999 Act 150, § 115, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.046, WI ST 66.046
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.047

66.047. Renumbered 66.0831 and amended by 1999 Act 150, § 116, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.047, WI ST 66.047
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.048

66.048. Renumbered 66.0915 and amended by 1999 Act 150, § 117, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.048, WI ST 66.048
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0485

66.0485. Renumbered 66.0141 by 1999 Act 150, § 118, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0485, WI ST 66.0485
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.049

66.049. Renumbered 66.0405 and amended by 1999 Act 150, § 119, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.049, WI ST 66.049
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.0495. Renumbered in part and repealed in part by 1999 Act 150, §§ 120 to 133, eff. Jan. 1, 2001

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W.S.A. 66.0495

66.0495. Renumbered in part and repealed in part by 1999 Act 150, §§ 120 to 133, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0495, WI ST 66.0495
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KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.05. Renumbered in part and repealed in part by 1999 Act 150, §§ 134 to 149, eff. Jan. 1, 2001

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W.S.A. 66.05

66.05. Renumbered in part and repealed in part by 1999 Act 150, §§ 134 to 149, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.05, WI ST 66.05
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0501

66.0501. Eligibility for office

Currentness

(1) Deputy sheriffs and municipal police. No person may be appointed deputy sheriff of any county or police officer for any city, village or town unless that person is a citizen of the United States. This section does not apply to common carriers or to a deputy sheriff not required to take an oath of office.

(2) Eligibility of other officers. Except as expressly authorized by statute, no member of a town, village or county board, or city council, during the term for which the member is elected, is eligible for any office or position which during that term has been created by, or the selection to which is vested in, the board or council, but the member is eligible for any elective office. The governing body may be represented on city, village or town boards and commissions where no additional compensation, except a per diem, is paid to the representatives of the governing body and may fix the tenure of these representatives notwithstanding any other statutory provision. A representative of a governing body who is a member of a city, village or town board or commission may receive a per diem only if the remaining members of the board or commission may receive a per diem. This subsection does not apply to a member of any board or council described in this subsection who resigns from the board or council before being appointed to an office or position which was not created during the member's term in office.

(3) Appointments on consolidation of offices. Whenever offices are consolidated, the occupants of which are members of the same statutory committee or board and which are serving in that office because of holding another office or position, the common council or village board may designate another officer or officers or make any additional appointments as may be necessary to procure the number of committee or board members provided for by statute.

(4) Compatible offices and positions. (a) A volunteer fire fighter, emergency medical services practitioner, or emergency medical responder in a city, village, or town whose annual compensation from one or more of those positions, including fringe benefits, does not exceed $25,000 if the city, village, or town has a population of 5,000 or less, or $15,000 if the city, village, or town has a population of more than 5,000, may also hold an elective office in that city, village, or town. It is compatible with his or her office for an elected village or town officer to receive wages under s. 60.37(4) or 61.327 for work that he or she performs for the village or town.

(b) It is compatible with his or her office for a local public official, as defined in s. 19.42(7x), to serve as an election official appointed under s. 7.30(2)(a) and be compensated for that service, as provided under s. 7.03.

(5) Employees may be candidates. (a) In this subsection:

1. “Political subdivision” means a city, village, town, or county.

2. “Public employee” means any individual employed by a political subdivision, other than an individual to whom s. 164.06 applies and other than an individual to whom 5 USC 1502(a)(3) applies.

(b) No political subdivision may prohibit a public employee from being a candidate for any elective public office, if that individual is otherwise qualified to be a candidate. No public employee may be required, as a condition of being a candidate for any elective public office, to take a leave of absence during his or her candidacy. This subsection does not affect the authority of a political subdivision to regulate the conduct of a public employee while the public employee is on duty or otherwise acting in an official capacity.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 267

Note: Amends the prohibition, in sub. (2), of payment of additional remuneration to a representative of a governing body who sits on a city, village or town board or commission. The amendment provides that a representative of a governing body who is a member of a city, village or town board or commission may receive a per diem if the remaining members of the board or commission also may receive a per diem.

Notes of Decisions (54)

W. S. A. 66.0501, WI ST 66.0501
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W.S.A. 66.05015

66.05015. Background investigation

Currentness

(1) In this section, "political subdivision" means a city, village, town, or county.

(2)(a)1. Notwithstanding ss. 111.321, 111.322, and 111.335 and with the assistance of the department of justice, a political subdivision shall conduct a background investigation of any person, including a person appointed under a civil service system competitive examination procedure established under s. 59.52(8) or ch. 63, selected to fill a position with the political subdivision and who, in fulfilling the duties of the position, will have access to federal tax information received directly from the federal Internal Revenue Service or from a source that is authorized by the federal Internal Revenue Service.

2. Notwithstanding ss. 111.321, 111.322, and 111.335, at any interval determined appropriate by the political subdivision, a political subdivision may conduct additional background investigations of any person, including a person appointed under a civil service system competitive examination procedure established under s. 59.52(8) or ch. 63, for whom an initial background investigation has been conducted under subd. 1. and background investigations of any other person, including a person appointed under a civil service system competitive examination procedure established under s. 59.52(8) or ch. 63, employed by the political subdivision who, in fulfilling the duties of his or her position, has access to federal tax information received directly from the federal Internal Revenue Service or from a source that is authorized by the federal Internal Revenue Service.

(b) A background investigation under this section may include requiring the person to be fingerprinted on 2 fingerprint cards each bearing a complete set of the person's fingerprints, or by other technologies approved by law enforcement agencies. The department of justice shall submit any such fingerprint cards to the federal bureau of investigation for the purposes of verifying the identity of the person fingerprinted and obtaining records of his or her criminal arrests and convictions.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.05015, WI ST 66.05015
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W.S.A. 66.0502

66.0502. Employee residency requirements prohibited

Currentness

(1) The legislature finds that public employee residency requirements are a matter of statewide concern.

(2) In this section, "local governmental unit" means any city, village, town, county, or school district.

(3)(a) Except as provided in sub. (4), no local governmental unit may require, as a condition of employment, that any employee or prospective employee reside within any jurisdictional limit.

(b) If a local governmental unit has a residency requirement that is in effect on July 2, 2013, the residency requirement does not apply and may not be enforced.

(4)(a) This section does not affect any statute that requires residency within the jurisdictional limits of any local governmental unit or any provision of state or local law that requires residency in this state.

(b) Subject to par. (c), a local governmental unit may impose a residency requirement on law enforcement, fire, or emergency personnel that requires such personnel to reside within 15 miles of the jurisdictional boundaries of the local governmental unit.

(c) If the local governmental unit is a county, the county may impose a residency requirement on law enforcement, fire, or emergency personnel that requires such personnel to reside within 15 miles of the jurisdictional boundaries of the city, village, or town to which the personnel are assigned.

(d) A residency requirement imposed by a local governmental unit under par. (b) or (c) does not apply to any volunteer law enforcement, fire, or emergency personnel who are employees of a local governmental unit.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

W. S. A. 66.0502, WI ST 66.0502
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W.S.A. 66.0503

66.0503. Combination of municipal offices

Currentness

(1) The office of county supervisor may be consolidated by charter ordinance under s. 66.0101:

(a) With the office of village president in any village which has boundaries coterminous with the boundaries of any supervisory district established under s. 59.10(3).

(b) With the office of alderperson or council member in any city in which the district from which the alderperson or council member is elected is coterminous with the boundaries of any supervisory district established under s. 59.10(3).

(2) After the effective date of adoption or repeal of a charter ordinance under this section, the clerk of the municipality shall file a copy of the ordinance with the clerk of the county within which the supervisory district lies. When so consolidated, nomination papers shall contain that number of signatures required under s. 8.10 for county supervisors and shall be filed in the office of the county clerk.

(3) Removal from office of any incumbent of an office consolidated under this section vacates the office in its entirety whether effected under ss. 17.09, 17.12 and 17.13 or other pertinent statute.

(4) Compensation for an office consolidated under this section shall be separately established by the several governing bodies affected by the consolidation as though no consolidation of offices had occurred.

(5) Tenure for an officer of an office consolidated under this section shall coincide with the term for county supervisors.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0503, WI ST 66.0503
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W.S.A. 66.0504

66.0504. Address confidentiality program

Currentness

(1) Definitions. In this section:

(a) "Actual address" has the meaning given in s. 165.68(1)(b).

(b) "Local clerk" means an individual, and an individual's deputy or assistant, who serves as one of the following:

1. A county clerk under s. 59.23.

2. A clerk of court under s. 59.40.

3. A municipal clerk as defined in s. 5.02(10).

4. A register of deeds under s. 59.43.

(c) "Program participant" has the meaning given in s. 165.68(1)(g).

(2) Identity protection. (a) If a program participant submits a written request to a local clerk that he or she keep the program participant's actual address private, the local clerk may not disclose any record in his or her possession that would reveal the program participant's actual address, except pursuant to a court order.

(b) The provisions of s. 165.68(3)(b)4. a., to the extent that they apply under s. 165.68, apply to a program participant's written request under par. (a).

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0504, WI ST 66.0504
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W.S.A. 66.0505

66.0505. Compensation of governing bodies

Currentness

(1) Definitions. In this section:

(a) “Elective officer” means a member or member-elect of the governing body of a political subdivision.

(b) “Political subdivision” means any city, village, town, or county.

(2) Establishment of salary. An elected official of any political subdivision, who by virtue of the office held by that official is entitled to participate in the establishment of the salary attending that office, shall not during the term of the office collect salary in excess of the salary provided at the time of that official's taking office. This provision is of statewide concern and applies only to officials elected after October 22, 1961.

(3) Refusal of salary. (a)1. Notwithstanding the provisions of s. 59.10(1)(c), (2)(c), (3)(f) to (j), 60.32, 61.193, 61.32, or 62.09(6), an elective officer may send written notification to the clerk and treasurer of the political subdivision on whose governing body he or she serves that he or she wishes to refuse to accept the salary that he or she is otherwise entitled to receive.

2. Except as provided in subd. 3., to be valid the notification must be sent no later than the day on which the elective officer takes the oath of office and before he or she performs any services in his or her official capacity, and the notification applies only to the taxable year in which the officer's election is certified or in which the officer is appointed, if the elective officer's current taxable year ends within 3 months of his or her certification or appointment, the notification applies until the end of his or her next taxable year.

3. Except as provided in subd. 2., to be valid the notification must be sent at least 30 days before the start of the elective officer's next taxable year, and the notification applies only to that taxable year although the notification may be renewed annually as provided in this subdivision.

4. If a clerk and treasurer receive notification as described in subd. 2. or 3., the treasurer may not pay the elective officer his or her salary during the time period to which the notification applies. Upon receipt of such notification, the political subdivision's treasurer shall not pay the elective officer the salary that he or she is otherwise entitled to receive, beginning with the first pay period that commences after notification applies.

(b) An elective officer, or officer-elect, who sends the written notification described under par. (a) may not rescind the notification. If an elective officer's notification no longer applies, the political subdivision's treasurer shall pay the elective officer any salary that he or she is entitled to receive, beginning with the first pay period that commences after the expiration of the notification.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (10)

W. S. A. 66.0505, WI ST 66.0505
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W.S.A. 66.0506

66.0506. Referendum; increase in employee wages

Currentness

(1) In this section, "local governmental unit" means any city, village, town, county, metropolitan sewerage district, long-term care district, local cultural arts district under subch. V of ch. 229, or any other political subdivision of the state, or instrumentality of one or more political subdivisions of the state.

(2) If any local governmental unit wishes to increase the total base wages of its general municipal employees, as defined in s. 111.70(1)(fm), who are part of a collective bargaining unit under subch. IV of ch. 111, in an amount that exceeds the limit under s. 111.70(4)(mb)2., the governing body of the local governmental unit shall adopt a resolution to that effect. The resolution shall specify the amount by which the proposed total base wages increase will exceed the limit under s. 111.70(4)(mb)2. The resolution may not take effect unless it is approved in a referendum called for that purpose. The referendum shall occur in November for collective bargaining agreements that begin the following January 1. The results of a referendum apply to the total base wages only in the next collective bargaining agreement.

(3) The referendum question shall be substantially as follows: "Shall the ... [general municipal employees] in the ... [local governmental unit] receive a total increase in wages from $...[current total base wages] to $...[proposed total base wages], which is a percentage wage increase that is ... [x] percent higher than the percent of the consumer price index increase, for a total percentage increase in wages of ... [x]?"

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

VALIDITY

<For validity of this section, see Madison Teachers, Inc. v. Walker, 2012 WL 4041495 (Wis.Cir.).>

Notes of Decisions (2)

W. S. A. 66.0506, WI ST 66.0506
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W.S.A. 66.0507

66.0507. Automatic salary schedules

Currentness

Whenever the governing body of any city, village, or town enacts by ordinance a salary schedule for some or all employees and officers of the city, village or town, other than members of the city council or village or town board, the salary schedule may include an automatic adjustment for some or all of the personnel in conformity with fluctuations upwards and downwards in the cost of living, notwithstanding ss. 60.32, 61.193, 61.32, 62.09(6) and 62.13(7).

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0507, WI ST 66.0507
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W.S.A. 66.0508

66.0508. Collective bargaining

Currentness

(1) In this section, "local governmental unit" has the meaning given in s. 66.0506(1).

(1m) Except as provided under subch. IV of ch. 111, no local governmental unit may collectively bargain with its employees.

(2) If a local governmental unit has in effect on June 29, 2011, an ordinance or resolution that is inconsistent with sub. (1m), the ordinance or resolution does not apply and may not be enforced.

(3) Each local governmental unit that is collectively bargaining with its employees shall determine the maximum total base wages expenditure that is subject to collective bargaining under s. 111.70(4)(mb)2., calculating the consumer price index change using the same method the department of revenue uses under s. 73.03(68).

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (3)

W. S. A. 66.0508, WI ST 66.0508
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W.S.A. 66.0509

66.0509. Civil service system; veterans preference

Currentness

(1) Any city or village may proceed under s. 61.34(1), 62.11(5) or 66.0101 to establish a civil service system of selection, tenure and status, and the system may be made applicable to all municipal personnel except the chief executive and members of the governing body, members of boards and commissions including election officials, employees subject to s. 62.13, members of the judiciary and supervisors. Any town may establish a civil service system under this subsection. For veterans there shall be no restrictions as to age, and veterans and their spouses shall be given preference points in accordance with s. 63.08(1)(fm). The system may also include uniform provisions in respect to attendance, leave regulations, compensation and payrolls for all personnel included in the system. The governing body of any city, village or town establishing a civil service system under this section may exempt from the system the librarians and assistants subject to s. 43.09(1).

(1m)(a) A local governmental unit, as defined in s. 66.0131(1)(a), that does not have a civil service system on June 29, 2011, shall establish a grievance system not later than October 1, 2011.

(b) To comply with the grievance system that is required under par. (a), a local governmental unit may establish either a civil service system under any provision authorized by law, to the greatest extent practicable, if no specific provision for the creation of a civil service system applies to that local governmental unit, or establish a grievance procedure as described under par. (d).

(c) Any civil service system that is established under any provision of law, and any grievance procedure that is created under this subsection, shall contain at least all of the following provisions:

1. A grievance procedure that addresses employee terminations.

2. Employee discipline.

3. Workplace safety.

(d) If a local governmental unit creates a grievance procedure under this subsection, the procedure shall contain at least all of the following elements:

1. A written document specifying the process that a grievant and an employer must follow.

2. A hearing before an impartial hearing officer.

3. An appeal process in which the highest level of appeal is the governing body of the local governmental unit.

(e) If an employee of a local governmental unit is covered by a civil service system on June 29, 2011, and if that system contains provisions that address the provisions specified in par. (c), the provisions that apply to the employee under his or her existing civil service system continue to apply to that employee.

(2)(a) Any town may establish a civil service system under sub. (1) and in the departments that the town board may determine. Any person who has been employed in a department for more than 5 years before the establishment of a civil service system applicable to that department is eligible to appointment without examination.

(b) Any town not having a civil service system and having exercised the option of placing assessors under civil service under s. 60.307(3) may establish a civil service system for assessors under sub. (1), unless the town has come within the jurisdiction of a county assessor under s. 70.99.

(3) When any town has established a system of civil service, the ordinance establishing the system may not be repealed for a period of 6 years after its enactment, and after the 6-year period it may be repealed only by proceedings under s. 9.20 by referendum vote. This subsection does not apply if a town comes, before the expiration of the 6 years, within the jurisdiction of a county assessor under s. 70.99.

(4) Any civil service system established under the provisions of this section shall provide for the appointment of a civil service board or commission and for the removal of the members of the board or commission for cause by the mayor with approval of the council, by the city manager and the council in a city organized under ss. 64.01 to 64.15, and by the board in a village or town.

(5) All examinations given in a civil service system established under this section, including minimum training and experience requirements, for positions in the classified service shall be job-related in compliance with appropriate validation standards and shall be subject to the approval of the board or commission appointed under sub. (4). All relevant experience, whether paid or unpaid, shall satisfy experience requirements.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (12)

W. S. A. 66.0509, WI ST 66.0509
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.051. Renumbered in part and repealed in part by 1999 Act 150, §§ 151 to 153, eff. Jan. 1, 2001

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
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W.S.A. 66.051

66.051. Renumbered in part and repealed in part by 1999 Act 150, §§ 151 to 153, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.051, WI ST 66.051
Current through 2023 Act 272, published April 10, 2024.

End of Document

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W.S.A. 66.0510

66.0510. Benefits to officers, employees, agents

Currentness

(1) Definitions. In this section:

(a) "Employee benefit plan" means a plan as defined in 29 USC 1002(3).

(b) "Local governmental unit" has the definition given in s. 66.0131(1)(a).

(2) Benefits. If a local governmental unit provides an employee benefit plan to its officers, agents, and employees, the plan may cover only such officers, agents, and employees and their spouses and dependent children.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0510, WI ST 66.0510
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
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W.S.A. 66.0511

66.0511. Law enforcement agencies; certain policies

Currentness

(1) Definitions. In this section:

(a) "Choke hold" means the intentional and prolonged application of force to the throat, windpipe, or carotid arteries that prevents or hinders breathing or blood flow, reduces the intake of air, or reduces blood flow to the head.

(b) "Law enforcement agency" has the meaning given under s. 165.83(1)(b).

(2) Use of force policy. Each person in charge of a law enforcement agency shall prepare in writing a policy or standard regulating the use of force by law enforcement officers in the performance of their duties. The law enforcement agency shall make the policy or standard publicly available on a website maintained by the law enforcement agency or, if the agency does not maintain its own site, on a website maintained by the municipality over which the law enforcement agency has jurisdiction. If the policy or standard is changed, the law enforcement agency shall ensure the website displays the updated policy or standard as soon as practically possible but no later than one year after the change is made. The law enforcement agency shall also prominently display a means of requesting a copy of the policy or standard. If a person requests a copy of the policy or standard, the law enforcement agency shall provide a copy of the current policy or standard free of charge as soon as practically possible but no later than 3 business days after the request is made. A law enforcement agency may not authorize the use of choke holds by law enforcement officers in a policy or standard under this subsection, except in life-threatening situations or in self-defense. [1]

(3) Citizen complaint procedure. Each person in charge of a law enforcement agency shall prepare in writing and make available for public scrutiny a specific procedure for processing and resolving a complaint by any person regarding the conduct of a law enforcement officer employed by the agency. The writing prepared under this subsection shall include a conspicuous notification of the prohibition and penalty under s. 946.66.

<Text of subsec. (4) effective July 1, 2025 and repealed by 2023 WI Act 239, § 7, on June 30, 2029.>

(4) Human trafficking prevention and enforcement. Each person in charge of a law enforcement agency in a county that has received a recommendation from the human trafficking council under s. 165.29(1)(d) is encouraged to designate a law enforcement officer of the law enforcement agency to coordinate the law enforcement agency's human trafficking prevention and enforcement efforts.

Credits

<<For credits, see Historical Note field.>>

Footnotes

1 Subsec. (2) shown as affected by 2021 Acts 48 and 49 and as merged by the legislative reference bureau.

W. S. A. 66.0511, WI ST 66.0511
Current through 2023 Act 272, published April 10, 2024.

End of Document

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W.S.A. 66.0513

66.0513. Police, pay when acting outside county or municipality

Currentness

(1) Any chief of police, sheriff, deputy sheriff, county traffic officer or other peace officer of any city, county, village or town, who is required by command of the governor, sheriff or other superior authority to maintain the peace, or who responds to the request of the authorities of another municipality, to perform police or peace duties outside territorial limits of the city, county, village or town where the officer is employed, is entitled to the same wage, salary, pension, worker's compensation, and all other service rights for this service as for service rendered within the limits of the city, county, village or town where regularly employed.

(2) All wage and disability payments, pension and worker's compensation claims, damage to equipment and clothing, and medical expense arising under sub. (1), shall be paid by the city, county, village or town regularly employing the officer. Upon making the payment the city, county, village or town shall be reimbursed by the state, county or other political subdivision whose officer or agent commanded the services out of which the payments arose.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (7)

W. S. A. 66.0513, WI ST 66.0513
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0515

66.0515. Receipts for fees

Currentness

Every officer or employee upon receiving fees shall, if requested to do so by the person paying the fees, deliver to that person a receipt for the fees, specifying for which account each portion of the fees respectively accrued.

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 270

Note: Renumbers and amends s. 66.113 to provide that a municipal employee, as well as an officer, must supply a receipt for any fee received when requested to do so by the person paying the fee. The penalty for failure to supply a receipt is eliminated; violations may be prosecuted under s. 946.12, relating to misconduct in public office.

W. S. A. 66.0515, WI ST 66.0515
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0517

66.0517. Weed commissioner

Currentness

(1) Definition. In this section, "noxious weeds" has the meaning given in s. 66.0407(1)(b).

(2) Appointment. (a) *Town, village and city weed commissioner.* The chairperson of each town, the president of each village and the mayor of each city may appoint one or more commissioners of noxious weeds on or before May 15 in each year. A weed commissioner shall take the official oath and the oath shall be filed in the office of the town, village or city clerk. A weed commissioner shall hold office for one year and until a successor has qualified or the town chairperson, village president or mayor determines not to appoint a weed commissioner. If more than one commissioner is appointed, the town, village or city shall be divided into districts by the officer making the appointment and each commissioner shall be assigned to a different district. The town chairperson, village president or mayor may appoint a resident of any district to serve as weed commissioner in any other district of the same town, village or city.

(b) *County weed commissioner.* A county may by resolution adopted by its county board provide for the appointment of a county weed commissioner and determine the duties, term and compensation for the county weed commissioner. When a weed commissioner has been appointed under this paragraph and has qualified, the commissioner has the powers and duties of a weed commissioner described in this section. Each town chairperson, village president or mayor may appoint one or more deputy weed commissioners, who shall work in cooperation with the county weed commissioner in the district assigned by the appointing officer.

(3) Powers, duties and compensation. (a) *Destruction of noxious weeds.* A weed commissioner shall investigate the existence of noxious weeds in his or her district. If a person in a district neglects to destroy noxious weeds as required under s. 66.0407(3), the weed commissioner shall destroy, or have destroyed, the noxious weeds in the most economical manner. A weed commissioner may enter upon any lands that are not exempt under s. 66.0407(5) and cut or otherwise destroy noxious weeds without being liable to an action for trespass or any other action for damages resulting from the entry and destruction, if reasonable care is exercised.

(b) *Compensation of weed commissioner.* 1. Except as provided in sub.(2)(b), a weed commissioner shall receive compensation for the destruction of noxious weeds as determined by the town board, village board, or city council upon presenting to the proper treasurer the account for noxious weed destruction, verified by oath and approved by the appointing officer. The account shall specify by separate items the amount chargeable to each piece of land, describing the land, and shall, after being paid by the treasurer, be filed with the town, village, or city clerk. The clerk shall enter the amount chargeable to each tract of land in the next tax roll in a column headed "For the Destruction of Weeds", as a tax on the lands upon which the weeds were destroyed. The tax shall be collected under ch. 74, except in case of lands which are exempt from taxation, railroad lands, or other lands for which taxes are not collected under ch. 74. A delinquent tax may be collected as is a delinquent real property tax under chs.

74 and 75 or as is a delinquent personal property tax under ch. 74. In case of railroad lands or other lands for which taxes are not collected under ch. 74, the amount chargeable against these lands shall be certified by the town, village, or city clerk to the secretary of administration who shall add the amount designated to the sum due from the company owning, occupying, or controlling the lands specified. The secretary of administration shall collect the amount chargeable as prescribed in subch. I of ch. 76 and return the amount collected to the town, city, or village from which the certification was received.

2. For the performance of duties other than the destruction of noxious weeds, a weed commissioner shall receive compensation to be determined by the town board, village board or city council.

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 154

Note: Creates s. 66.0517 of the statutes in order to combine the provisions regarding weed commissioners contained in ss. 66.97 to 66.99. The latter statutes are repealed in Section 620 of this bill. The new provision specifies that the appointment of a town, village or city weed commissioner is optional. The provision also differs from s. 66.97 by treating a 1st class city in the same manner as any other city. Otherwise, ss. 66.97 to 66.99 are restated.

Notes of Decisions (9)

W. S. A. 66.0517, WI ST 66.0517
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0518

66.0518. Defined benefit pension plans

Currentness

A local governmental unit, as defined in s. 66.0131(1)(a), may not establish a defined benefit pension plan for its employees unless the plan requires the employees to pay half of all actuarially required contributions for funding benefits under the plan and prohibits the local governmental unit from paying on behalf of an employee any of the employee's share of the actuarially required contributions.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0518, WI ST 66.0518
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.052

66.052. Renumbered 66.0415 and amended by 1999 Act 150, § 155, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.052, WI ST 66.052
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.053

66.053. Renumbered 66.0433 and amended by 1999 Act 150, § 156, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.053, WI ST 66.053
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.054, 66.055. Repealed by L.1981, c. 79, § 4, eff. July 1, 1982

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W.S.A. 66.054

66.054, 66.055. Repealed by L.1981, c. 79, § 4, eff. July 1, 1982

Currentness

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--L.1981, C. 79

The substance of ss. 66.054 and 66.055, relating to the regulation of the sale of fermented malt beverages, is recodified in ch. 125.

W. S. A. 66.054, WI ST 66.054
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.054, 66.055. Repealed by L.1981, c. 79, § 4, eff. July 1, 1982

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W.S.A. 66.055

66.054, 66.055. Repealed by L.1981, c. 79, § 4, eff. July 1, 1982

Currentness

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--L.1981, C. 79

The substance of ss. 66.054 and 66.055, relating to the regulation of the sale of fermented malt beverages, is recodified in ch. 125.

W. S. A. 66.055, WI ST 66.055
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.056

66.056. Renumbered 125.08 by L.1981, c. 202, § 1, eff. July 1, 1982

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.056, WI ST 66.056
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.057

66.057. Renumbered 157.129 and amended by 1999 Act 150, § 157, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.057, WI ST 66.057
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.058

66.058. Renumbered 66.0435(1) to (8) and amended by 1999 Act 150, §§ 158 to 160, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.058, WI ST 66.058
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0585

66.0585. Renumbered 66.0435(9) and amended by 1999 Act 150, § 161, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0585, WI ST 66.0585
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.059

66.059. Renumbered 66.0619 and amended by 1999 Act 150, § 162, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.059, WI ST 66.059
Current through 2023 Act 272, published April 10, 2024.

End of Document


KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.06. Repealed by 1999 Act 150, § 163, eff. Jan. 1, 2001

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Subchapter V. Officers and Employees

W.S.A. 66.06

66.06. Repealed by 1999 Act 150, § 163, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.06, WI ST 66.06
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
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Subchapter VI. Finance; Revenues

W.S.A. 66.0601

66.0601. Appropriations

Currentness

(1) Prohibited appropriations. (a) *Bonus to state institution.* No appropriation or bonus, except a donation, may be made by a town, village, or city, nor municipal liability created nor tax levied, as a consideration or inducement to the state to locate any public educational, charitable, reformatory, or penal institution.

(b) *Payments for abortions restricted.* No city, village, town, long-term care district under s. 46.2895 or agency or subdivision of a city, village or town may authorize funds for or pay to a physician or surgeon or a hospital, clinic or other medical facility for the performance of an abortion except those permitted under and which are performed in accordance with s. 20.927.

(c) *Payments for abortion-related activity restricted.* No city, village, town, long-term care district under s. 46.2895 or agency or subdivision of a city, village or town may authorize payment of funds for a grant, subsidy or other funding involving a pregnancy program, project or service if s. 20.9275(2) applies to the pregnancy program, project or service.

(2) Celebration of holidays. A town, county, school board, or school district may appropriate money for the purpose of initiating or participating in appropriate celebrations of any legal holiday listed in s. 995.20.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0601, WI ST 66.0601
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
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Subchapter VI. Finance; Revenues

W.S.A. 66.0602

66.0602. Local levy limits

Currentness

(1) Definitions. In this section:

(a) "Debt service" includes debt service on debt issued or reissued to fund or refund outstanding municipal or county obligations, interest on outstanding municipal or county obligations, and related issuance costs and redemption premiums.

(ak) "Joint emergency medical services district" means a joint emergency medical services district organized by any combination of 2 or more cities, villages, or towns under s. 66.0301(2).

(am) "Joint fire department" means a joint fire department organized under s. 61.65(2)(a)3. or 62.13(1m), or a joint fire department organized by any combination of 2 or more cities, villages, or towns under s. 66.0301(2).

(au) "Municipality" means a city, village, or town.

(b) "Penalized excess" means the levy, in an amount that is at least $500 over the limit under sub. (2) for the political subdivision, not including any amount that is excepted from the limit under subs. (3), (4), and (5).

(c) "Political subdivision" means a city, village, town, or county.

(cm) "Tax incremental base" has the meaning given in s. 66.1105(2)(j).

(d) "Valuation factor" means a percentage equal to the greater of either the percentage change in the political subdivision's January 1 equalized value due to new construction less improvements removed between the previous year and the current or 0 percent. For a tax incremental district created after December 31, 2024, and for Tax Incremental District Number 10 created by the common council of the city of Evansville, and for Tax Incremental District Number 14 created by the common council of the city of Stevens Point, the valuation factor includes 90 percent of the equalized value increase due to new construction that is located in a tax incremental district, but does not include any improvements removed in a tax incremental district. [1]

(e) "Value increment" has the meaning given in s. 66.1105(2)(m).

(2) Levy limit. (a) Except as provided in subs. (3), (4), and (5), no political subdivision may increase its levy in any year by a percentage that exceeds the political subdivision's valuation factor. Except as provided in par. (b), the base amount in any year, to which the limit under this section applies, shall be the actual levy for the immediately preceding year. In determining its levy in any year, a city, village, or town shall subtract any tax increment that is calculated under s. 59.57(3)(a), 60.85(1)(L), or 66.1105(2)(i). The base amount in any year, to which the limit under this section applies, may not include any amount to which sub. (3)(e)8. applies.

(b) For purposes of par. (a), in 2018, and in each year thereafter, the base amount to which the limit under this section applies is the actual levy for the immediately preceding year, plus the amount of the payments under ss. 79.096 and 79.0965, and the levy limit is the base amount multiplied by the valuation factor, minus the amount of the payments under ss. 79.096 and 79.0965, except that the adjustments for payments received under s. 79.096 or 79.0965 do not apply to payments received under s. 79.096(3) or 79.0965(3) for a tax incremental district that has been terminated.

(2m) Negative adjustment. (a) If a political subdivision's levy for the payment of any general obligation debt service, including debt service on debt issued or reissued to fund or refund outstanding obligations of the political subdivision and interest on outstanding obligations of the political subdivision, on debt originally issued before July 1, 2005, is less in the current year than it was in the previous year, the political subdivision shall reduce its levy limit in the current year by an amount equal to the amount that its levy was reduced as described in this subsection.

(b)1. In this paragraph, "covered service" means garbage collection, fire protection, snow plowing, street sweeping, or storm water management, except that garbage collection may not be a covered service for any political subdivision that owned and operated a landfill on January 1, 2013. With regard to fire protection, "covered service" does not include the production, storage, transmission, sale and delivery, or furnishing of water for public fire protection purposes.

2. Except as provided in subd. 4., if a political subdivision receives revenues that are designated to pay for a covered service that was funded in 2013 by the levy of the political subdivision, the political subdivision shall reduce its levy limit in the current year by an amount equal to the estimated amount of fee revenue collected for providing the covered service, less any previous reductions made under this subdivision, not to exceed the amount funded in 2013 by the levy of the political subdivision.

3. Except as provided in subd. 4., if a political subdivision receives payments in lieu of taxes that are designated to pay for a covered service that was funded in 2013 by the levy of the political subdivision, the political subdivision shall reduce its levy limit in the current year by the estimated amount of payments in lieu of taxes received by the political subdivision to pay for the covered service, less any previous reductions made under this subdivision, not to exceed the amount funded in 2013 by the levy of the political subdivision.

4. The requirement under subd. 2. or 3. does not apply if the governing body of the political subdivision adopts a resolution that the levy limit should not be reduced and if the resolution is approved in a referendum. The procedure under sub. (4) applies to a referendum under this subdivision, except that the resolution and referendum question need not specify an amount of increase in the levy limit or the length of time for which the levy limit increase will apply .

(3) Exceptions. (a) If a political subdivision transfers to another governmental unit responsibility for providing any service that the political subdivision provided in the preceding year, the levy increase limit otherwise applicable under this section to the political subdivision in the current year is decreased to reflect the cost that the political subdivision would have incurred to provide that service, as determined by the department of revenue. The levy increase limit adjustment under this paragraph applies only if the transferor and transferee file a notice of service transfer with the department of revenue.

(b) If a political subdivision increases the services that it provides by adding responsibility for providing a service transferred to it from another governmental unit that provided the service in the preceding year, the levy increase limit otherwise applicable under this section to the political subdivision in the current year is increased to reflect the cost of that service, as determined by the department of revenue. The levy increase limit adjustment under this paragraph applies only if the transferor and transferee file a notice of service transfer with the department of revenue.

(c) If a city or village annexes territory from a town, the city's or village's levy increase limit otherwise applicable under this section is increased in the current year by an amount equal to the town levy on the annexed territory in the preceding year and the levy increase limit otherwise applicable under this section in the current year for the town from which the territory is annexed is decreased by that same amount, as determined by the department of revenue.

(d)1. If the amount of debt service for a political subdivision in the preceding year is less than the amount of debt service needed in the current year, as a result of the political subdivision adopting a resolution before July 1, 2005, authorizing the issuance of debt, the levy increase limit otherwise applicable under this section to the political subdivision in the current year is increased by the difference between these 2 amounts, as determined by the department of revenue.

2. The limit otherwise applicable under this section does not apply to amounts levied by a political subdivision for the payment of any general obligation debt service, including debt service on debt issued or reissued to fund or refund outstanding obligations of the political subdivision, interest on outstanding obligations of the political subdivision, or the payment of related issuance costs or redemption premiums, authorized on or after July 1, 2005, and secured by the full faith and credit of the political subdivision.

3. The limit otherwise applicable under this section does not apply to amounts levied by a county having a population of 750,000 or more for the payment of debt service on appropriation bonds issued under s. 59.85, including debt service on appropriation bonds issued to fund or refund outstanding appropriation bonds of the county, to pay related issuance costs or redemption premiums, or to make payments with respect to agreements or ancillary arrangements authorized under s. 59.86.

4. If the amount of a lease payment related to a lease revenue bond for a political subdivision in the preceding year is less than the amount of the lease payment needed in the current year, as a result of the issuance of a lease revenue bond before July 1, 2005, the levy increase limit otherwise applicable under this section to the political subdivision in the current year is increased by the difference between these 2 amounts.

5. The limit otherwise applicable under this section does not apply to amounts levied by a 1st class city for the payment of debt service on appropriation bonds issued under s. 62.62, including debt service on appropriation bonds issued to fund or refund outstanding appropriation bonds of the city, to pay related issuance costs or redemption premiums, or to make payments with respect to agreements or ancillary arrangements authorized under s. 62.621.

6. The limit otherwise applicable under this section does not apply to the amount that a political subdivision levies to make up any revenue shortfall for the debt service on a special assessment B bond issued under s. 66.0713(4).

(dm) For a tax incremental district created before January 1, 2025, if the department of revenue does not certify a value increment for a tax incremental district for the current year as a result of the district's termination, the levy increase limit otherwise applicable under this section in the current year to the political subdivision in which the district is located is increased by an amount equal to the political subdivision's maximum allowable levy for the immediately preceding year, multiplied by a percentage equal to 50 percent of the amount determined by dividing the value increment of the terminated tax incremental district, calculated for the previous year, by the political subdivision's equalized value, exclusive of any tax incremental district value increments, for the previous year, all as determined by the department of revenue.

(dq)1. For a tax incremental district created after December 31, 2024, and for Tax Incremental District Number 10 created by the common council of the city of Evansville, and for Tax Incremental District Number 14 created by the common council of the city of Stevens Point, if the department of revenue does not certify a value increment for the tax incremental district for the current year as a result of the district's termination, the levy increase limit otherwise applicable under this section in the current year to the political subdivision in which the district is located is increased by all of the following amounts: [2]

a. An amount equal to the political subdivision's maximum allowable levy for the immediately preceding year, multiplied by the amount determined by dividing 10 percent of the equalized value increase of the terminated tax incremental district, calculated as provided in subd. 2., by the political subdivision's equalized value, less any tax incremental district value increments, for the previous year, all as determined by the department of revenue.

b. If the life span of the tax incremental district was 75 percent or less of the length of the expected life span of the tax incremental district, measured as the period between the year the tax incremental district was created and the expected year of termination, as designated under s. 66.1105(4m)(b)2m., an additional amount equal to the political subdivision's maximum allowable levy for the immediately preceding year, multiplied by the amount determined by dividing 15 percent of the equalized value increase of the terminated tax incremental district, calculated as provided in subd. 2., by the political subdivision's equalized value, less any tax incremental district value increments, for the previous year, all as determined by the department of revenue.

2. The equalized value increase under subd. 1. and par. (dv) is calculated by adding the annual amounts reported under s. 66.1105(6m)(c)8. of the value of new construction in the district for each year that the district is active.

(ds) For a tax incremental district created before January 1, 2025, if the department of revenue recertifies the tax incremental base of a tax incremental district as a result of the district's subtraction of territory under s. 66.1105(4)(h)2., the levy limit otherwise applicable under this section shall be adjusted in the first levy year in which the subtracted territory is not part of the value increment. In that year, the political subdivision in which the district is located shall increase the levy limit otherwise applicable by an amount equal to the political subdivision's maximum allowable levy for the immediately preceding year, multiplied by a percentage equal to 50 percent of the amount determined by dividing the value increment of the tax incremental district's territory that was subtracted, calculated for the previous year, by the political subdivision's equalized value, exclusive of any tax incremental district value increments, for the previous year, all as determined by the department of revenue.

(dv) For a tax incremental district created after December 31, 2024, and for Tax Incremental District Number 10 created by the common council of the city of Evansville, and for Tax Incremental District Number 14 created by the common council

of the city of Stevens Point, if the department of revenue recertifies the tax incremental base of a tax incremental district as a result of the district's subtraction of territory under s. 66.1105(4)(h)2., the levy limit otherwise applicable under this section shall be adjusted in the first levy year in which the subtracted territory is not part of the value increment. In that year, the political subdivision in which the district is located shall increase the levy limit otherwise applicable by an amount equal to the political subdivision's maximum allowable levy for the immediately preceding year, multiplied by a percentage equal to 10 percent of the amount determined by dividing the equalized value increase, calculated as provided in par. (dq)2., attributable to the territory that was subtracted, calculated for the previous year, by the political subdivision's equalized value, exclusive of any tax incremental district value increments, for the previous year, all as determined by the department of revenue. [3]

(e) The limit otherwise applicable under this section does not apply to any of the following:

1. The amount that a county levies in that year for a county children with disabilities education board.

2. The amount that a 1st class city levies in that year for school purposes.

3. The amount that a county levies in that year under s. 82.08(2) for bridge and culvert construction and repair.

4. The amount that a county levies in that year to make payments to public libraries under s. 43.12.

5. The amount that a political subdivision levies in that year to make up any revenue shortfall for the debt service on a revenue bond issued under s. 66.0621 by the political subdivision or by a joint fire department if the joint fire department uses the proceeds of the bond to pay for a fire station and assesses the political subdivision for its share of that debt, under an agreement entered into under s. 66.0301, which is incurred by the joint fire department but is the responsibility of the political subdivision.

6. The amount that a county levies in that year for a countywide emergency medical system.

7. The amount that a village levies in that year for police protection services, but this subdivision applies only to a village's levy for the year immediately after the year in which the village changes from town status and incorporates as a village, and only if the town did not have a police force.

8. The amount that a political subdivision levies in that year to pay the unreimbursed expenses related to an emergency declared under s. 323.10, including any amounts levied in that year to replenish cash reserves that were used to pay any unreimbursed expenses related to that emergency. A levy under this subdivision that relates to a particular emergency initially shall be imposed in the year in which the emergency is declared or in the following year.

9. The political subdivision's share of any refund or rescission determined by the department of revenue and certified under s. 74.41(5).

(f)1. Subject to subd. 3., and unless a political subdivision makes an adjustment under par. (fm), if a political subdivision's allowable levy under this section in the prior year was greater than its actual levy in that year, the levy increase limit otherwise applicable under this section to the political subdivision in the next succeeding year is increased by the difference between

the prior year's allowable levy and the prior year's actual levy, as determined by the department of revenue, up to a maximum increase of 1.5 percent of the actual levy in that prior year.

3. The adjustment described in subd. 1. may occur only if the political subdivision's governing body approves of the adjustment by one of the following methods:

a. With regard to a city, village, or county, if the governing body consists of at least 5 members, by a majority vote of the governing body if the increase is 0.5 percent or less and by a three-quarters majority vote of the governing body if the increase is more than 0.5 percent, up to a maximum increase of 1.5 percent.

b. With regard to a city, village, or county, if the governing body consists of fewer than 5 members, by a majority vote of the governing body if the increase is 0.5 percent or less and by a two-thirds majority vote of the governing body if the increase is more than 0.5 percent, up to a maximum increase of 1.5 percent.

c. With a regard to a town, by a majority vote of the annual town meeting, or a special town meeting, if the town board has adopted a resolution approving of the adjustment by a majority vote of the town board if the increase is 0.5 percent or less and by a two-thirds majority vote of the town board if the increase is more than 0.5 percent, up to a maximum increase of 1.5 percent.

(fm)1. Subject to subds. 3. and 4., a political subdivision's levy increase limit otherwise applicable under this section may be increased by any amount up to the maximum adjustment specified under subd. 2.

2. The maximum adjustment allowed under subd. 1. shall be calculated by adding the difference between the political subdivision's valuation factor in the previous year and the actual percent increase in a political subdivision's levy attributable to the political subdivision's valuation factor in the previous year, for the 5 years before the current year, less any amount claimed under subd. 1. in one of the 5 preceding years, except that the calculation may not include any year before 2014, and the maximum adjustment as calculated under this subdivision may not exceed 5 percent.

3. The adjustment described in subd. 1. may occur only if the political subdivision's governing body approves of the adjustment by a two-thirds majority vote of the governing body and if the political subdivision's level of outstanding general obligation debt in the current year is less than or equal to the political subdivision's level of outstanding general obligation debt in the previous year.

4. This paragraph first applies to a levy that is imposed in 2015, and no political subdivision may make an adjustment under this paragraph if it makes an adjustment under par. (f) for the same year.

(g) If a county has provided a service in a part of the county in the preceding year and if a city, village, or town has provided that same service in another part of the county in the preceding year, and if the provision of that service is consolidated at the county level, the levy increase limit otherwise applicable under this section to the county in the current year is increased to reflect the total cost of providing that service, as determined by the department of revenue.

(h) 1. Subject to subd. 2., the limit otherwise applicable under this section does not apply to the amount that a city, village, or town levies in that year to pay for charges assessed by a joint fire department or a joint emergency medical services district,

but only to the extent that the amount levied to pay for such charges would cause the city, village, or town to exceed the limit that is otherwise applicable under this section.

2. The exception to the limit that is described under subd. 1. applies only if all of the following apply:

a. The total charges assessed by the joint fire department or the joint emergency medical services district for the current year increase, relative to the total charges assessed by the joint fire department or the joint emergency medical services district for the previous year, by a percentage that is less than or equal to the percentage change in the U.S. consumer price index for all urban consumers, U.S. city average, as determined by the U.S. department of labor, for the 12 months ending on August 31 of the year of the levy, plus 2 percent.

b. The governing body of each city, village, and town that is served by the joint fire department or the joint emergency medical services district adopts a resolution in favor of exceeding the limit as described in subd. 1.

(i)1. If a political subdivision enters into an intergovernmental cooperation agreement under s. 66.0301 to jointly provide a service on a consolidated basis with another political subdivision, and if one of the political subdivisions increases its levy from the previous year by an amount the parties to the agreement agree is needed to provide a more equitable distribution of payments for services received, the levy increase limit otherwise applicable under this section to that political subdivision in the current year is increased by that agreed amount.

2. If a political subdivision increases its levy as described in subd. 1. the other political subdivision, which is a party to the intergovernmental cooperation agreement and has agreed to the adjustment under subd. 1., shall decrease its levy in the current year by the same amount that the first political subdivision is allowed to increase its levy under subd. 1.

(j)1. Subject to subd. 2., if a municipality experiences a shortfall in its general fund due to a loss of revenue received by the municipality from the sale of water or another commodity to a manufacturing facility as a result of the manufacturer discontinuing operations at the facility, the limit otherwise applicable under this section may be increased by the amount that the municipality levies to make up for the revenue shortfall.

2. The maximum adjustment claimed under subd. 1. shall equal the revenue received by the municipality from the sale of water or another commodity, as described in subd. 1., in the year prior to the year in which the manufacturing facility closed. A municipality may claim the adjustment in more than one year, except that the sum of all such adjustments may not exceed the revenue loss to the municipality's general fund in the year that the manufacturer discontinues operations at the facility.

(k)1. Subject to subds. 2. and 3., if the village of Shorewood reduces its levy from the amount it would have levied for 2011 if not for an error in the valuation of Tax Incremental District Number 1 in the village, to compensate for that error, the limit otherwise applicable under this section to the village in 2012 is increased by the amount of the reduction, as determined by the department of revenue. The amounts added to the village's limit for 2012 under this subdivision may not exceed the amount by which the village underutilized its limit for 2011, as determined by the department of revenue.

2. If the village of Shorewood applies funds from the village's general fund in 2011 to replace amounts not levied to compensate for an error in the valuation of Tax Incremental District Number 1 in the village, the limits otherwise applicable under this section to the village in 2012 and 2013 are increased by the amount applied from the general fund in 2011, as determined by

the department of revenue. The village's limit increases under this subdivision for 2012 and 2013 do not increase the village's limit for any subsequent year.

3. The combined amount of increased levy in 2012 and 2013 by the village of Shorewood under subd. 2. may not exceed the amount of the funds applied from the general fund to replace amounts not levied in 2011 to compensate for an error in the valuation of Tax Incremental District Number 1 in the village.

(L) If the village of Warrens reduces its levy from the amount it would have levied for 2012 if not for an error in the valuation of Tax Incremental District Number 1 in the village, to compensate for that error, the limit otherwise applicable under this section to the village in 2013 is increased by the amount of the reduction, as determined by the department of revenue. The amounts added to the village's limit for 2013 under this paragraph may not exceed the amount by which the village underutilized its limit for 2012, as determined by the department of revenue.

(Lm) If the city of Fox Lake reduces its levy from the amount it would have levied for 2012 if not for an error in the valuation of Tax Incremental District Number 1 in the city, to compensate for that error, the limit otherwise applicable under this section to the city in 2013 is increased by the amount of the reduction, as determined by the department of revenue. The amounts added to the city's limit for 2013 under this paragraph may not exceed the amount by which the city underutilized its limit for 2012, as determined by the department of revenue.

(m)1. The levy increase limit otherwise applicable under this section to a city, village, or town in the current year is increased by $1,000 for each new single-family residential dwelling unit for which a city, village, or town issues an occupancy permit in the preceding year and that is all of the following:

a. Located on a parcel of no more than 0.25 acre in a city or village, or on a parcel of no more than one acre in a town.

b. Sold in the preceding year for not more than 80 percent of the median price of a new residential dwelling unit in the city, village, or town in the preceding year.

2. Amounts levied under this paragraph may be used only for police protective services, fire protective service, or emergency medical services.

3. If a city, village, or town levies an amount under this paragraph, the city, village, or town may not decrease the amount it spends for police protective services, fire protective services, or emergency medical services below the amount the city, village, or town spent in the preceding year.

(n)1. For a political subdivision that receives a payment under s. 79.04(5)(a) or (b), the limit otherwise applicable under this section is increased by the amount that the political subdivision levies in that year to replace a revenue reduction incurred under s. 79.04(5)(a) or (b). Subject to subd. 2., the amount levied under this paragraph for a particular property may not exceed the amount paid to the political subdivision under s. 79.04(5)(a)1. or (b)1. less the amount to be paid to the political subdivision under s. 79.04(5)(a) or (b) in the year in which the levy is imposed and less any amounts previously levied under this paragraph. A revenue reduction is incurred under this paragraph when the amount received by a political subdivision under s. 79.04(5)(a) or (b) in the current year is less than the amount received under s. 79.04(5)(a) or (b) in the previous year.

2. This paragraph applies to revenue reductions for which a payment under s. 79.04(5)(a) or (b) is made after November 23, 2019. If the first payment made under s. 79.04(5)(a) or (b) after November 23, 2019, is under s. 79.04(5)(a)2. to 5. or (b)2. to 5., the amount of the payment made under s. 79.04(5)(a) or (b) in the previous year shall be used in determining the maximum amount of revenue reduction incurred.

(4) Referendum exception. (a) A political subdivision may exceed the levy increase limit under sub. (2) if its governing body adopts a resolution to that effect and if the resolution is approved in a referendum. For purposes of this paragraph, the political subdivision may use its best estimate of its valuation factor, based on the most current data available to it. The resolution shall specify the proposed amount of increase in the levy, the purpose for which the increase will be used, and whether the proposed amount of increase is for the next fiscal year only or if it will apply on an ongoing basis. With regard to a referendum relating to any levy in an odd-numbered year, the political subdivision may call a special referendum for the purpose of submitting the resolution to the electors of the political subdivision for approval or rejection on the same election dates as when a school board may call for a referendum under s. 121.91(3). Otherwise, the referendum shall be held at the spring primary or election or partisan primary or general election.

(b) The clerk of the political subdivision shall publish type A, B, C, D, and E notices of the referendum under s. 10.01(2). Section 5.01(1) applies in the event of failure to comply with the notice requirements of this paragraph.

(c) The referendum shall be held in accordance with chs. 5 to 12. The political subdivision shall provide the election officials with all necessary election supplies. The form of the ballot shall correspond substantially with the standard form for referendum ballots under ss. 5.64(2) and 7.08(1)(a). The question shall be submitted as follows: “Under state law, the increase in the levy of the .... (name of political subdivision) for the tax to be imposed for the next fiscal year, ... (year), is limited to ....% (based on actual data or the political subdivision's best estimate), which results in a levy of $.... Shall the .... (name of political subdivision) be allowed to exceed this limit and increase the levy for the next fiscal year, ... (year), for .... (purpose for which the increase will be used), by a total of ....% (based on actual data or the political subdivision's best estimate), which results in a levy of $....?”. If the increase is for the next fiscal year only, the question shall include the percentage increase in the levy from the previous year's levy, and, if the increase is on an ongoing basis, the question shall include the amount of the increase for each fiscal year for which the increase applies.

(d) Within 14 days after the referendum, the clerk of the political subdivision shall certify the results of the referendum to the department of revenue. The levy increase limit otherwise applicable to the political subdivision under this section is increased in the next fiscal year by the percentage approved by a majority of those voting on the question. If the resolution specifies that the increase is for one year only, the amount of the increase shall be subtracted from the base used to calculate the limit for the 2nd succeeding fiscal year.

(5) Exception, certain towns. A town with a population of less than 3,000 may exceed the levy increase limit otherwise applicable under this section to the town if the town board adopts a resolution supporting an increase and places the question on the agenda of an annual town meeting or a special town meeting and if the annual or special town meeting adopts a resolution endorsing the town board's resolution. The limit otherwise applicable to the town under this section is increased in the next fiscal year by the percentage approved by a majority of those voting on the question. Within 14 days after the adoption of the resolution, the town clerk shall certify the results of the vote to the department of revenue.

(6) Penalties. Except as provided in sub. (6m), if the department of revenue determines that a political subdivision has a penalized excess in any year, the department of revenue shall do all of the following:

(a) Reduce the amount of the payment to the political subdivision under s. 79.02(1) in the following year by an amount equal to the amount of the penalized excess.

(b) Ensure that the amount of any reductions in payments under par. (a) lapses to the general fund.

(c) Ensure that the amount of the penalized excess is not included in determining the limit described under sub. (2) for the political subdivision for the following year.

(d) Ensure that, if a political subdivision's penalized excess exceeds the amount of aid payment that may be reduced under par. (a), the excess amount is subtracted from the aid payments under par. (a) in the following years until the total amount of penalized excess is subtracted from the aid payments.

(6m) Mistakes in levies. The department of revenue may issue a finding that a political subdivision is not liable for a penalty that would otherwise be imposed under sub. (6) if the department determines that the political subdivision's penalized excess is caused by one of the following clerical errors:

(a) The department, through mistake or inadvertence, has assessed to any county or taxation district, in the current year or in the previous year, a greater or less valuation for any year than should have been assessed, causing the political subdivision's levy to be erroneous in a way that directly causes a penalized excess.

(b) A taxation district clerk or a county clerk, through mistake or inadvertence in preparing or delivering the tax roll, causes a political subdivision's levy to be erroneous in a way that directly causes a penalized excess.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

JOINT LEGISLATIVE COUNCIL PREFATORY NOTES--2015 ACT 256

This bill was prepared for the Joint Legislative Council's Study Committee on Review of Tax Incremental Financing.

Industrial Zoning Requirement in Tax Incremental Districts

Under current law, a resolution to create a tax incremental district (TID) must include a finding that not less than 50 percent, by area, of the real property within the district is at least one of the following: a blighted area; in need of rehabilitation or conservation work; suitable for industrial sites and zoned for industrial use; or suitable for mixed-use development. The resolution must also confirm that any real property within the district that is found suitable for industrial sites and is zoned for industrial use will remain zoned for industrial use for the life of the tax incremental district, and must declare that the district is a blighted area district, a rehabilitation or conservation district, an industrial district, or a mixed-use district based on the identification and classification of the property included within the district.

The bill specifies that the requirement related to maintenance of industrial zoning applies on to districts that declared to be industrial districts.

Planning Commission Notice for TID Amendments

Under current law, a TID's project plan may be amended for several reasons, including modification of the expenditures allowed in a TID's project plan, addition or subtraction of territory to the TID's boundaries, extension of the TID's lifespan, and donation of tax increments to another TID.

Generally, the process to amend a TID's project plan is similar to the process of creating a TID, requiring a public hearing held by the planning commission and adoption of resolutions by the planning commission, municipality, and joint review board (JRB) to approve the plan or amendment. As part of this process, the planning commission must publish a class 2 notice of its public hearing. The JRB must publish notice of its meeting as a class 1 notice, at least five days before the meeting.

Under current law, a class 2 notice consists of insertions of the notice for two consecutive weeks, with the last insertion at least a week prior to the meeting date, in the appropriate newspaper of record under ch. 985, stats. A class 1 notice, unless otherwise specified (for example, the requirement that the JRB must publish a notice five days before its meeting), requires a single insertion of the notice, at least a week prior to the meeting date, in the appropriate newspaper of record.

The bill amends the notice requirement of the planning commission from a class 2 notice to a class 1 notice with regard to notices relating to the TID amendment process.

Obsolete References

Over time, the statutes relating to tax incremental financing have been amended to include numerous provisions that are significantly limited in their scope, often relating to a single municipality or a particular TID. Often, these amendments offer special statutory authorization regarding creation, amendment, or lifespan of a particular district or class of districts or to TIDs in a particular municipality.

The bill repealed certain provisions of the statutes relating to tax incremental financing that the Department of Revenue (DOR) identified as obsolete.

Timing Penalty

Under current law, certain statutory and administrative deadlines relating to the allocation of positive tax increments to a TID combine to resolute in variation in the maximum number of positive increments that may be allocated to a TID, depending on the date on which a municipality acted to create the TID and its project plan. In particular, the maximum number of positive increments that a TID may receive is one fewer for a TID and project plan created after September 30 and before May 15 than for TIDs created on or after May 15 and before October 1.

For newly created TIDs, the bill extends a TID's lifespan and allocation period of positive tax increments by one year if the municipality that created the TID adopts the project plan for the TID after September 30 and before May 15.

Joint Review Board Review Period

Before a municipality's resolution to create a TID, amend a TID's project plan, or require DOR to redetermine a TID's base value may take effect, several steps are required. One of these steps is JRB approval of a municipality's

TID resolution. A JRB consists of members who represent the overlying taxation districts. In general, the JRB must approve the resolution by a majority vote within 30 days after receiving the resolution. The review period applicable to an industry-specific TID located in a town and an environmental remediation TID is not less than 10 days nor more than 30 days.

The bill amends the maximum review period the JRB has to approve a municipality's TID resolution from 30 days to 45 days after receiving the resolution.

Calculation of Levy Limit Exception

Generally, under the current local levy law, and subject to a number of exceptions, a city, village, town, or county (political subdivision) may not increase its base levy (the prior year's actual levy) in any year by more than the percentage change in the political subdivision's equalized value due to new construction, less improvements removed, including new construction that occurs in a TID between the previous year and the current year, but not less than 0 percent. Also, when determining its levy limit, a municipality must exclude the amount of any tax increment generated by property in a TID located in the municipality.

There are numerous exceptions that may be used to adjust a political subdivision's levy limit. One exception authorizes an increase in a municipality's levy limit for the year that a TID terminates. If DOR does not certify a TID as a result of the district's termination, the levy limit otherwise applicable is increased by an amount equal to the municipality's maximum allowable levy for the preceding year, multiplied by a percentage equal to 50 percent of the amount determined by dividing the terminated TID's value increment by the municipality's equalized value, as determined by DOR. The increase must be applied to the municipality's levy limit in the year that the TID terminates.

The bill specifies that the municipality's equalized value for the preceding year, as used in the calculation of the levy limit exception for the year that a TID terminates, excludes the value of any TID value increments.

[Section 2] This section excludes the value of any TID increments from the calculation of the levy limit exception that applies for the year a TID terminates.

LAW REVISION COMMITTEE NOTES--2015 ACT 191

This bill is a remedial legislation proposal, requested by the Department of Revenue and introduced by the Law Revision Committee under s. 13.83(1)(c)4. and 5., stats. After careful consideration of the various provisions of the bill, the Law Revision Committee has determined that this bill makes minor substantive changes in the statutes, and that these changes are desirable as a matter of public policy.

[Section 1] Removes the reference to the elections board, which was eliminated by 2007 Wisconsin Act 1.

Footnotes

1 Par. (d) is shown as amended by 2023 Wis. Acts 135 and 136 and as merged by the legislative reference bureau under s. 13.92 (2) (i).

2 Subd. 1. (intro.) is shown as amended by 2023 Wis. Acts 135 and 136 and as merged by the legislative reference bureau under s. 13.92 (2) (i).

3 Par. (dv) is shown as amended by 2023 Wis. Acts 135 and 136 and as merged by the legislative reference bureau under s. 13.92 (2) (i).

W. S. A. 66.0602, WI ST 66.0602
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter VI. Finance; Revenues

W.S.A. 66.0603

66.0603. Investments

Currentness

(1g) Definition. In this section, "governing board" has the meaning given under s. 34.01(1) but does not include a local exposition district board created under subch. II of ch. 229 or a local cultural arts district board created under subch. V of ch. 229.

(1m) Investments. (a) A county, city, village, town, school district, drainage district, technical college district or other governing board, other than a local professional football stadium district board created under subch. IV of ch. 229, may invest any of its funds not immediately needed in any of the following:

1. Time deposits in any credit union, bank, savings bank, trust company, or savings and loan association which is authorized to transact business in this state.

2. Bonds or securities issued or guaranteed as to principal and interest by the federal government, or by a commission, board or other instrumentality of the federal government.

3. Bonds or securities of any county, city, drainage district, technical college district, village, town or school district of this state.

3m. Bonds issued by a local exposition district under subch. II of ch. 229.

3p. Bonds issued by a local professional baseball park district created under subch. III of ch. 229.

3q. Bonds issued by a local professional football stadium district created under subch. IV of ch. 229.

3s. Bonds issued by the University of Wisconsin Hospitals and Clinics Authority.

3t. Bonds issued by a local cultural arts district under subch. V of ch. 229.

3u. Bonds issued by the Wisconsin Aerospace Authority.

4. Any security which matures or which may be tendered for purchase at the option of the holder within not more than 7 years of the date on which it is acquired, if that security has a rating which is the highest or 2nd highest rating category assigned by Standard & Poor's corporation, Moody's investors service or other similar nationally recognized rating agency or if that security is senior to, or on a parity with, a security of the same issuer which has such a rating.

5. Securities of an open-end management investment company or investment trust, if the investment company or investment trust does not charge a sales load, if the investment company or investment trust is registered under the investment company act of 1940, 15 USC 80a-1 to 80a-64, and if the portfolio of the investment company or investment trust is limited to the following:

a. Bonds and securities issued by the federal government or a commission, board or other instrumentality of the federal government.

b. Bonds that are guaranteed as to principal and interest by the federal government or a commission, board or other instrumentality of the federal government.

c. Repurchase agreements that are fully collateralized by bonds or securities under subd. 5.a. or b.

(b)1. A town, city, or village may invest surplus funds in any bonds or securities issued under the authority of the municipality, whether the bonds or securities create a general municipality liability or a liability of the property owners of the municipality for special improvements, and may sell or hypothecate the bonds or securities. Funds of an employer, as defined by s. 40.02(28), in a deferred compensation plan may also be invested and reinvested in the same manner authorized for investments under s. 881.01.

2. Funds of any school district operating under ch. 119, held in trust for pension plans intended to qualify under section 401(a) of the Internal Revenue Code, other than funds held in the public employee trust fund, may be invested and reinvested in the same manner as is authorized for investments under s. 881.01.

3. A school district may invest and reinvest funds that are held in trust, other than funds held in the public employee trust fund, solely to provide any of the following benefits, in the same manner as is authorized for investments under s. 881.01:

a. Post-employment health care benefits provided either separately or through a defined benefit pension plan.

b. Other post-employment benefits provided separately from a defined benefit pension plan.

4. A school board may not discuss or vote on establishing a trust fund to provide the benefits described in subd. 3. unless the notice of the school board meeting at which the discussion or vote may occur includes the issue as a separate agenda item.

5. A city, village, town, county, drainage district, technical college district, or other governing board as defined by s. 34.01(1) may invest and reinvest funds that are held in trust, other than funds held in the public employee trust fund, solely to provide any of the following benefits, in the same manner as is authorized for investments under s. 881.01:

a. Post-employment health care benefits provided either separately or through a defined benefit pension plan.

b. Other post-employment benefits provided separately from a defined benefit pension plan.

6. Funds that are held in trust to provide the benefits described in subds. 3. and 5. shall be held in a trust fund that is separate from all other trust funds created by, or under the control of, the local governmental unit.

(c) A local government, as defined under s. 25.50(1)(d), may invest surplus funds in the local government pooled-investment fund. Cemetery care funds, including gifts where the principal is to be kept intact, may also be invested under ch. 881.

(d) A county, city, village, town, school district, drainage district, technical college district or other governing board as defined by s. 34.01(1) may engage in financial transactions in which a public depository, as defined in s. 34.01(5), agrees to repay funds advanced to it by the local government plus interest, if the agreement is secured by bonds or securities issued or guaranteed as to principal and interest by the federal government.

(e) Subject to s. 67.11(2) with respect to funds on deposit in a debt service fund for general obligation promissory notes issued under s. 67.12(12), a county having a population of 750,000 or more, or a person to whom the county has delegated investment authority under sub. (5), may invest and reinvest in the same manner as is authorized for investments and reinvestments under s. 881.01, any of the following:

1. Moneys held in any stabilization fund established under s. 59.87(3).

2. Moneys held in a fund or account, including any reserve fund, created in connection with the issuance of appropriation bonds under s. 59.85 or general obligation promissory notes under s. 67.12(12) issued to provide funds for the payment of all or a part of the county's unfunded prior service liability.

3. Moneys appropriated or held by the county to pay debt service on appropriation bonds or general obligation promissory notes under s. 67.12(12).

4. Moneys constituting proceeds of appropriation bonds or general obligation promissory notes described in subd. 2. that are available for investment until they are spent.

5. Moneys held in an employee retirement system of the county.

(f) Subject to s. 67.11(2) with respect to funds on deposit in a debt service fund for general obligation promissory notes issued under s. 67.12(12), a 1st class city, or a person to whom the city has delegated investment authority under sub. (5), may invest and reinvest in the same manner as is authorized for investments and reinvestments under s. 881.01, any of the following:

1. Moneys held in any stabilization fund established under s. 62.622(3).

2. Moneys held in a fund or account, including any reserve fund, created in connection with the issuance of appropriation bonds under s. 62.62 or general obligation promissory notes under s. 67.12(12) issued to provide funds for the payment of all or a part of the city's unfunded prior service liability.

3. Moneys appropriated or held by the city to pay debt service on appropriation bonds or general obligation promissory notes under s. 67.12(12).

4. Moneys constituting proceeds of appropriation bonds or general obligation promissory notes described in subd. 2. that are available for investment until they are spent.

5. Moneys held in an employee retirement system of the city.

(g) A technical college district that receives funds from participation in an auction of digital broadcast spectrum administered by the federal communications commission may hold those funds in trust and may invest and reinvest those funds in the same manner authorized for investments under s. 881.01. Funds held in trust under this paragraph may only be distributed from the trust in a manner consistent with ch. 38 and in accordance with the terms of the trust. Any trust formed pursuant to this paragraph shall be separate from any other trust created by, or under the control of, the technical college district.

(2) Delegation of investment authority. A county, city, village, town, school district, drainage district, technical college district or other governing board, as defined in s. 34.01(1), may delegate the investment authority over any of its funds not immediately needed to a state or national bank, or trust company, which is authorized to transact business in this state if all of the following conditions are met:

(a) The institution is authorized to exercise trust powers under s. 221.0316 or ch. 223.

(b) The governing board renews annually the investment agreement under which it delegates its investment authority, and reviews annually the performance of the institution with which its funds are invested.

(3) Additional delegation of investment authority. (a) In addition to the authority granted under sub. (2), a school district operating under ch. 119 may delegate the investment authority over any of its funds not immediately needed and held in trust for its qualified pension plans to an investment manager who meets the requirements and qualifications specified in the trust's investment policy and who is registered as an investment adviser under the Investment Advisers Act of 1940, 15 USC 80b-3.

(b) In addition to the authority granted under sub. (2), a school district may delegate the investment authority over the funds described under sub. (1m)(b)3. to an investment manager who meets the requirements and qualifications specified in the trust's investment policy and who is registered as an investment adviser under 15 USC 80b-3.

(c)1. In addition to the authority granted under sub. (2), a city, village, town, county, drainage district, technical college district, or other governing board as defined by s. 34.01(1) may delegate the investment authority over the funds described under sub. (1m)(b)5. to an investment manager who meets the requirements and qualifications specified in the trust's investment policy and who is registered as an investment adviser under 15 USC 80b-3.

2. If a unit of government described under subd. 1. has established a trust described in sub. (1m)(b)5., it shall annually publish a written report that states the amount in the trust, the investment return earned by the trust since the last report was published, the total disbursements made from the trust since the last report was published, and the name of the investment manager if investment authority has been delegated under subd. 1.

(d)1. In addition to the authority granted under sub. (2), a technical college district may delegate the investment authority over the funds described under sub. (1m)(g) to an investment manager who meets the requirements and qualifications specified in the trust's investment policy and who is registered as an investment adviser under the Investment Advisers Act of 1940, 15 USC 80b-3.

2. If a technical college district has established a trust described in sub. (1m)(g), it shall annually publish a written report that states the amount in the trust, the investment return earned by the trust since the last report was published, the total disbursements made from the trust since the last report was published, and the name of the investment manager if investment authority has been delegated under subd. 1.

(4) Invested fund proceeds in populous cities, use. In a 1st class city, all interest derived from invested funds held by the city treasurer in a custodial capacity on behalf of any political entity, except for pension funds, is general revenue of the city and shall revert to the city's general fund upon the approval by the political entity evidenced by a resolution adopted for that purpose.

(5) Delegation of investment authority in connection with pension financing in populous cities and counties. The governing body of a county having a population of 750,000 or more, or a 1st class city, may delegate investment authority over any of the moneys described in sub. (1m)(e) or (f) to any of the following persons, which shall be responsible for the general administration and proper operation of the county's or city's employee retirement system, subject to the governing body's finding that such person has expertise in the field of investments:

(a) A public board that is organized for such purpose under county or city ordinances.

(b) A trustee, investment advisor, or investment banking or consulting firm.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (10)

W. S. A. 66.0603, WI ST 66.0603
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0605

66.0605. Local government audits and reports

Currentness

Notwithstanding any other statute, the governing body of a county, city, village or town may require or authorize a financial audit of a municipal or county officer, department, board, commission, function or activity financed in whole or part from municipal or county funds, or if any portion of the funds are the funds of the county, city, village or town. The governing body may require submission of periodic financial reports by the officer, department, board, commission, function or activity.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0605, WI ST 66.0605
Current through 2023 Act 272, published April 10, 2024.

End of Document

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W.S.A. 66.0607

66.0607. Withdrawal or disbursement from local treasury

Currentness

(1) Except as otherwise provided in subs. (2) to (5) and in s. 66.0608(3m), in a county, city, village, town, or school district, all disbursements from the treasury shall be made by the treasurer upon the written order of the county, city, village, town, or school clerk after proper vouchers have been filed in the office of the clerk. If the statutes provide for payment by the treasurer without an order of the clerk, the clerk shall draw and deliver to the treasurer an order for the payment before or at the time that the payment is required to be made by the treasurer. This section applies to all special and general provisions of the statutes relative to the disbursement of money from the county, city, village, town, or school district treasury except s. 67.10(2).

(2) Notwithstanding other law, a county having a population of 750,000 or more may, by ordinance, adopt any other method of allowing vouchers, disbursing funds, reconciling outstanding county orders, reconciling depository accounts, examining county orders, and accounting consistent with accepted accounting and auditing practices, if the ordinance prior to its adoption is submitted to the department of revenue, which shall submit its recommendations on the proposed ordinance to the county board of supervisors.

(3) Except as provided in subs. (2), (3m) and (5), disbursements of county, city, village, town or school district funds from demand deposits shall be by draft or order check and withdrawals from savings or time deposits shall be by written transfer order. Written transfer orders may be executed only for the purpose of transferring deposits to an authorized deposit of the public depositor in the same or another authorized public depository. The transfer shall be made directly by the public depository from which the withdrawal is made. No draft or order check issued under this subsection may be released to the payee, nor is the draft or order check valid, unless signed by the clerk and treasurer. No transfer order is valid unless signed by the clerk and the treasurer. Unless otherwise directed by ordinance or resolution adopted by the governing body, a certified copy of which shall be filed with each public depository concerned, the chairperson of the county board, mayor, village president, town chairperson or school district president shall countersign all drafts or order checks and all transfer orders. The governing body may also, by ordinance or resolution, authorize additional signatures. In lieu of the personal signatures of the clerk and treasurer and any other required signature, the facsimile signature adopted by the person and approved by the governing body may be affixed to the draft, order check or transfer order. The use of a facsimile signature does not relieve an official from any liability to which the official is otherwise subject, including the unauthorized use of the facsimile signature. A public depository is fully warranted and protected in making payment on any draft or order check or transferring pursuant to a transfer order bearing a facsimile signature affixed as provided by this subsection notwithstanding that the facsimile signature may have been affixed without the authority of the designated persons.

(3m) A county, city, village, town or school district may process periodic payments through the use of money transfer techniques, including direct deposit, electronic funds transfer and automated clearinghouse methods. The county, municipal or school district treasurer shall keep a record of the date, payee and amount of each disbursement made by a money transfer technique.

(4) Except as provided in sub. (3m), if a board, commission or committee of a county, city, village, town or school district is vested by statute with exclusive control and management of a fund, including the audit and approval of payments from the fund, independently of the governing body, payments under this section shall be made by drafts or order checks issued by the county, city, village, town or school clerk upon the filing with the clerk of certified bills, vouchers or schedules signed by the proper officers of the board, commission or committee, giving the name of the claimant or payee, and the amount and nature of each payment.

(5) In a 1st class city, municipal disbursements of public moneys shall be by draft, order, check, order check or as provided under sub. (3m). Checks or drafts shall be signed by the treasurer and countersigned by the comptroller. Orders shall be signed by the mayor and clerk and countersigned by the comptroller, as provided in the charter of the city. Disbursements of school moneys shall be as provided by s. 119.50.

(6) Withdrawal or disbursement of moneys deposited in a public depository as defined in s. 34.01(5) by a treasurer as defined in s. 34.01(7), other than the elected, appointed or acting official treasurer of a county, city, village, town or school district, shall be by endorsement, written order, draft, share draft, check or other draft signed by the person or persons designated by written authorization of the governing board as defined in s. 34.01(1). The authorization shall conform to any statute covering the disbursement of the funds. A public depository is fully warranted and protected in making payment in accordance with the latest authorization filed with it.

(7) No order may be issued by a county, city, village, town, special purpose district, school district, cooperative education service agency or technical college district clerk in excess of funds available or appropriated for the purposes for which the order is drawn, unless authorized by a resolution adopted by the affirmative vote of two-thirds of the entire membership of the governing body.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (3)

W. S. A. 66.0607, WI ST 66.0607
Current through 2023 Act 272, published April 10, 2024.

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Subchapter VI. Finance; Revenues

W.S.A. 66.0608

66.0608. Protective services

Currentness

(1) Definitions. In this section:

(ak) "Emergency medical responder" has the meaning given in s. 256.01(4p).

(am) "Emergency medical responder volunteer funds" means funds of a municipality that are raised by employees of the municipality's emergency medical responder department, by volunteers, or by donation to the emergency medical responder department, for the benefit of the municipality's emergency medical responder department.

(aw) "Emergency medical services practitioner" has the meaning given in s. 256.01(5).

(b) "Emergency medical services practitioner volunteer funds" means funds of a municipality that are raised by employees of the municipality's emergency medical services practitioner department, by volunteers, or by donation to the emergency medical services practitioner department, for the benefit of the municipality's emergency medical services practitioner department.

(c) "Fire volunteer funds" means funds of a municipality that are raised by employees of the municipality's fire department, by volunteers, or by donation to the fire department, for the benefit of the municipality's fire department.

(f) "Municipality" means any city, village, or town.

(fm) "Political subdivision" means a city, village, town, or county.

(g) "Public depository" has the meaning given in s. 34.01(5).

(h) "Volunteer funds" means emergency medical services practitioner volunteer funds, fire volunteer funds, or emergency medical responder volunteer funds.

(2m) Maintenance of effort. (a) Beginning July 1, 2024, annually not later than July 1, except as provided in par. (c), all of the following apply:

1. A city, village, or town with a population of greater than 20,000 shall certify to the department of revenue that the city, village, or town has maintained a level of law enforcement that is at least equivalent to that provided in the city, village, or town in the previous year. The certification shall include a statement under par. (b)1. from the person in charge of providing law enforcement service for the city, village, or town, or for the city, village, or town under contract to provide this service.

2. A political subdivision shall certify to the department of revenue that the political subdivision has maintained a level of fire protective and emergency medical service that is at least equivalent to that provided in the political subdivision in the previous year. The certification shall include a statement under par. (b)2. from the person in charge of providing fire protective and emergency medical services for the political subdivision, or for the political subdivision under contract to provide this service.

3. A certification under this paragraph is not required to certify the same items under par. (b) or (c) that were certified in a prior statement.

(b)1. Except as provided in par. (c)1., [a certification under par. (a)1. shall include] [1] a statement that certifies that any of the following has been maintained at a level at least equivalent to the previous year:

a. Moneys raised by tax levy by the city, village, or town and expended for employment costs of law enforcement officers, as defined in s. 165.85(2)(c).

b. The percentage of the total moneys raised by tax levy by the city, village, or town that is expended for employment costs of law enforcement officers, as defined in s. 165.85(2)(c).

c. The number of full-time equivalent law enforcement officers, as defined in s. 165.85(2)(c), employed by or assigned to the city, village, or town, not including officers whose positions are funded by grants received from the state or federal government. The person in charge of providing law enforcement service for the city, village, or town may use any reasonable method of estimating the average number of full-time equivalent law enforcement officers employed by or assigned to the city, village, or town for the year, but may consider only positions that are actually filled.

2. Except as provided in par. (c)1., [a certification under par. (a)2. shall include] [2] a statement that certifies that any 2 of the following have been maintained at a level at least equivalent to the previous year:

a. The political subdivision's expenditures, not including capital expenditures or expenditures of grant moneys received from the state or federal government, for fire protective and emergency medical services.

b. The number of full-time equivalent fire fighters and emergency medical services personnel employed by or assigned to the political subdivision, not including fire fighters and emergency medical services personnel whose positions are funded by grants received from the state or federal government. For volunteer fire and emergency medical services, those volunteer fire fighters and emergency medical services personnel who responded to at least 40 percent of calls to which volunteer fire protective or

emergency medical services responded may be counted as full-time equivalent volunteer fire fighters and emergency medical services personnel under this subd. 2. b. The person in charge of providing fire protective and emergency medical services for the political subdivision may use any reasonable method of estimating the average number of full-time equivalent fire fighters and emergency medical services personnel employed by or assigned to the political subdivision for the year, but may consider only positions that are actually filled.

c. The level of training of and maintenance of licensure for fire fighters and emergency medical services personnel providing fire protective and emergency medical services within the political subdivision.

d. Response times for fire protective and emergency medical services throughout the political subdivision, adjusted for the location of calls for service.

(c)1. Except for a political subdivision that made a certification under subds. 2. to 4., if a political subdivision failed to make a certification under par. (b)1. or 2. in the previous year, in making the certification under par. (b)1. or 2., the political subdivision shall certify that the political subdivision has maintained a level of law enforcement or fire protective and emergency medical service that is at least equivalent to that provided in the most recent year that the political subdivision made a certification under par. (b)1. or 2. or to that provided in 2023, whichever year is most recent.

2. A political subdivision that has consolidated its law enforcement services or fire protective or emergency medical services with another political subdivision or entered into a contract with a private entity to provide fire protective or emergency medical services may provide a certified statement to that effect in lieu of certification under par. (b)1. or 2. This subdivision applies only to the year following consolidation or entry into a contract.

3. A political subdivision that has a newly established or joined a newly established law enforcement agency or fire protection or emergency medical service agency may provide a certified statement to that effect, in lieu of certification under par. (b)1. or 2. This subdivision applies only to the year following establishment of the agency.

4. If law enforcement services in a city, village, or town are provided solely by the county sheriff on a noncontractual basis, the city, village, or town may provide a certified statement to that effect, in lieu of certification under par. (b)1.

(3m) Separate accounts for municipal fire, emergency medical services practitioner, and emergency medical responder volunteer funds. (a) *General authority*. Subject to pars. (b) and (c), the governing body of a municipality may enact an ordinance that does all of the following:

1. Authorizes a particular official or employee of the municipality's fire department, emergency medical services practitioner department, or emergency medical responder department to deposit volunteer funds of the department for which the individual serves as an official or employee, in an account in the name of the fire department, emergency medical services practitioner department, or emergency medical responder department, in a public depository.

2. Gives the municipality's fire department, emergency medical services practitioner department, or emergency medical responder department, through the official or employee described under subd. 1., exclusive control over the expenditure of volunteer funds of the department for which the individual serves as an official or employee in an account described under subd. 1.

(b) *Limitations, requirements*. An ordinance enacted under par. (a) may include any of the following limitations or requirements:

1. A limit on the type and amount of funds that may be deposited into the account described under par. (a)1.

2. A limit on the amount of withdrawals from the account described under par. (a)1. that may be made, and a limit on the purposes for which such withdrawals may be made.

3. Reporting and audit requirements that relate to the account described under par. (a)1.

(c) *Ownership of funds*. Notwithstanding an ordinance enacted under par. (a), volunteer funds shall remain the property of the municipality until the funds are disbursed.

Credits

<<For credits, see Historical Note field.>>

Footnotes

1 Missing phrase shown in brackets, corrective legislation is pending.

2 Missing phrase shown in brackets. Corrective legislation pending.

W. S. A. 66.0608, WI ST 66.0608
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0609

66.0609. Financial procedure; alternative system of approving claims

Currentness

(1) The governing body of a village or of a city of the 2nd, 3rd or 4th class may by ordinance enact an alternative system of approving financial claims against the municipal treasury other than claims subject to s. 893.80. The ordinance shall provide that payments may be made from the city or village treasury after the comptroller or clerk of the city or village audits and approves each claim as a proper charge against the treasury, and endorses his or her approval on the claim after having determined that all of the following conditions have been complied with:

(a) That funds are available for the claim pursuant to the budget approved by the governing body.

(b) That the item or service covered by the claim has been duly authorized by the proper official, department head or board or commission.

(c) That the item or service has been actually supplied or rendered in conformity with the authorization described in par. (b).

(d) That the claim is just and valid pursuant to law. The comptroller or clerk may require the submission of proof to support the claim as the officer considers necessary.

(2) The ordinance under sub. (1) shall require that the clerk or comptroller file with the governing body not less than monthly a list of the claims approved, showing the date paid, name of claimant, purpose and amount.

(3) The ordinance under sub. (1) shall require that the governing body of the city or village obtain an annual detailed audit of its financial transactions and accounts by a certified public accountant licensed or certified under ch. 442 and designated by the governing body.

(4) The system under sub. (1) is operative only if the comptroller or clerk is covered by a fidelity bond or insurance policy of not less than $5,000 in villages and 4th class cities, of not less than $10,000 in 3rd class cities, and of not less than $20,000 in 2nd class cities, as described in s. 61.25(intro.) or 62.09(4)(b).

(5) If an alternative procedure is adopted by ordinance in conformity with this section, the claim procedure required by ss. 61.25(6), 61.51, 62.09(10), 62.11 and 62.12 and other relevant provisions, except s. 893.80, is not applicable in the city or village.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0609, WI ST 66.0609
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.061

66.061. Renumbered 66.0815 and amended by 1999 Act 150, § 169, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.061, WI ST 66.061
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0611

66.0611. Political subdivisions prohibited from levying tax on incomes

Currentness

No county, city, village, town, or other unit of government authorized to levy taxes may assess, levy or collect any tax on income, or measured by income, and any tax so assessed or levied is void.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (1)

W. S. A. 66.0611, WI ST 66.0611
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W.S.A. 66.0613

66.0613. Assessment on racing prohibited

Currentness

Notwithstanding subch. V of ch. 77, no county, town, city or village may levy or collect from any licensee, as defined in s. 562.01(7), any fee, tax or assessment on any wager in any race, as defined in s. 562.01(10), or on any admission to any racetrack, as defined in s. 562.01(12), except as provided in s. 562.08.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0613, WI ST 66.0613
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0615

66.0615. Room tax; forfeitures

Currentness

(1) In this section:

(a) "Commission" means an entity created by one municipality or by 2 or more municipalities in a zone, to coordinate tourism promotion and tourism development for the zone.

(am) "District" has the meaning given in s. 229.41(4m).

(b) "Hotel" has the meaning given in s. 77.52(2)(a)1.

(bt) "Marketplace provider" has the meaning given in s. 77.51(7i), to the extent that the marketplace provider facilitates the sale or furnishing of rooms, lodging, or other accommodations to transients under sub. (1m)(a).

(bu) "Marketplace seller" has the meaning given in s. 77.51(7j).

(c) "Motel" has the meaning given in s. 77.52(2)(a)1.

(d) "Municipality" means any city, village or town.

(de) "Occupant" means a person who rents a short-term rental through a marketplace provider.

(df) "Owner" means the person who owns the residential dwelling that has been rented.

(di) "Residential dwelling" means any building, structure, or part of the building or structure, that is used or intended to be used as a home, residence, or sleeping place by one person or by 2 or more persons maintaining a common household, to the exclusion of all others.

(dk) “Short-term rental” means a residential dwelling that is offered for rent for a fee and for fewer than 30 consecutive days.

(dm) “Sponsoring municipality” means a city, village or town that creates a district either separately or in combination with another city, village, town or county.

(e) “Tourism” means travel for recreational, business or educational purposes.

(f) “Tourism entity” means a nonprofit organization that came into existence before January 1, 2015, spends at least 51 percent of its revenues on tourism promotion and tourism development, and provides destination marketing staff and services for the tourism industry in a municipality, except that if no such organization exists, a municipality may contract with one of the following entities:

1. A nonprofit organization that spends at least 51 percent of its revenues on tourism promotion and tourism development, and provides destination marketing staff and services for the tourism industry in a municipality.

2. A nonprofit organization that was incorporated before January 1, 2015, spends 100 percent of the room tax revenue it receives from a municipality on tourism promotion and tourism development, and provides destination marketing staff and services for the tourism industry in a municipality.

(fm) “Tourism promotion and tourism development” means any of the following that are significantly used by transient tourists and reasonably likely to generate paid overnight stays at more than one establishment on which a tax under sub. (1m)(a) may be imposed, that are owned by different persons and located within a municipality in which a tax under this section is in effect; or, if the municipality has only one such establishment, reasonably likely to generate paid overnight stays in that establishment:

1. Marketing projects, including advertising media buys, creation and distribution of printed or electronic promotional tourist materials, or efforts to recruit conventions, sporting events, or motorcoach groups.

2. Transient tourist informational services.

3. Tangible municipal development, including a convention center.

(g) “Transient” has the meaning given in s. 77.52(2)(a)1.

(h) “Zone” means an area made up of 2 or more municipalities that, those municipalities agree, is a single destination as perceived by the traveling public.

(1m)(a) The governing body of a municipality may enact an ordinance, and a district, under par. (e), may adopt a resolution, imposing a tax on the sales price from selling or furnishing, at retail, except sales for resale, rooms or lodging to transients by hotelkeepers, motel operators, marketplace providers, owners of short-term rentals, and other persons or retailers selling or furnishing accommodations that are available to the public, irrespective of whether membership is required for use of the

accommodations. A tax imposed under this paragraph may be collected from the consumer or user, but may not be imposed on sales to the federal government and persons listed under s. 77.54(9a). A tax imposed under this paragraph by a municipality shall be paid to the municipality and, with regard to any tax revenue that may not be retained by the municipality, shall be forwarded by the municipality to a tourism entity or a commission if one is created under par. (c), as provided in par. (d). Except as provided in par. (am), a tax imposed under this paragraph by a municipality may not exceed 8 percent of the sales price. Except as provided in par. (am), if a tax greater than 8 percent of the sales price under this paragraph is in effect on May 13, 1994, the municipality imposing the tax shall reduce the tax to 8 percent, effective on June 1, 1994.

(am) A municipality that imposes a room tax under par. (a) is not subject to the limit on the maximum amount of tax that may be imposed under that paragraph if any of the following apply:

1. The municipality is located in a county with a population of at least 380,000 and a convention center is being constructed or renovated within that county.

2. The municipality intends to use at least 60 percent of the revenue collected from its room tax, of any room tax that is greater than 7 percent, to fund all or part of the construction or renovation of a convention center that is located in a county with a population of at least 380,000.

3. The municipality is located in a county with a population of less than 380,000 and that county is not adjacent to a county with a population of at least 380,000, and the municipality is constructing a convention center or making improvements to an existing convention center.

4. The municipality has any long-term debt outstanding with which it financed any part of the construction or renovation of a convention center.

(b)1. If a single municipality imposes a room tax under par. (a), the municipality may create a commission under par. (c). The commission shall contract with another organization to perform the functions of a tourism entity if no tourism entity exists in that municipality.

2. If 2 or more municipalities in a zone impose a room tax under par. (a), the municipalities shall enter into a contract under s. 66.0301 to create a commission under par. (c). If no tourism entity exists in any of the municipalities in the zone that have formed a commission, the commission shall contract with another organization in the zone to perform the functions of the tourism entity. Each municipality in a single zone that imposes a room tax shall levy the same percentage of tax. If the municipalities are unable to agree on the percentage of tax for the zone, the commission shall set the percentage.

3. A commission shall monitor the collection of room taxes from each municipality in a zone that has a room tax.

4. A commission shall contract with one tourism entity from the municipalities in the zone to obtain staff, support services and assistance in developing and implementing programs to promote the zone to visitors.

(c)1. If a commission is created by a single municipality, the commission shall consist of 4 to 6 members. One of the commission members shall represent the Wisconsin hotel and motel industry. Members shall be appointed under subd. 3.

2. a. If the commission is created by more than one municipality in a zone, the commission shall consist of 3 members from each municipality in which annual tax collections exceed $1,000,000, 2 members from each municipality in which annual tax collections exceed $300,000 but are not more than $1,000,000 and one member from each municipality in which annual tax collections are $300,000 or less. Except as provided in subd. 2.b., members shall be appointed under subd. 3.

b. Two additional members, who represent the Wisconsin hotel and motel industry, shall be appointed to the commission by the chairperson of the commission, shall serve for a one-year term at the pleasure of the chairperson and may be reappointed.

3. Members of the commission shall be appointed by the principal elected official in the municipality and shall be confirmed by a majority vote of the members of the municipality's governing body who are present when the vote is taken. Commissioners shall serve for a one-year term, at the pleasure of the appointing official, and may be reappointed.

4. The commission shall meet regularly, and, from among its members, it shall elect a chairperson, vice chairperson and secretary.

5. The commission shall report any delinquencies or inaccurate reporting to the municipality that is due the tax.

(d)1. A municipality that first imposes a room tax under par. (a) after May 13, 1994, shall spend at least 70 percent of the amount collected on tourism promotion and tourism development. Any amount of room tax collected that must be spent on tourism promotion and tourism development shall either be forwarded to the commission for its municipality or zone if the municipality has created a commission, or forwarded to a tourism entity.

2. Subject to par. (dm), if a municipality collects a room tax on May 13, 1994, it may retain not more than the same percentage of the room tax that it retains on May 13, 1994. If a municipality that collects a room tax on May 1, 1994, increases its room tax after May 1, 1994, the municipality may retain not more than the same percentage of the room tax that it retains on May 1, 1994, except that if the municipality is not exempt under par. (am) from the maximum tax that may be imposed under par. (a), the municipality shall spend at least 70 percent of the increased amount of room tax that it begins collecting after May 1, 1994, on tourism promotion and development. Any amount of room tax collected that must be spent on tourism promotion and tourism development shall either be forwarded to the commission for its municipality or zone if the municipality has created a commission, or forwarded to a tourism entity.

3. A commission shall use the room tax revenue that it receives from a municipality for tourism promotion and tourism development in the zone or in the municipality.

4. The commission shall report annually to each municipality from which it receives room tax revenue the purposes for which the revenues were spent.

5. The commission may not use any of the room tax revenue to construct or develop a lodging facility.

6. If a municipality issued debt or bond anticipation notes before January 1, 2005, to finance the construction of a municipally owned convention center or conference center, nothing in this section may prevent the municipality from meeting all of the terms of its obligation.

7. Notwithstanding the provisions of subds. 1. and 2., any amount of room tax revenue that a municipality described under s. 77.994(3) is required to spend on tourism promotion and tourism development shall be forwarded to, and spent by, the municipality's tourism entity, unless the municipality creates a commission and forwards the revenue to the commission.

8. The governing body of a tourism entity shall include either at least one owner or operator of a lodging facility that collects the room tax described in this section and that is located in the municipality for which the room tax is collected or at least 4 owners or operators of lodging facilities that collect the room tax described in this section and that are located in the zone for which the room tax is collected. Subdivision 4., as it applies to a commission, applies to a tourism entity.

(dm) Beginning with the room tax collected on January 1, 2017, by a municipality that collected a room tax on May 13, 1994, as described in par. (d)2., and retained more than 30 percent of the room tax collected for purposes other than tourism promotion and tourism development, such a municipality may continue to retain, each year, the greater of either 30 percent of its current year revenues or one of the following amounts:

1. For fiscal year 2017, the same dollar amount of the room tax retained as the municipality retained in its 2014 fiscal year.

2. For fiscal year 2018, the same dollar amount of the room tax retained as the municipality retained in its 2013 fiscal year.

3. For fiscal year 2019, the same dollar amount of the room tax retained as the municipality retained in its 2012 fiscal year.

4. For fiscal year 2020, the same dollar amount of the room tax retained as the municipality retained in its 2011 fiscal year.

5. For fiscal year 2021 and thereafter, the same dollar amount of the room tax retained as the municipality retained in its 2010 fiscal year.

(e)1. Subject to subd. 2., a district may adopt a resolution imposing a room tax under par. (a) in an amount not to exceed 3 percent of total room charges. A majority of the authorized members of the district's board may vote that, if the balance in a special debt service reserve fund of the district is less than the requirement under s. 229.50(5), the room tax imposed by the district under this subdivision is 3 percent of total room charges beginning on the next January 1, April 1, July 1 or October 1 after the payment and this tax is irrepealable if any bonds issued by the district and secured by the special debt service reserve fund are outstanding. A room tax imposed by a district under this subdivision applies within the district's jurisdiction, as specified in s. 229.43, and the proceeds of the tax may be used only for the district's debt service on its bond obligations. If a district stops imposing and collecting a room tax, the district's sponsoring municipality may impose and collect a room tax under par. (a) on the date on which the district stops imposing and collecting its room tax.

2. In addition to the room tax that a district may impose under subd. 1, if the district's only sponsoring municipality is a 1st class city, the district may adopt a resolution imposing an additional room tax. The additional percentage of room tax under

this subdivision shall be equal to the percentage of room tax imposed by the sponsoring municipality on the date on which the sponsoring municipality agrees to stop imposing and collecting its room tax, as described under s. 229.44(15). A district shall begin collecting the additional room tax imposed under this subdivision on the date on which the sponsoring municipality stops imposing and collecting its room tax. A room tax imposed by a district under this subdivision applies only within the borders of the sponsoring municipality and may be used for any lawful purpose of the district.

3. A district adopting a resolution to impose the taxes under subd. 1. or 2. shall deliver a certified copy of the resolution to the secretary of revenue at least 120 days before its effective date.

(f)1. The department of revenue shall administer the tax that is imposed under par. (a) by a district and may take any action, conduct any proceeding and impose interest and penalties.

2. Sections 77.51(12m), (13), (14), (14g), (15a), (15b), and (17), 77.52(3), (3m), (13), (14), (18), and (19), 77.522, 77.523, 77.58(1) to (5), (6m), and (7), 77.585, 77.59, 77.60, 77.61(2), (3m), (5), (8), (9), (12) to (15), and (19m), and 77.62, as they apply to the taxes under subch. III of ch. 77, apply to the tax described under subd. 1.

3. From the appropriation under s. 20.835(4)(gg), the department of revenue shall distribute 97.45 percent of the taxes collected under this paragraph for each district to that district and shall indicate to the district the taxes reported by each taxpayer in that district, no later than the end of the month following the end of the calendar quarter in which the amounts were collected. The taxes distributed shall be increased or decreased to reflect subsequent refunds, audit adjustments and all other adjustments. Interest paid on refunds of the tax under this paragraph shall be paid from the appropriation under s. 20.835(4)(gg) at the rate under s. 77.60(1)(a). Any district that receives a report along with a payment under this subdivision or subd. 2. is subject to the duties of confidentiality to which the department of revenue is subject under s. 77.61(5).

5. Persons who are subject to the tax under this subsection, if that tax is administered by the department of revenue, shall register with the department. Any person who is required to register, including any person authorized to act on behalf of a person who is required to register, who fails to do so is guilty of a misdemeanor.

(g) Sections 77.51(10), (12m), (13), (13g), (14), (14g), (15a), (15b), and (17), 77.52 (3), (3m), (13), (14), (18), and (19), 77.522, 77.523, 77.53(7), 77.54, 77.58(6m), and 77.585, as they apply to the taxes under subch. III of ch. 77, shall apply to the tax imposed under par. (a) by a municipality.

(1r)(a) A marketplace provider shall collect the tax imposed by a municipality under sub. (1m) for a marketplace seller, unless the marketplace provider has been issued a waiver under s. 77.52(3m)(b) or (c), and forward it to the municipality, on a quarterly basis, along with a form prepared by the department of revenue as described under par. (b), except that a marketplace provider shall forward the tax to the municipality more frequently if the marketplace provider and the municipality enter into a written agreement providing for more frequent submissions. The marketplace provider shall notify the marketplace seller that the marketplace provider has collected and forwarded the taxes described in this paragraph. A municipality may not impose and collect a room tax from the marketplace seller if the municipality collects the room tax as described in this paragraph.

(b) The form prepared by the department of revenue as described under par. (a) shall contain at least the following information about the room tax imposed under sub. (1m) on the marketplace provider:

1. The total sales for properties located in a municipality with a room tax.

2. The total number of nights properties located in a municipality with a room tax were rented.

3. The rate of the room tax applied to the amount specified in subd. 1.

4. The total tax due for properties located in a municipality with a room tax.

(c) No later than September 29, 2021, and updated annually, the department of revenue shall create a website that contains the following information about room tax collections:

1. The name and mailing address of each municipality that imposes a room tax under sub. (1m).

2. The rate of the room tax imposed by each municipality specified in subd. 1.

(2) As a means of enforcing the collection of any room tax imposed by a municipality or a district under sub. (1m), the municipality or district may do any of the following:

(a) If a municipality or district has probable cause to believe that the correct amount of room tax has not been assessed or that the tax return is not correct, inspect and audit the records of any person subject to sub. (1m) pertaining to the furnishing or selling of accommodations to determine the correct amount of room tax due. A determination under this paragraph shall be provided in writing within 4 years after the due date of the return, unless no return has been filed.

(b) Enact a schedule of forfeitures, not to exceed 5 percent of the tax under sub. (1m) or par. (c), to be imposed on any person subject to sub. (1m) who fails to comply with a request to inspect and audit the person's records under par. (a).

(c) Determine the tax under sub. (1m) according to its best judgment if a person required to make a return fails, neglects or refuses to do so for the amount, in the manner and form and within the time prescribed by the municipality or district.

(d) Require each person who is subject to par. (c) to pay an amount of taxes that the municipality or district determines to be due under par. (c) plus interest at the rate of 1 percent per month on the unpaid balance. No refund or modification of the payment determined may be granted until the person files a correct room tax return and permits the municipality or district to inspect and audit his or her financial records under par. (a).

(e) Enact a schedule of forfeitures, not to exceed 25 percent of the room tax due for the previous year under sub. (1m) or par. (c) or $5,000, whichever is less, to be imposed for failure to pay the tax under sub. (1m). This paragraph also applies to a marketplace provider that is required to collect and remit taxes imposed by a municipality under sub. (1m), but that fails to file a return as required in sub. (1r) or pay the required tax.

(2m)(a) To enforce the collection of a room tax imposed by a district under sub. (1m), the district may exchange audit and other information relating to the room tax with the department of revenue.

(b) To enforce the collection of a room tax imposed by a municipality under sub. (1m), the municipality may jointly inspect and audit the room tax records of a person subject to sub. (1m) with other municipalities only for the purpose of conducting a joint room tax audit. A municipality may provide audit and other information to the department of revenue, and may exchange audit and other room tax related information with any municipality that took part in conducting the joint audit.

(3) The municipality shall provide by ordinance and the district shall provide by resolution for the confidentiality of information obtained under subs. (1r) and (2) but shall provide exceptions for persons using the information in the discharge of duties imposed by law or of the duties of their office or by order of a court. The municipality or district may provide for the publishing of statistics classified so as not to disclose the identity of particular returns. The municipality or district shall provide that persons violating ordinances or resolutions enacted under this subsection may be required to forfeit not less than $100 nor more than $500.

(4)(a) Except as provided in par. (d), annually, on or before May 1, on a form created and provided by the department of revenue, every municipality that imposes a tax under sub. (1m) shall certify and report to the department all of the following:

1. The amount of room tax revenue collected, and the room tax rate imposed, by the municipality in the previous year.

2. A detailed accounting of the amounts of such revenue that were forwarded in the previous year for tourism promotion and tourism development, specifying the commission or tourism entity that received the revenue. The detailed accounting shall include expenditures of at least $1,000 made by a commission or a tourism entity.

3. A list of each member of the commission and each member of the governing body of a tourism entity to which the municipality forwarded room tax revenue in the previous year, and the name of the business entity the member owns, operates, or is employed by, if any.

4. For a municipality subject to sub. (1m)(dm), the amount of the room tax retained by the municipality in each of the following fiscal years: 2010, 2011, 2012, 2013, and 2014.

(b) The department of revenue shall collect the reports described in par. (a) and shall make them available to the public.

(c) The department of revenue may impose a penalty of not more than $3,000 on a municipality that does not submit to the department the reports described in par. (a). A municipality may not use room tax revenue to pay a penalty imposed under this paragraph. The penalty shall be paid to the department of revenue.

(d) Notwithstanding the requirement in par. (a)(intro.), the information specified in par. (a)4. may be certified and reported to the department only once if the municipality submits the information not later than May 1, 2022. The department shall make such information available to the public annually in the report described in par. (a)(intro.).

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (6)

W. S. A. 66.0615, WI ST 66.0615
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter VI. Finance; Revenues

W.S.A. 66.0617

66.0617. Impact fees

Currentness

(1) Definitions. In this section:

(a) "Capital costs" means the capital costs to construct, expand or improve public facilities, including the cost of land, and including legal, engineering and design costs to construct, expand or improve public facilities, except that not more than 10 percent of capital costs may consist of legal, engineering and design costs unless the municipality can demonstrate that its legal, engineering and design costs which relate directly to the public improvement for which the impact fees were imposed exceed 10 percent of capital costs. "Capital costs" does not include other noncapital costs to construct, expand or improve public facilities, vehicles; or the costs of equipment to construct, expand or improve public facilities.

(b) "Developer" means a person that constructs or creates a land development.

(c) "Impact fees" means cash contributions, contributions of land or interests in land or any other items of value that are imposed on a developer by a municipality under this section.

(d) "Land development" means the construction or modification of improvements to real property that creates additional residential dwelling units within a municipality or that results in nonresidential uses that create a need for new, expanded or improved public facilities within a municipality.

(e) "Municipality" means a city, village, or town.

(f) "Public facilities" means all of the following:

1. Highways as defined in s. 340.01(22), and other transportation facilities, traffic control devices, facilities for collecting and treating sewage, facilities for collecting and treating storm and surface waters, facilities for pumping, storing, and distributing water, parks, playgrounds, and land for athletic fields, solid waste and recycling facilities, fire protection facilities, law enforcement facilities, emergency medical facilities and libraries. "Public facilities" does not include facilities owned by a school district.

2. Notwithstanding subd. 1., with regard to impact fees that were first imposed before June 14, 2006, "public facilities" includes other recreational facilities that were substantially completed by June 14, 2006. This subdivision does not apply on or after January 1, 2018.

(g) "Service area" means a geographic area delineated by a municipality within which there are public facilities.

(h) "Service standard" means a certain quantity or quality of public facilities relative to a certain number of persons, parcels of land or other appropriate measure, as specified by the municipality.

(2) General. (a) A municipality may enact an ordinance under this section that imposes impact fees on developers to pay for the capital costs that are necessary to accommodate land development.

(b) Subject to par. (c), this section does not prohibit or limit the authority of a municipality to finance public facilities by any other means authorized by law, except that the amount of an impact fee imposed by a municipality shall be reduced, under sub. (6)(d), to compensate for any other costs of public facilities imposed by the municipality on developers to provide or pay for capital costs.

(c) Beginning on May 1, 1995, a municipality may impose and collect impact fees only under this section.

(3) Public hearing; notice. Before enacting an ordinance that imposes impact fees, or amending an existing ordinance that imposes impact fees, a municipality shall hold a public hearing on the proposed ordinance or amendment. Notice of the public hearing shall be published as a class 1 notice under ch. 985, and shall specify where a copy of the proposed ordinance or amendment and the public facilities needs assessment may be obtained.

(4) Public facilities needs assessment. (a) Before enacting an ordinance that imposes impact fees or amending an ordinance that imposes impact fees by revising the amount of the fee or altering the public facilities for which impact fees may be imposed, a municipality shall prepare a needs assessment for the public facilities for which it is anticipated that impact fees may be imposed. The public facilities needs assessment shall include, but not be limited to, the following:

1. An inventory of existing public facilities, including an identification of any existing deficiencies in the quantity or quality of those public facilities, for which it is anticipated that an impact fee may be imposed.

2. An identification of the new public facilities, or improvements or expansions of existing public facilities, that will be required because of land development for which it is anticipated that impact fees may be imposed. This identification shall be based on explicitly identified service areas and service standards.

3. A detailed estimate of the capital costs of providing the new public facilities or the improvements or expansions in existing public facilities identified in subd. 2., including an estimate of the cumulative effect of all proposed and existing impact fees on the availability of affordable housing within the municipality.

(b) A public facilities needs assessment or revised public facilities needs assessment that is prepared under this subsection shall be available for public inspection and copying in the office of the clerk of the municipality at least 20 days before the hearing under sub. (3).

(5) Differential fees, impact fee zones. (a) An ordinance enacted under this section may impose different impact fees on different types of land development.

(b) An ordinance enacted under this section may delineate geographically defined zones within the municipality and may impose impact fees on land development in a zone that differ from impact fees imposed on land development in other zones within the municipality. The public facilities needs assessment that is required under sub. (4) shall explicitly identify the differences, such as land development or the need for those public facilities, which justify the differences between zones in the amount of impact fees imposed.

(6) Standards for impact fees. Impact fees imposed by an ordinance enacted under this section:

(a) Shall bear a rational relationship to the need for new, expanded or improved public facilities that are required to serve land development.

(am) May not include amounts for an increase in service capacity greater than the capacity necessary to serve the development for which the fee is imposed.

(b) May not exceed the proportionate share of the capital costs that are required to serve land development, as compared to existing uses of land within the municipality.

(c) Shall be based upon actual capital costs or reasonable estimates of capital costs for new, expanded or improved public facilities.

(d) Shall be reduced to compensate for other capital costs imposed by the municipality with respect to land development to provide or pay for public facilities, including special assessments, special charges, land dedications or fees in lieu of land dedications under ch. 236 or any other items of value.

(e) Shall be reduced to compensate for moneys received from the federal or state government specifically to provide or pay for the public facilities for which the impact fees are imposed.

(f) May not include amounts necessary to address existing deficiencies in public facilities.

(fm) May not include expenses for operation or maintenance of a public facility.

(g) Except as provided under this paragraph, shall be payable by the developer or the property owner to the municipality in full upon the issuance of a building permit by the municipality. Except as provided in this paragraph, if the total amount of impact

fees due for a development will be more than $75,000, a developer may defer payment of the impact fees for a period of 4 years from the date of the issuance of the building permit or until 6 months before the municipality incurs the costs to construct, expand, or improve the public facilities related to the development for which the fee was imposed, whichever is earlier. If the developer elects to defer payment under this paragraph, the developer shall maintain in force a bond or irrevocable letter of credit in the amount of the unpaid fees executed in the name of the municipality. A developer may not defer payment of impact fees for projects that have been previously approved.

(7) Low-cost housing. An ordinance enacted under this section may provide for an exemption from, or a reduction in the amount of, impact fees on land development that provides low-cost housing, except that no amount of an impact fee for which an exemption or reduction is provided under this subsection may be shifted to any other development in the land development in which the low-cost housing is located or to any other land development in the municipality.

(7r) Impact fee reports. At the time that the municipality collects an impact fee, it shall provide to the developer from which it received the fee an accounting of how the fee will be spent.

(8) Requirements for impact fee revenues. Revenues from each impact fee that is imposed shall be placed in a separate segregated interest-bearing account and shall be accounted for separately from the other funds of the municipality. Impact fee revenues and interest earned on impact fee revenues may be expended only for the particular capital costs for which the impact fee was imposed, unless the fee is refunded under sub. (9).

(9) Refund of impact fees. Except as provided in this subsection, impact fees that are not used within 8 years after they are collected to pay the capital costs for which they were imposed shall be refunded to the payer of fees for the property with respect to which the impact fees were imposed, along with any interest that has accumulated, as described in sub. (8). Impact fees that are collected for capital costs related to lift stations or collecting and treating sewage that are not used within 10 years after they are collected to pay the capital costs for which they were imposed, shall be refunded to the payer of fees for the property with respect to which the impact fees were imposed, along with any interest that has accumulated, as described in sub. (8). The 10-year time limit for using impact fees that is specified under this subsection may be extended for 3 years if the municipality adopts a resolution stating that, due to extenuating circumstances or hardship in meeting the 10-year limit, it needs an additional 3 years to use the impact fees that were collected. The resolution shall include detailed written findings that specify the extenuating circumstances or hardship that led to the need to adopt a resolution under this subsection. For purposes of the time limits in this subsection, an impact fee is paid on the date a developer obtains a bond or irrevocable letter of credit in the amount of the unpaid fees executed in the name of the municipality under sub. (6)(g).

(10) Appeal. A municipality that enacts an impact fee ordinance under this section shall, by ordinance, specify a procedure under which a developer upon whom an impact fee is imposed has the right to contest the amount, collection or use of the impact fee to the governing body of the municipality.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (2)

W. S. A. 66.0617, WI ST 66.0617
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0619

66.0619. Public improvement bonds: issuance

Currentness

(1) A municipality, in addition to any other authority to borrow money and issue its municipal obligations, may borrow money and issue its public improvement bonds to finance the cost of construction or acquisition, including site acquisition, of any revenue-producing public improvement of the municipality. In this section, unless the context or subject matter otherwise requires:

(a) "Debt service" means the amount of principal, interest and premium due and payable with respect to public improvement bonds.

(b) "Deficiency" means the amount by which debt service required to be paid in a calendar year exceeds the amount of revenues estimated to be derived from the ownership and operation of the public improvement for the calendar year, after first subtracting from the estimated revenues the estimated cost of paying the expenses of operating and maintaining the public improvement for the calendar year.

(c) "Municipality" means a county, sanitary district, public inland lake protection and rehabilitation district, town, city or village.

(d) "Public improvement" means any public improvement which a municipality may lawfully own and operate from which the municipality expects to derive revenues.

(2) The governing body of the municipality proposing to issue public improvement bonds shall adopt a resolution authorizing their issuance. The resolution shall set forth the amount of bonds authorized, or a sum not to exceed a stated amount, and the purpose for which the bonds are to be issued. The resolution shall prescribe the terms, form and contents of the bonds and other matters that the governing body considers necessary or advisable. The bonds may be in any denomination of not less than $1,000, shall bear interest payable annually or semiannually, shall be payable not later than 20 years from the date of the bonds, at times and places that the governing body determines, and may be subject to redemption prior to maturity on terms and conditions that the governing body determines. The bonds may be issued either payable to bearer with interest coupons attached to the bonds or may be registered under s. 67.09. The bonds may be sold at public competitive sale or by private negotiation. Sections 67.08 and 67.10 apply to public improvement bonds, except insofar as they are in conflict with this section, in which case this section controls.

(2m)(a) A resolution, adopted under sub. (2) by the governing body of a municipality, need not be submitted to the electors of the municipality for approval, unless within 30 days after the resolution is adopted there is filed with the clerk of the municipality a petition, conforming to the requirements of s. 8.40 and requesting a referendum on the resolution, signed by electors numbering

at least 10 percent of the votes cast in the municipality for governor at the last general election. A resolution, adopted under sub. (2), may be submitted by the governing body of the municipality to the electors without waiting for the filing of a petition.

(b) If a referendum is to be held on a resolution, the municipal governing body shall file the resolution as provided in s. 8.37 and shall direct the municipal clerk to call a special election for the purpose of submitting the resolution to the electors for a referendum on approval or rejection. In lieu of a special election, the municipal governing body may specify that the election be held at the next succeeding spring primary or election or partisan primary or general election.

(c) The municipal clerk shall publish a class 2 notice, under ch. 985, containing a statement of the purpose of the referendum, giving the amount of the bonds proposed to be issued and the purpose for which they will be issued, and stating the time and places of holding the election and the hours during which the polls will be open.

(d) The referendum shall be held and conducted and the votes cast shall be canvassed as at regular municipal elections and the results certified to the municipal clerk. A majority of all votes cast in the municipality decides the question.

(3) The reasonable cost and value of any services rendered by the public improvement to the municipality shall be charged against the municipality and shall be paid by it in monthly installments.

(4)(a) Gross revenues derived from the ownership and operation of the public improvement shall be first pledged to debt service on issued public improvement bonds. When in excess of debt service, the revenues are subject to all of the following requirements set by resolution or ordinance of the governing body fixing:

1. The proportion of revenues of the public improvement necessary for the reasonable and proper operation and maintenance of the public improvement.

2. The proportion of revenues necessary for the payment of debt service on the public improvement bonds. The revenues shall be paid into a special fund in the treasury of the municipality known as the “Public Improvement Bond Account”.

(b) At any time after one year's operation, the governing body may recompute the proportion of revenues assignable under par. (a) based upon experience of operation.

(c) All funds on deposit in a public improvement bond account, which are not immediately required for the purposes specified in this section, shall be invested in accordance with s. 66.0605.

(5) Annually, on or before August 1 the officer or department of the municipality responsible for the operation of the public improvement shall file with the governing body, or its designated representative, a detailed statement setting forth the amount of the debt service on the public improvement bonds issued for the public improvement for the succeeding calendar year and an estimate for that year of the total revenues to be derived from the ownership and operation of the public improvement and the total cost of operating and maintaining the public improvement.

(6)(a) If it is determined that there will be a deficiency for the ensuing calendar year, the municipality shall make up the deficiency, but the obligation to do so is limited to a sum which does not cause the municipality to exceed its municipal debt limits. The deficiency may be made up by the municipality from any available revenues, including a tax levy. The amount contributed by the municipality shall be deposited in the public improvement bond account and applied to the payment of debt service. Taxes levied under this paragraph are not subject to statutory limitations of rate or amount.

(b) The amount of any deficiency determined under par. (a) for the ensuing calendar year shall be related to the total debt service for that year. The ratio determines the outstanding indebtedness of the issue to be reflected as part of the municipality's indebtedness for the year.

(7) If revenue bonds have been issued by a municipality pursuant to law and an ordinance authorizing their issuance without limitation as to amount has been enacted by the governing body of the municipality, public improvement bonds may be issued under the ordinance with the same effect as though they were revenue bonds. The bonds are public improvement bonds and this section applies to the bonds, except that nothing contained in this subsection shall impair the contract between the municipality and the holders of outstanding revenue bonds. Liens created in favor of any outstanding revenue bonds issued under the ordinance apply to public improvement bonds issued under this subsection. The public improvement bonds are payable on a parity with the revenue bonds issued under the ordinance if the public improvement bonds are issued in compliance with the requirements of the ordinance for the issuance of parity bonds under the ordinance.

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.0619, WI ST 66.0619
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.062. Repealed by 1985 Act 187, § 8, eff. April 22, 1986

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter VI. Finance; Revenues

W.S.A. 66.062

66.062. Repealed by 1985 Act 187, § 8, eff. April 22, 1986

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.062, WI ST 66.062
Current through 2023 Act 272, published April 10, 2024.

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

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Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter VI. Finance; Revenues

W.S.A. 66.0621

66.0621. Revenue obligations

Currentness

(1) In this section:

(a) "Municipality" means a city, village, town, county, commission created by contract under s. 66.0301, public inland lake protection and rehabilitation district established under s. 33.23, 33.235 or 33.24, metropolitan sewerage district created under ss. 200.01 to 200.15 and 200.21 to 200.65, town sanitary district under subch. IX of ch. 60, a local professional baseball park district created under subch. III of ch. 229, a local professional football stadium district created under subch. IV of ch. 229, a local cultural arts district created under subch. V of ch. 229 or a municipal water district or power district under ch. 198 and any other public or quasi-public corporation, officer, board or other public body empowered to borrow money and issue obligations to repay the money and obligations out of revenues. "Municipality" does not include the state or a local exposition district created under subch. II of ch. 229.

(b) "Public utility" means any revenue producing facility or enterprise owned by a municipality and operated for a public purpose as defined in s. 67.04(1)(b) including garbage incinerators, toll bridges, swimming pools, tennis courts, parks, playgrounds, golf links, bathing beaches, bathhouses, street lighting, city halls, village halls, town halls, courthouses, jails, schools, cooperative educational service agencies, hospitals, homes for the aged or indigent, child care centers, regional projects, waste collection and disposal operations, sewerage systems, local professional baseball park facilities, local professional football stadium facilities, local cultural arts facilities, and any other necessary public works projects undertaken by a municipality.

(c) "Revenue" means all moneys received from any source by a public utility and all rentals and fees and, in the case of a local professional baseball park district created under subch. III of ch. 229 includes tax revenues deposited into a special fund under s. 229.685 and payments made into a special debt service reserve fund under s. 229.74 and, in the case of a local professional football stadium district created under subch. IV of ch. 229 includes tax revenues deposited into a special fund under s. 229.825 and payments made into a special debt service reserve fund under s. 229.830.

(2) This section does not limit the authority of a municipality to acquire, own, operate and finance in the manner provided in this section a source of water and necessary transmission facilities, including all real and personal property, beyond its corporate limits. A source of water 50 miles beyond a municipality's corporate limits shall be within the municipality's authority.

(3) A municipality may, by action of its governing body, provide for purchasing, acquiring, leasing, constructing, extending, adding to, improving, conducting, controlling, operating or managing a public utility, motor bus or other systems of public

transportation from the general fund, or from the proceeds of municipal obligations, including revenue bonds. An obligation created under sub. (4) or (5) is not an indebtedness of the municipality, and shall not be included in arriving at the constitutional debt limitation.

(3m) A county in which an electronics and information technology manufacturing zone designated under s. 238.396(1m) exists may issue bonds under this section whose principal and interest are paid only through sales and use tax revenues imposed by the county under s. 77.70. The county shall be and continue without power to repeal such tax or obstruct the collection of the tax until all such payments have been made or provided for.

(4) If payment of obligations is provided by revenue bonds, the following is the procedure for payment:

(a)1. The governing body of the municipality, by ordinance or resolution, shall order the issuance and sale of bonds, executed as provided in s. 67.08(1) and payable at times not exceeding 40 years from the date of issuance, and at places, that the governing body of the municipality determines. The bonds shall be payable only out of the special redemption fund. Each bond shall include a statement that it is payable only from the special redemption fund, naming the ordinance or resolution creating it, and that it does not constitute an indebtedness of the municipality. The bonds may be issued either as registered bonds under s. 67.09 or as coupon bonds payable to bearer. Bonds shall be sold in the manner and upon the terms determined by the governing body of the municipality.

2. Interest, if any, on bonds shall be paid at least annually to bondholders. Payment of principal on the bonds shall commence not later than 3 years after the date of issue or 2 years after the estimated date that construction will be completed, whichever is later. After the commencement of the payment of principal on the bonds, at least annually, the municipality shall make principal payments and, if any, interest payments to bondholders or provide by ordinance or resolution that payments be made into a separate fund for payment to bondholders as specified in the ordinance or resolution authorizing the issuance of the bonds. The amount of the annual debt service payments made or provided for shall be reasonable in accordance with prudent municipal utility management practices.

3. All revenue bonds may contain a provision authorizing redemption of the bonds, in whole or in part, at stipulated prices, at the option of the municipality on any interest payment date. The governing body of a municipality may provide in a contract for purchasing, acquiring, leasing, constructing, extending, adding to, improving, conducting, controlling, operating or managing a public utility, that payment shall be made in bonds at not less than 95 percent of the par value of the bonds.

(b) All moneys received from bonds issued under this section shall be applied solely for purchasing, acquiring, leasing, constructing, extending, adding to, improving, conducting, controlling, operating or managing a public utility, and in the payment of the cost of subsequent necessary additions, improvements and extensions. Bonds issued under this section shall be secured by a pledge of the revenues of the public utility to the holders of the bonds and to the holders of coupons of the bonds and may be additionally secured by a mortgage lien upon the public utility to the holders of the bonds and to the holders of coupons of the bonds. If a mortgage lien is created by ordinance or resolution, the lien is perfected by publication of the ordinance or resolution or by recording of the ordinance or resolution in the records of the municipality. In addition, the municipality may record the lien by notifying the register of deeds of the county in which the public utility is located concerning its issuance of bonds. If the register of deeds receives notice from the municipality, the register of deeds shall record any mortgage lien created. The public utility remains subject to the pledge and, if created, the mortgage lien until the payment in full of the principal and interest of the bonds. Upon repayment of bonds for which a mortgage lien has been created, the register of deeds shall, upon notice from the municipality, record a satisfaction of the mortgage lien. Any holder of a bond or of coupons attached to a bond may protect and enforce this pledge and, if created, the mortgage lien and compel performance of all duties required of the

municipality by this section. A municipality may provide for additions, extensions and improvements to a public utility that it owns by additional issues of bonds under this section. The additional issues of bonds are subordinate to all prior issues of bonds under this section, but a municipality may in the ordinance or resolution authorizing bonds permit the issue of additional bonds on a parity with prior issues. A municipality may issue new bonds under this section to provide funds for refunding any outstanding municipal obligations, including interest, issued for any of the purposes stated in sub. (3). Refunding bonds issued under this section are subject to all of the following provisions:

1. Refunding bonds may be issued to refinance more than one issue of outstanding municipal obligations notwithstanding that the outstanding municipal obligations may have been issued at different times and may be secured by the revenues of more than one public utility. Public utilities may be operated as a single public utility, subject to contract rights vested in holders of bonds or promissory notes being refinanced. A determination by the governing body of a municipality that any refinancing is advantageous or necessary to the municipality is conclusive.

4. The refunding bonds are not an indebtedness of a municipality, and shall not be included in arriving at the constitutional debt limitation.

5. The governing body of a municipality may include a provision in any ordinance or resolution authorizing the issuance of refunding bonds pledging all or part of the revenues of any public utility or utilities originally financed, extended or improved from the proceeds of any of the municipal obligations being refunded, and pledging all or part of the surplus income derived from the investment of a trust created in relation to the refunding.

6. This subsection constitutes full authority for the authorization and issuance of refunding bonds and for all other acts authorized by this subsection to be done or performed and the refunding bonds may be issued under this subsection without regard to the requirements, restrictions or procedural provisions contained in any other law.

(c) The governing body of a municipality shall, in the ordinance or resolution authorizing the issuance of bonds, establish a system of funds and accounts and provide for sufficient revenues to operate and maintain the public utility and to provide fully for annual debt service requirements of bonds issued under this section. The governing body of a municipality may establish a fund or account for depreciation of assets of the public utility.

(d) If a governing body of a municipality creates a depreciation fund under par. (c) it shall use the funds set aside to restore any deficiency in the special redemption fund specified in par. (e) for the payment of the principal and interest due on the bonds and for the creation and maintenance of any reserves established by the bond ordinance or resolution to secure these payments. If the special redemption fund is sufficient for these purposes, moneys in the depreciation fund may be expended for repairs, replacements, new constructions, extensions or additions of the public utility. Accumulations of the depreciation fund may be invested and the income from the investment shall be deposited in the depreciation fund.

(e) The governing body of a municipality shall by ordinance or resolution create a special fund in the treasury of the municipality to be identified as “the .... special redemption fund” into which shall be paid the amount which is set aside for the payment of the principal and interest due on the bonds and for the creation and maintenance of any reserves established by bond ordinance or resolution to secure these payments.

(f) At the close of the public utility's fiscal year, if any surplus has accumulated in any of the funds specified in this subsection, it may be disposed of in the order set forth under s. 66.0811(2).

(g) The reasonable cost and value of any service rendered to a municipality by a public utility shall be charged against the municipality and shall be paid by it in installments.

(h) The rates for all services rendered by a public utility to a municipality or to other consumers shall be reasonable and just, taking into account and consideration the value of the public utility, the cost of maintaining and operating the public utility, the proper and necessary allowance for depreciation of the public utility, and a sufficient and adequate return upon the capital invested.

(i) The governing body of a municipality may adopt all ordinances and resolutions necessary to carry into effect this subsection. An ordinance or resolution providing for the issuance of bonds may contain such provisions or covenants, without limiting the generality of the power to adopt an ordinance or resolution, as are considered necessary or desirable for the security of bondholders or the marketability of the bonds. The provisions or covenants may include but are not limited to provisions relating to the sufficiency of the rates or charges to be made for service, maintenance and operation, improvements or additions to and sale or alienation of the public utility, insurance against loss, employment of consulting engineers and accountants, records and accounts, operating and construction budgets, establishment of reserve funds, issuance of additional bonds, and deposit of the proceeds of the sale of the bonds or revenues of the public utility in trust, including the appointment of depositories or trustees. An ordinance or resolution authorizing the issuance of bonds or other obligations payable from revenues of a public utility constitutes a contract with the holder of bonds or other obligations issued pursuant to the ordinance or resolution.

(j) The ordinance or resolution required under par. (c) may set apart bonds equal to the amount of any secured debt or charge subject to which a public utility may be purchased, acquired, leased, constructed, extended, added to or improved. The ordinance or resolution shall set aside for interest and debt service fund from the income and revenues of the public utility a sum sufficient to comply with the requirements of the instrument creating the lien, or, if the instrument does not make any provision for it, the ordinance or resolution shall fix the amount which shall be set aside into a secured debt fund from month to month for interest on the secured debt, and a fixed amount or proportion not exceeding a stated sum, which shall be not less than 1 percent of the principal, to be set aside into the fund to pay the principal of the debt. Any surplus after satisfying the debt may be transferred to the special redemption fund. Public utility bonds set aside for the debt may be issued to an amount sufficient with the amount then in the debt service fund to pay and retire the debt or any portion of it. The bonds may be issued at not less than 95 percent of the par value in exchange for, or satisfaction of, the secured debt, or may be sold in the manner provided in this paragraph, and the proceeds applied in payment of the secured debt at maturity or before maturity by agreement with the holder. The governing body of a municipality and the owners of a public utility acquired, purchased, leased, constructed, extended, added to or improved under this paragraph may contract that public utility bonds providing for the secured debt or for the whole purchase price shall be deposited with a trustee or depository and released from deposit to secure the payment of the debt.

(k) A municipality purchasing, acquiring, leasing, constructing, extending, adding to or improving, conducting, controlling, operating or managing a public utility subject to a mortgage or deed of trust by the vendor or the vendor's predecessor in title to secure the payment of outstanding and unpaid bonds made by the vendor or the vendor's predecessor in title, may readjust, renew, consolidate or extend the obligation evidenced by the outstanding bonds and continue the lien of the mortgage, securing the mortgage by issuing bonds to refund the outstanding mortgage or revenue bonds at or before their maturity. The refunding bonds are payable only out of a special redemption fund created and set aside by ordinance or resolution under par. (e). The refunding bonds shall be secured by a mortgage lien upon the public utility, and the municipality may adopt all ordinances or resolutions and take all proceedings, following the procedure under this subsection. The lien has the same priority on the

public utility as the mortgage securing the outstanding bonds, unless otherwise expressly provided in the proceedings of the governing body of the municipality.

(L)1. If the governing body of a municipality, by ordinance or resolution, declares its intentions to authorize the issuance or sale of revenue bonds under this section, the governing body may, prior to issuance of the bonds and in anticipation of their sale, authorize the issuance of bond anticipation notes by the adoption of a resolution or ordinance. The notes shall be named "bond anticipation notes". Bond anticipation notes may be issued for the purposes for which the municipality has authority to issue revenue bonds. The ordinance or resolution authorizing the bond anticipation notes shall state the purposes for which the bond anticipation notes are to be issued and shall set forth a covenant of the municipality to issue the revenue bonds in an amount sufficient to retire the outstanding bond anticipation notes. The ordinance or resolution may contain other covenants and provisions, including a description of the terms of the revenue bonds to be issued. The municipality may pledge revenues of the public utility to payment of the principal and interest on the bond anticipation notes. Prior to issuance of the bond anticipation notes, the governing body may adopt an ordinance or resolution authorizing the revenue bonds.

2. Bond anticipation notes may be issued for periods of up to 5 years and may, by ordinance or resolution of the governing body of a municipality, be refunded one or more times, if the refunding bond anticipation notes do not exceed 5 years in term and if they will be paid within 10 years after the date of issuance of the original bond anticipation notes. Bond anticipation notes shall be executed as provided in s. 67.08(1) and may be registered under s. 67.09. These notes shall state the sources from which they are payable. Bond anticipation notes are not an indebtedness of the municipality issuing them, and no lien may be created or attached with respect to any property of the municipality as a consequence of the issuance of the notes.

3. Any funds derived from the issuance and sale of revenue bonds under this section and issued subsequent to the execution and sale of bond anticipation notes constitute a trust fund, and the fund shall be expended first for the payment of principal and interest of the bond anticipation notes, and then may be expended for other purposes set forth in the ordinance or resolution authorizing the revenue bonds. No bond anticipation notes may be issued unless a financial officer of the municipality certifies to the governing body of the municipality that contracts with respect to additions, improvements and extensions are to be let and that the proceeds of the notes are required for the payment of the contracts.

4. Following the issuance of the bond anticipation notes, revenues of the public utility may be paid into a fund to pay principal and interest on the bond anticipation notes, which moneys or any part of them may, by the ordinance or resolution authorizing the issuance of bond anticipation notes, be pledged for the payment of the principal of and interest on the notes. The ordinance or resolution shall pledge to the payment of the principal of the notes the proceeds of the sale of the revenue bonds in anticipation of the sale of which the notes were authorized to be issued and may provide for use of revenue of the public utility or other available funds for payment of principal on the notes. The notes are negotiable instruments.

6. A municipality authorized to issue or sell bond anticipation notes under this paragraph may, in addition to the revenue sources or bond proceeds, appropriate funds out of its annual tax levy for the payment of the notes. The payment of the notes out of funds from a tax levy is not an obligation of the municipality to make any other appropriation.

7. Bond anticipation notes are a legal form of investment for municipal funds under s. 66.0603(1m).

(5) A municipality which may own, purchase, acquire, lease, construct, extend, add to, improve, conduct, control, operate or manage any public utility may, by action of its governing body, in lieu of issuing bonds or levying taxes and in addition to any other lawful methods of paying obligations, provide for or secure the payment of the cost of purchasing, acquiring, leasing,

constructing, extending, adding to, improving, conducting, controlling, operating or managing a public utility by pledging, assigning or otherwise hypothecating, shares of stock evidencing a controlling interest in a public utility, or the net earnings or profits derived, or to be derived, from the operation of the public utility. The municipality may enter into the contracts and may mortgage the public utility and issue obligations to carry out this subsection. A municipality may issue additional obligations under this section, but those obligations are subordinate to all prior obligations, except that the municipality may in the ordinance or resolution authorizing obligations under this subsection permit the issue of additional obligations on a parity with those previously issued.

(6)(a) Revenue bonds issued by a local professional baseball park district created under subch. III of ch. 229 are subject to the provisions in ss. 229.72 to 229.81.

(b) Revenue bonds issued by a local professional football stadium district created under subch. IV of ch. 229 are subject to the provisions in ss. 229.829 to 229.834.

(c) Revenue bonds issued by a local cultural arts district created under subch. V of ch. 229 are subject to the provisions in ss. 229.849 to 229.853.

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 176

Note: 1999 Wis. Act 65 authorized the creation of local cultural arts districts and provided, in s. 66.067, that local cultural arts facilities "are public utilities within the meaning of s. 66.066." Similarly, 1999 Wis. Act 167 authorized the creation of local professional football districts and provided, in s. 66.067, that local professional football stadium facilities "are public utilities within the meaning of s. 66.066." 1999 Wis. Act 150 repealed s. 66.067 and added to the definition of "public utility" under s. 66.066(1)(b) the list of facilities which s. 66.067 had identified as public utilities. At the same time, Act 150 renumbered s. 66.066(1)(b) to be s. 66.0621(1)(b). However, Act 150 did not take into account the treatments of s. 66.067 by Acts 65 and 167 and so failed to include local cultural arts facilities and professional football stadium facilities in the definition of "public utility" in the new s. 66.0621(1)(b). It appears there was no intent in the Act 150 repeal to effect any substantive change. A note to the treatment of s. 66.067 by Act 150 states that the act "[r]epeals s. 66.067, relating to permissible public works projects, since the substance of the section has been incorporated into s. 66.0621(1)(b)." Further, the prefatory note to Act 150 states:

This bill is recommended by the joint legislative council's special committee on general municipal law recodification. The special committee was directed to recodify chapter 66 of the statutes by the process of reorganization into logical subchapters, sections and subunits, repeal of unnecessary or archaic and obsolete language, relocation of those provisions more appropriately placed elsewhere in the statutes and modernization of language where appropriate. The special committee was directed to refrain from recommending substantive changes that would significantly affect relationships between governmental units or engender substantial controversy in the legislative process.

COMMENTS--1999 ACT 150, § 176

Note: Repeals an archaic provision of the statutes regulating proceedings relating to a public utility that were begun prior to May 6, 1911.

Notes of Decisions (23)

W. S. A. 66.0621, WI ST 66.0621
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W.S.A. 66.0623

66.0623. Refunding village, town, sanitary, and inland lake district bonds

Currentness

A village, town, town sanitary district established under s. 60.71(1), or public inland lake protection and rehabilitation district established under ch. 33 that has undertaken to construct a combined sewer and water system and issued revenue bonds payable from the combined revenues of the system and that is unable to provide sufficient funds to complete the construction of the system and to meet maturing principal of the revenue bonds, may, with the consent of all of the holders of noncallable bonds, refund all or any part of its outstanding indebtedness, including revenue bonds, by issuing term bonds maturing in not more than 20 years, payable solely from the revenues of the combined sewer and water system and redeemable at par on any interest payment date. The bonds may be issued as provided in s. 66.0621(4) and shall pledge income from hydrant rentals and all sewer and water charges and may contain any covenants authorized by law, except if bonds are issued under this section to refund floating indebtedness, the bonds are subject to the prior lien and claim of all bonds issued to refund revenue bonds issued prior to the refunding.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0623, WI ST 66.0623
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0625

66.0625. Joint issuance of mass transit bonding

Currentness

(1) In this section:

(a) “Political subdivision” means a county, city, village or town.

(b) “Public transit body” means any transit or transportation commission or authority and public corporation established by law or by interstate compact to provide mass transportation services and facilities.

(2) In addition to the provisions of any other statutes specifically authorizing cooperation between political subdivisions or public transit bodies, unless those statutes specifically exclude action under this section, any political subdivision or public transit body may, for mass transit purposes, issue bonds or, with any other political subdivision or public transit body, jointly issue bonds.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0625, WI ST 66.0625
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0626

66.0626. Special assessments or charges for contaminated well or wastewater system loans

Currentness

(1) In this section:

(a) "Contaminated private water supply" has the meaning provided in s. 281.75(1)(b).

(b) "Failing private on-site wastewater treatment system" has the meaning provided in s. 145.01(4m).

(c) "Political subdivision" means a city, village, town, or county.

(d) "Private on-site wastewater treatment system" has the meaning provided in s. 145.01(12).

(e) "Private water supply" has the meaning provided in s. 281.75(1)(f).

(f) "Well subject to abandonment" has the meaning provided in s. 281.75(1)(i).

(2) A political subdivision or its designee may, with the agreement of the owner of the private water supply, well, or wastewater treatment system, remediate a contaminated private water supply, fill and seal a well subject to abandonment, or rehabilitate, replace, or abandon a failing private on-site wastewater treatment system, that is located in the political subdivision, or may make a loan at or below the market interest rate, as defined in s. 281.59(1)(b), including an interest-free loan, to the owner of a contaminated private water supply, a well subject to abandonment, or a failing private on-site wastewater treatment system, that is located in the political subdivision, for those purposes. If a political subdivision takes any of the actions under this subsection, the political subdivision may, as a special charge under s. 66.0627 or special assessment under s. 66.0703, recover the costs of the remediation, the filling and sealing, or the rehabilitation, replacement, or abandonment, or collect the loan repayment. Notwithstanding s. 66.0627(4), a special charge imposed under this subsection may be collected in installments and may be included in the current or next tax roll for collection and settlement under ch. 74 even if the special charge is not delinquent.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0626, WI ST 66.0626
Current through 2023 Act 272, published April 10, 2024.

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W.S.A. 66.0627

66.0627. Special charges for current services and certain loan repayments

Currentness

(1) In this section:

(ad) “Brownfield revitalization project” means any of the following actions when taken upon premises that are located on, or that constitute, brownfields, as defined in s. 238.13 (1)(a):

1. Site assessment.

2. Remediation.

3. Lead or asbestos abatement.

4. Demolition.

5. Standard site preparation actions not included in subds. 1. to 4.

(am) “Energy efficiency or reliability improvement” means an improvement to a premises that reduces the usage of energy, or increases the efficiency or reliability of energy usage, at the premises, including energy storage or backup power generation improvements or improvements that facilitate participation in a microgrid.

(ao) “EV infrastructure improvement” means an improvement to a premises to provide facilities for charging vehicles that are fully or partially powered by electricity.

(b) “Political subdivision” means a city, village, town, or county.

(bk) “Renewable resource application” means any of the following:

1. An improvement to a premises that allows for the production of energy through the incorporation of solar thermal electric or photovoltaic energy.

2. An improvement to a premises that allows for the small scale derivation of electricity from a renewable resource listed under s. 196.378(1)(h).

3. A manure digestion or other biomass system that produces natural gas.

(bm) "Resiliency improvement" means an improvement to a premises intended to increase resilience or improve the durability of infrastructure, including an improvement intended to improve storm and wind durability or wind resistance or to assist in fire suppression or mitigation of damage from flooding.

(c) "Service" includes snow and ice removal, weed elimination, street sprinkling, oiling and tarring, repair of sidewalks or curb and gutter, garbage and refuse disposal, recycling, storm water management, including construction of storm water management facilities, tree care, removal and disposition of dead animals under s. 60.23(20), loan repayment under s. 70.57(4)(b), soil conservation work under s. 92.115, and snow removal under s. 86.105.

(cg) "Storm water control measure" means an improvement to a premises that uses structural or nonstructural measures, practices, techniques, or devices designed to mitigate the negative impacts of storm water runoff or other surface runoff to the premises, including an infiltration system, wet detention pond, constructed wetland, grassed swale, or vegetative roofing system. "Storm water control measure" does not include a rain barrel or cistern designed for temporary storage of precipitation.

(d) "Water efficiency improvement" means an improvement to a premises that reduces the usage of water, or increases the efficiency of water usage, at the premises.

(2) Except as provided in sub. (5), the governing body of a city, village or town may impose a special charge against real property for current services rendered by allocating all or part of the cost of the service to the property served. The authority under this section is in addition to any other method provided by law.

(3)(a) Except as provided in par. (b), the governing body of the city, village or town may determine the manner of providing notice of a special charge.

(b) Before a special charge for street tarring or the repair of sidewalks, curbs or gutters may be imposed, a public hearing shall be held by the governing body on whether the service in question will be funded in whole or in part by a special charge. Any interested person may testify at the hearing. Notice of the hearing shall be by class 1 notice under ch. 985, published at least 20 days before the hearing. A copy of the notice shall be mailed at least 10 days before the hearing to each interested person whose address is known or can be ascertained with reasonable diligence. The notice under this paragraph shall state the date, time and location of the hearing, the subject matter of the hearing and that any interested person may testify.

(4) A special charge is not payable in installments. If a special charge is not paid within the time determined by the governing body, the special charge is delinquent. A delinquent special charge becomes a lien on the property against which it is imposed

as of the date of delinquency. The delinquent special charge shall be included in the current or next tax roll for collection and settlement under ch. 74.

(5) Except with respect to storm water management, including construction of storm water management facilities, no special charge may be imposed under this section to collect arrearages owed a municipal public utility.

(6) If a special charge imposed under this section is held invalid because this section is found unconstitutional, the governing body may reassess the special charge under any applicable law.

(7) Notwithstanding sub. (2), no political subdivision may enact an ordinance, or enforce an existing ordinance, that imposes a fee on the owner or occupant of property for a call for assistance that is made by the owner or occupant requesting law enforcement services that relate to any of the following:

(a) Domestic abuse, as defined in s. 813.12(1)(am).

(b) Sexual assault, as described under ss. 940.225, 948.02, and 948.025.

(c) Stalking, as described in s. 940.32.

(8)(a)1. Except as provided in subd. 2., a political subdivision may make a loan, or enter into an agreement regarding loan repayments to a 3rd party for owner-arranged or lessee-arranged financing, to an owner or lessee of a premises that is a residential property containing at least 5 dwelling units or a nonresidential property and that is located in the political subdivision for a brownfield revitalization project or for the financing or refinancing of a project for making, installing, operating, or maintaining any of the following with regard to the premises:

a. An energy efficiency or reliability improvement.

b. A water efficiency improvement.

c. A renewable resource application.

d. An EV infrastructure improvement.

e. A resiliency improvement.

f. A storm water control measure.

2. A political subdivision may not make a loan or enter into an agreement under subd. 1. for the financing or refinancing of a project for making, installing, operating, or maintaining a resiliency improvement for a premises to which a floodplain zoning ordinance applies unless all of the following apply:

a. If the premises is a nonconforming building, as defined in s. 87.30(1d)(a)1., the building would be permanently repaired, reconstructed, or improved so as to comply with all applicable requirements of the floodplain zoning ordinance for the area of the floodplain that it occupies after completion of the resiliency improvement.

b. If the political subdivision participates in the National Flood Insurance Program, the owner or lessee of the premises agrees to maintain any flood insurance policy required under the program for the premises.

(ag)1. Subject to subd. 2., a political subdivision may make a loan, or enter into an agreement regarding loan repayments to a 3rd party for owner-arranged financing, to an owner of a premises located in the political subdivision for the purpose of replacing customer-side water service lines, as defined in s. 196.372(1)(a), containing lead.

2. If a political subdivision makes a loan under subd. 1., the political subdivision shall require each owner of a premises located in the political subdivision that is serviced by a customer-side water service line, as defined in s. 196.372(1)(a), containing lead to replace that customer-side water service line.

(am) If a political subdivision makes a loan or enters into an agreement under par. (a) 1. or (ag), the political subdivision may collect the amounts due under the loan or agreement as a special charge under this section. Notwithstanding sub. (4), a special charge imposed under this paragraph may be collected in installments and may be included in the current or next tax roll for collection and settlement under ch. 74 even if the special charge is not delinquent. If a political subdivision makes a loan, or enters into an agreement regarding loan repayments to a 3rd party, the repayment period may not exceed 30 years.

(b) A political subdivision that imposes a special charge under par. (am) may permit special charge installments to be collected by a 3rd party that has provided financing for the project under par. (a)1. and may require that the 3rd party inform the political subdivision if a special charge installment is delinquent.

(c) An installment payment authorized under par. (am) that is delinquent becomes a lien on the property that benefits from the project under par. (a)1. or (ag) as of the date of delinquency. A lien under this paragraph runs with the land and has the same priority as a special assessment lien.

(cm)1. If an installment payment authorized under par. (am) is delinquent, a lien under par. (c) may be enforced by foreclosure under s. 75.521.

2. The governing body of a county may assign the county's right to take judgment with respect to any parcel that is subject to subd. 1. to a 3rd party that is party to a loan repayment agreement under par. (a)1. or (ag). An assignment under this subdivision shall be in accordance with s. 75.106, except that s. 75.106(1) and (2)(d), (e), and (f) do not apply.

(d) A political subdivision that, under par. (a)1., makes a loan to, or enters an agreement with, an owner or lessee for a project under par. (a)1. shall require the owner or lessee to do all of the following:

1. For an energy efficiency or reliability improvement or water efficiency improvement, obtain a 3rd-party assessment of the baseline water or energy use of the owner or lessee's property and an assessment of the expected monetary savings due to the improvement or, for a renewable resource application, obtain an assessment of the renewable energy production of the application and the expected monetary benefit to be generated by the application. This subdivision does not apply to a loan or agreement for a brownfield revitalization project, a customer-side water service line replacement, an EV infrastructure improvement, a resiliency improvement, or a storm water control measure.

2. After the project under par. (a)1. is complete, provide a verification that the project was properly made, installed, or maintained or, for a loan or agreement solely for the operation of a project, that at the time the loan is made or the agreement entered into the project was in proper operational condition.

(f) A political subdivision shall require that the owner or lessee obtain the written consent of all holders of a mortgage of record on the premises as a condition of making a loan or entering into an agreement under par. (a)1.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 170

Note: Restates s. 66.60(16), relating to special charges, and renumbers the provision to make it a separate section within ch. 66.

In addition:

1. Expands the examples in the definition of service to expressly include removal and disposition of dead animals under s. 60.23(20), conservation work under s. 92.115 [as renumbered by this bill] and snow removal under s. 86.105. Previously, these services were authorized to be funded by special assessment under s. 66.345, repealed by this bill. See Section 372 of this bill.

2. Expands the examples in the definition of service to expressly include recycling to reflect prevailing interpretation and current practice.

Notes of Decisions (6)

W. S. A. 66.0627, WI ST 66.0627
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0628

66.0628. Fees imposed by a political subdivision

Currentness

(1) In this section:

(a) “Political subdivision” means a city, village, town, or county.

(b) “Reasonable relationship” means that the cost charged by a political subdivision for a service provided to a person may not exceed the political subdivision's reasonable direct costs that are associated with any activity undertaken by the political subdivision that is related to the fee.

(2) Any fee that is imposed by a political subdivision shall bear a reasonable relationship to the service for which the fee is imposed.

(2m) A political subdivision may not impose a fee or charge related to the political subdivision enforcing an ordinance related to noxious weeds, electronic waste, or other building or property maintenance standards unless the political subdivision first notifies the person against whom the fee or charge is to be imposed that the fee or charge may be imposed. If the notice relates to a building that is not owner-occupied, the notice shall be provided to the owner by 1st class mail or electronic mail. If the owner of a property provides an electronic mail address to a political subdivision, the political subdivision may not impose a fee or charge related to the political subdivision enforcing an ordinance related to noxious weeds, electronic waste, or other building or property maintenance standards at that property unless the political subdivision first notifies the owner of the property using the electronic mail address provided. This subsection does not apply to a fee or charge related to the clearing of snow or ice from a sidewalk or to an ordinance violation that creates an immediate danger to public health, safety, or welfare.

(3) If a political subdivision enters into a contract to purchase engineering, legal, or other professional services from another person and the political subdivision passes along the cost for such professional services to another person under a separate contract between the political subdivision and that person, the rate charged that other person for the professional services may not exceed the rate customarily paid for similar services by the political subdivision.

(4)(a) Any person aggrieved by a fee imposed by a political subdivision because the person does not believe that the fee bears a reasonable relationship to the service for which the fee is imposed may appeal the reasonableness of the fee to the tax appeals commission by filing a petition with the commission within 90 days after the fee is due and payable. The commission's decision may be reviewed under s. 73.015. For appeals brought under this subsection, the filing fee required under s. 73.01(5)(a) does not apply.

(b) With regard to an appeal filed with the tax appeals commission under par. (a), the political subdivision shall bear the burden of proof to establish that a reasonable relationship exists between the fee imposed and the services for which the fee is imposed.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (2)

W. S. A. 66.0628, WI ST 66.0628
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.063. Repealed by 1985 Act 187, § 9, eff. April 22, 1986

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W.S.A. 66.063

66.063. Repealed by 1985 Act 187, § 9, eff. April 22, 1986

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.063, WI ST 66.063
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.064

66.064. Renumbered 66.0807 and amended by 1999 Act 150, § 171, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.064, WI ST 66.064
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.065

66.065. Renumbered 66.0803 and amended by 1999 Act 150, §§ 172 to 174, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.065, WI ST 66.065
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.066

66.066. Renumbered in part and repealed in part by 1999 Act 150, §§ 175 to 177, eff. Jan. 1, 2001; 2001 Act 30, § 36, eff. Dec. 14, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

W. S. A. 66.066, WI ST 66.066
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.067. Repealed by 1999 Act 150, § 178, eff. Jan. 1, 2001

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W.S.A. 66.067

66.067. Repealed by 1999 Act 150, § 178, eff. Jan. 1, 2001

Currentness

Credits

<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 178

Note: Repeals s. 66.067, relating to permissible public works projects, since the substance of the section has been incorporated into s. 66.0621(1)(b).

W. S. A. 66.067, WI ST 66.067
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.068

66.068. Renumbered in part and repealed in part by 1999 Act 150, §§ 179 to 183, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.068, WI ST 66.068
Current through 2023 Act 272, published April 10, 2024.

End of Document


KeyCite Red Flag - Severe Negative Treatment
KeyCite Red Flag Negative Treatment 66.069. Renumbered in part and repealed in part by 1999 Act 150, §§ 184 to 189, eff. Jan. 1, 2001

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Subchapter VI. Finance; Revenues

W.S.A. 66.069

66.069. Renumbered in part and repealed in part by 1999 Act 150, §§ 184 to 189, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.069, WI ST 66.069
Current through 2023 Act 272, published April 10, 2024.

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Subchapter VI. Finance; Revenues

W.S.A. 66.07

66.07. Renumbered 66.0817 and amended by 1999 Act 150, § 190, eff. Jan. 1, 2001

Currentness

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.07, WI ST 66.07
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0701

66.0701. Special assessments by local ordinance

Currentness

(1) Except as provided in s. 66.0721, in addition to other methods provided by law, the governing body of a town, village or 2nd, 3rd or 4th class city may, by ordinance, provide that the cost of installing or constructing any public work or improvement shall be charged in whole or in part to the property benefited, and make an assessment against the property benefited in the manner that the governing body determines. The special assessment is a lien against the property from the date of the levy.

(2) Every ordinance under this section shall contain provisions for reasonable notice and hearing. Any person against whose land a special assessment is levied under the ordinance may appeal in the manner prescribed in s. 66.0703(12) within 40 days of the date of the final determination of the governing body.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (22)

W. S. A. 66.0701, WI ST 66.0701
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0703

66.0703. Special assessments, generally

Currentness

(1)(a) Except as provided in s. 66.0721, as a complete alternative to all other methods provided by law, any city, town or village may, by resolution of its governing body, levy and collect special assessments upon property in a limited and determinable area for special benefits conferred upon the property by any municipal work or improvement; and may provide for the payment of all or any part of the cost of the work or improvement out of the proceeds of the special assessments.

(b) The amount assessed against any property for any work or improvement which does not represent an exercise of the police power may not exceed the value of the benefits accruing to the property. If an assessment represents an exercise of the police power, the assessment shall be upon a reasonable basis as determined by the governing body of the city, town or village.

(c) If any property that is benefited is by law exempt from assessment, the assessment shall be computed and shall be paid by the city, town or village.

(2) The cost of any work or improvement to be paid in whole or in part by special assessment on property may include the direct and indirect cost, the resulting damages, the interest on bonds or notes issued in anticipation of the collection of the assessments, a reasonable charge for the services of the administrative staff of the city, town or village and the cost of any architectural, engineering and legal services, and any other item of direct or indirect cost that may reasonably be attributed to the proposed work or improvement. The amount to be assessed against all property for the proposed work or improvement shall be apportioned among the individual parcels in the manner designated by the governing body.

(3) A parcel of land against which a special assessment has been levied for the sanitary sewer or water main laid in one of the streets that the parcel abuts is entitled to a deduction or exemption that the governing body determines to be reasonable and just under the circumstances of each case, when a special assessment is levied for the sanitary sewer or water main laid in the other street that the corner lot abuts. The governing body may allow a similar deduction or exemption from special assessments levied for any other public improvement.

(4) Before the exercise of any powers conferred by this section, the governing body shall declare by preliminary resolution its intention to exercise the powers for a stated municipal purpose. The resolution shall describe generally the contemplated purpose, the limits of the proposed assessment district, the number of installments in which the special assessments may be paid, or that the number of installments will be determined at the hearing required under sub. (7), and direct the proper municipal officer or employee to make a report on the proposal. The resolution may limit the proportion of the cost to be assessed.

(5) The report required by sub. (4) shall consist of:

(a) Preliminary or final plans and specifications.

(b) An estimate of the entire cost of the proposed work or improvement.

(c) Except as provided in par. (d), an estimate, as to each parcel of property affected, of:

1. The assessment of benefits to be levied.

2. The damages to be awarded for property taken or damaged.

3. The net amount of the benefits over damages or the net amount of the damages over benefits.

(d) A statement that the property against which the assessments are proposed is benefited, if the work or improvement constitutes an exercise of the police power. If this paragraph applies, the estimates required under par. (c) shall be replaced by a schedule of the proposed assessments.

(6) A copy of the report when completed shall be filed with the municipal clerk for public inspection. If property of the state may be subject to assessment under s. 66.0705, the municipal clerk shall file a copy of the report with the state agency which manages the property. If the assessment to the property of the state for a project, as defined under s. 66.0705(2), is $50,000 or more, the state agency shall submit a request for approval of the assessment, with its recommendation, to the building commission. The building commission shall review the assessment and shall determine within 90 days of the date on which the commission receives the report if the assessment is just and legal and if the proposed improvement is compatible with state plans for the facility which is the subject of the proposed improvement. If the building commission so determines, it shall approve the assessment. No project in which the property of the state is assessed at $50,000 or more may be commenced and no contract on the project may be let without approval of the assessment by the building commission under this subsection. The building commission shall submit a copy of its determination under this subsection to the state agency that manages the property which is the subject of the determination.

(7)(a) Upon the completion and filing of the report required by sub. (4), the city, town or village clerk shall prepare a notice stating the nature of the proposed work or improvement, the general boundary lines of the proposed assessment district including, in the discretion of the governing body, a small map, the place and time at which the report may be inspected, and the place and time at which all interested persons, or their agents or attorneys, may appear before the governing body, a committee of the governing body or the board of public works and be heard concerning the matters contained in the preliminary resolution and the report. The notice shall be published as a class 1 notice, under ch. 985, in the city, town or village and a copy of the notice shall be mailed, at least 10 days before the hearing or proceeding, to every interested person whose post-office address is known, or can be ascertained with reasonable diligence. The hearing shall commence not less than 10 nor more than 40 days after publication.

(b) The notice and hearing requirements under par. (a) do not apply if they are waived, in writing, by all the owners of property affected by the special assessment.

(8)(a) After the hearing upon any proposed work or improvement, the governing body may approve, disapprove or modify, or it may rerefer the report prepared under subs. (4) and (5) to the designated officer or employee with directions to change the plans and specifications and to accomplish a fair and equitable assessment.

(b) If an assessment of benefits is made against any property and an award of compensation or damages is made in favor of the same property, the governing body shall assess against or award in favor of the property only the difference between the assessment of benefits and the award of damages or compensation.

(c) When the governing body finally determines to proceed with the work or improvement, it shall approve the plans and specifications and adopt a resolution directing that the work or improvement be carried out and paid for in accordance with the report as finally approved.

(d) The city, town or village clerk shall publish the final resolution as a class 1 notice, under ch. 985, in the assessment district and a copy of the resolution shall be mailed to every interested person whose post-office address is known, or can be ascertained with reasonable diligence.

(e) When the final resolution is published, all work or improvements described in the resolution and all awards, compensations and assessments arising from the resolution are then authorized and made, subject to the right of appeal under sub. (12).

(9) If more than a single type of project is undertaken as part of a general improvement affecting any property, the governing body may finally combine the assessments for all purposes as a single assessment on each property affected, if each property owner may object to the assessment for any single purpose or for more than one purpose.

(10) If the actual cost of any project, upon completion or after the receipt of bids, is found to vary materially from the estimates, if any assessment is void or invalid, or if the governing body decides to reconsider and reopen any assessment, it may, after giving notice as provided in sub. (7)(a) and after a public hearing, amend, cancel or confirm the prior assessment. A notice of the resolution amending, canceling or confirming the prior assessment shall be given by the clerk as provided in sub. (8)(d). If the assessments are amended to provide for the refunding of special assessment B bonds under s. 66.0713(6), all direct and indirect costs reasonably attributable to the refunding of the bonds may be included in the cost of the public improvements being financed.

(11) If the cost of the project is less than the special assessments levied, the governing body, without notice or hearing, shall reduce each special assessment proportionately and if any assessments or installments have been paid the excess over cost shall be applied to reduce succeeding unpaid installments, if the property owner has elected to pay in installments, or refunded to the property owner.

(12)(a) A person having an interest in a parcel of land affected by a determination of the governing body, under sub. (8)(c), (10) or (11), may, within 90 days after the date of the notice or of the publication of the final resolution under sub. (8)(d), appeal the determination to the circuit court of the county in which the property is located. The person appealing shall serve a written notice of appeal upon the clerk of the city, town or village and execute a bond to the city, town or village in the sum of $150 with 2 sureties or a bonding company to be approved by the city, town or village clerk, conditioned for the faithful prosecution of the appeal and the payment of all costs that may be adjudged against that person. The clerk, if an appeal is taken, shall prepare

a brief statement of the proceedings in the matter before the governing body, with its decision on the matter, and shall transmit the statement with the original or certified copies of all the papers in the matter to the clerk of the circuit court.

(b) The appeal shall be tried and determined in the same manner as cases originally commenced in circuit court, and costs awarded as provided in s. 893.80.

(c) If a contract has been made for making the improvement the appeal does not affect the contract, and certificates or bonds may be issued in anticipation of the collection of the entire assessment for the improvement, including the assessment on any property represented in the appeal as if the appeal had not been taken.

(d) Upon appeal under this subsection, the court may, based on the improvement as actually constructed, render a judgment affirming, annulling or modifying and affirming, as modified, the action or decision of the governing body. If the court finds that any assessment or any award of damages is excessive or insufficient, the assessment or award need not be annulled, but the court may reduce or increase the assessment or award of damages and affirm the assessment or award as so modified.

(e) An appeal under this subsection is the sole remedy of any person aggrieved by a determination of the governing body, whether or not the improvement was made according to the plans and specifications, and shall raise any question of law or fact, stated in the notice of appeal, involving the making of the improvement, the assessment of benefits or the award of damages or the levy of any special assessment. The limitation in par. (a) does not apply to appeals based on fraud or on latent defects in the construction of the improvement discovered after the period of limitation.

(f) It is a condition to the maintenance of an appeal that any assessment appealed from shall be paid when the assessment or any installments become due. If there is a default in making a payment, the appeal shall be dismissed.

(13) Every special assessment levied under this section is a lien on the property against which it is levied on behalf of the municipality levying the assessment or the owner of any certificate, bond or other document issued by public authority, evidencing ownership of or any interest in the special assessment, from the date of the determination of the assessment by the governing body. The governing body shall provide for the collection of the assessments and may establish penalties for payment after the due date. The governing body shall provide that all assessments or installments that are not paid by the date specified shall be extended upon the tax roll as a delinquent special assessment, as defined under s. 74.01(3), against the property and all proceedings in relation to the collection, return and sale of property for delinquent real estate taxes apply to the special assessment, except as otherwise provided by statute.

(14) If a special assessment levied under this section is held invalid because this section is found to be unconstitutional, the governing body may reassess the special assessment under any applicable law.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (224)

W. S. A. 66.0703, WI ST 66.0703

Current through 2023 Act 272, published April 10, 2024.

End of Document

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Chapter 66. General Municipality Law (Refs & Annos)
Subchapter VII. Special Assessments

W.S.A. 66.0705

66.0705. Property of public and private entities subject to special assessments

Currentness

(1)(a) The property of this state, except that held for highway right-of-way purposes or acquired and held for purposes under s. 85.08 or 85.09, and the property of every county, city, village, town, school district, sewerage district or commission, sanitary or water district or commission, or any public board or commission within this state, and of every corporation, company, or individual operating any railroad, telegraph, telecommunications, electric light, or power system, or doing any of the business mentioned in ch. 76, and of every other corporation or company is in all respects subject to all special assessments for local improvements.

(b) Certificates and improvement bonds for special assessments may be issued and the lien of the special assessments enforced against property described in par. (a), except property of the state, in the same manner and to the same extent as the property of individuals. Special assessments on property described in par. (a) may not extend to the right, easement or franchise to operate or maintain railroads, telegraph, telecommunications or electric light or power systems in streets, alleys, parks or highways. The amount represented by any certificate or improvement bond issued under this paragraph is a debt due personally from the corporation, company or individual, payable in the case of a certificate when the taxes for the year of its issue are payable, and in the case of a bond according to the terms of the bond.

(2) In this subsection, “assessment” means a special assessment on property of this state and “project” means any continuous improvement within overall project limits regardless of whether small exterior segments are left unimproved. If the assessment of a project is less than $50,000, or if the assessment of a project is $50,000 or more and the building commission approves the assessment under s. 66.0703(6), the state agency which manages the property shall pay the assessment from the revenue source which supports the general operating costs of the agency or program against which the assessment is made.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (18)

W. S. A. 66.0705, WI ST 66.0705
Current through 2023 Act 272, published April 10, 2024.

End of Document

W.S.A. 66.0707

66.0707. Assessment or special charge against property in adjacent city, village or town

Currentness

(1) A city, village or town may levy special assessments for municipal work or improvement under s. 66.0703 on property in an adjacent city, village or town, if the property abuts and benefits from the work or improvement and if the governing body of the municipality where the property is located by resolution approves the levy by resolution. The owner of the property is entitled to the use of the work or improvement on which the assessment is based on the same conditions as the owner of property within the city, village or town.

(2) A city, village or town may impose a special charge under s. 66.0627 against real property in an adjacent city, village or town that is served by current services rendered by the municipality imposing the special charge if the municipality in which the property is located approves the imposition by resolution. The owner of the property is entitled to the use and enjoyment of the service for which the special charge is imposed on the same conditions as the owner of property within the city, village or town.

(3) A special assessment or special charge under this section is a lien against the benefited property and shall be collected by the treasurer in the same manner as the taxes of the municipality and paid over by the treasurer to the treasurer of the municipality levying the assessment.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 192

Note: [The creation of subsec. (2)] Expands the scope of s. 66.65, renumbered s. 66.0707, to include special charges. Currently, the provision is limited to special assessments against property in an adjacent city, village or town that abuts and benefits from a public work or improvement. See Sections 550 and 551 of this bill [sections 550 and 551 renumber § 66.65 as subsecs. (1) and (3) of this section].

Notes of Decisions (1)

W. S. A. 66.0707, WI ST 66.0707
Current through 2023 Act 272, published April 10, 2024.

End of Document

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Subchapter VII. Special Assessments

W.S.A. 66.0709

66.0709. Preliminary payment of improvements funded by special assessments

Currentness

(1) In this section:

(a) "Local governmental unit" has the meaning given in s. 66.0713(1)(c).

(b) "Public improvement" has the meaning given in s. 66.0713(1)(d).

(2) If it is determined that the cost of a public improvement is to be paid, in whole or in part, by special assessments against the property to be benefited by the improvement, the resolution authorizing the public improvement shall provide that the whole, or any stated proportion, or no part of the estimated aggregate cost of the public improvement, which is to be levied as special assessments, shall be paid into the treasury of the local governmental unit in cash. The public improvement may not be commenced nor any contract for the improvement let until the payment required by the resolution is paid into the treasury of the local governmental unit by the owner or persons having an interest in the property to be benefited. The payment shall be credited against the amount of the special assessments levied or to be levied against benefited property designated by the payer. If a preliminary payment is required by the resolution, the refusal of one or more owners or persons having an interest in the property to be benefited to pay any preliminary payments does not prevent the making of the improvement if the entire specified sum is obtained from the remaining owners or interested parties.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.0709, WI ST 66.0709
Current through 2023 Act 272, published April 10, 2024.

End of Document

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Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter VIII. Public Utilities

W.S.A. 66.0801

66.0801. Definitions; effect on other authority

Currentness

(1) In this subchapter:

(a) "Municipal public utility" means a public utility owned or operated by a city, village or town.

(b) "Public utility" has the meaning given in s. 196.01(5).

(2) Sections 66.0803 to 66.0825 do not deprive the office of the commissioner of railroads, department of transportation or public service commission of any power under ss. 195.05 and 197.01 to 197.10 and ch. 196.

Credits
<<For credits, see Historical Note field.>>

Editors' Notes

COMMENTS--1999 ACT 150, § 235

Note: Restates a portion of s. 66.06, repealed by this bill, and provides a definition of municipal public utility for purposes of the subchapter. The current provision stating that the phrase resolution or ordinance, when used in specified sections, means ordinances only is deleted as unnecessary.

W. S. A. 66.0801, WI ST 66.0801
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter IX. Public Works and Projects

W.S.A. 66.0901

66.0901. Public works, contracts, bids

Currentness

(1) Definitions. In this section:

(ae) "Agreement with a labor organization" means any agreement with a labor organization, including a collective bargaining agreement, a project labor agreement, or a community workforce agreement.

(am) "Labor organization" has the meaning given in s. 5.02(8m).

(as) "Municipality" means the state or a town, city, village, school district, board of school directors, sewer district, drainage district, technical college district or other public or quasi-public corporation, officer, board or other public body charged with the duty of receiving bids for and awarding any public contracts.

(b) "Person" means an individual, partnership, association, limited liability company, corporation or joint stock company, lessee, trustee or receiver.

(bm) "Political subdivision" means a city, village, town, or county.

(c) "Public contract" means a contract for the construction, execution, repair, remodeling or improvement of a public work or building or for the furnishing of supplies or material of any kind, proposals for which are required to be advertised for by law.

(d) "Subcontractor" means a person whose relationship to the principal contractor is substantially the same as to a part of the work as the latter's relationship is to the proprietor. A "subcontractor" takes a distinct part of the work in a way that the "subcontractor" does not contemplate doing merely personal service.

(1m) Method of bidding. (a) Except when necessary to secure federal aid, whenever a political subdivision lets a public contract by bidding, the political subdivision shall comply with all of the following:

1. The bidding shall be on the basis of sealed competitive bids.

2. The contract shall be awarded to the lowest responsible bidder.

(b) Except when necessary to secure federal aid, a political subdivision may not use a bidding method that gives preference based on the geographic location of the bidder or that uses criteria other than the lowest responsible bidder in awarding a contract.

(2) Bidder's proof of responsibility. A municipality intending to enter into a public contract may, before delivering any form for bid proposals, plans, and specifications to any person, except suppliers, and others not intending to submit a direct bid, require the person to submit a full and complete statement sworn to before an officer authorized by law to administer oaths. The statement shall consist of information relating to financial ability, equipment, experience in the work prescribed in the public contract, and other matters that the municipality requires for the protection and welfare of the public in the performance of a public contract. The statement shall be in writing on a standard form of a questionnaire that is adopted and furnished by the municipality. The statement shall be filed in the manner and place designated by the municipality. The statement shall not be received less than 5 days prior to the time set for the opening of bids. The contents of the statement shall be confidential and may not be disclosed except upon the written order of the person furnishing the statement, for necessary use by the public body in qualifying the person, or in cases of actions against, or by, the person or municipality. The governing body of the municipality or the committee, board, or employee charged with, or delegated by the governing body with, the duty of receiving bids and awarding contracts shall properly evaluate the statement and shall find the maker of the statement either qualified or unqualified.

(3) Proof of responsibility, condition precedent. No bid shall be received from any person who has not submitted the statement as provided in sub. (2), provided that any prospective bidder who has once qualified to the satisfaction of the municipality, committee, board or employee, and who wishes to become a bidder upon subsequent public contracts under the same jurisdiction, need not separately qualify on each public contract unless required so to do by the municipality, committee, board or employee.

(4) Rejection of bids. If the municipality, committee, board or employee is not satisfied with the sufficiency of the answer contained in the statement provided under sub. (2), the municipality, committee, board or employee may reject or disregard the bid.

(5) Corrections of errors in bids. If a person submits a bid or proposal for the performance of public work under any public contract to be let by a municipality and the bidder claims that a mistake, omission or error has been made in preparing the bid, the bidder shall, before the bids are opened, make known the fact that an error, omission or mistake has been made. If the bidder makes this fact known, the bid shall be returned to the bidder unopened and the bidder may not bid upon the public contract unless it is readvertised and relet upon the readvertisement. If a bidder makes an error, omission or mistake and discovers it after the bids are opened, the bidder shall immediately and without delay give written notice and make known the fact of the mistake, omission or error which has been committed and submit to the municipality clear and satisfactory evidence of the mistake, omission or error and that it was not caused by any careless act or omission on the bidder's part in the exercise of ordinary care in examining the plans or specifications and in conforming with the provisions of this section. If the discovery and notice of a mistake, omission or error causes a forfeiture, the bidder may not recover the moneys or certified check forfeited as liquidated damages unless it is proven before a court of competent jurisdiction in an action brought for the recovery of the amount forfeited, that in making the mistake, error or omission the bidder was free from carelessness, negligence or inexcusable neglect.

(6) Separation of contracts; classification of contractors. In public contracts for the construction, repair, remodeling or improvement of a public building or structure, other than highway structures and facilities, a municipality may bid projects based on a single or multiple division of the work. Public contracts shall be awarded according to the division of work selected for

bidding. Except as provided in sub. (6m), the municipality may set out in any public contract reasonable and lawful conditions as to the hours of labor, wages, residence, character and classification of workers to be employed by any contractor, classify contractors as to their financial responsibility, competency and ability to perform work and set up a classified list of contractors. The municipality may reject the bid of any person, if the person has not been classified for the kind or amount of work in the bid.

(6m) Prohibited practices. A municipality may not do any of the following in a specification for bids for a public contract under this section:

(a) Require that a bidder enter into or adhere to an agreement with a labor organization.

(b) Consider as a factor in making an award under this section whether any bidder has or has not entered into an agreement with a labor organization.

(c) Require that a bidder enter into, adhere to, or enforce any agreement that requires, as a condition of employment, that the bidder or bidder's employees become or remain members of, or be affiliated with, a labor organization or pay any dues, fees, assessments, or other charges or expenses of any kind or amount, or provide anything of value, to a labor organization or a labor organization's health, welfare, retirement, or other benefit plan or program.

(6s) Protected activity. Nothing in this section prohibits employers or employees from entering into agreements or engaging in any other activity protected by the National Labor Relations Act, 29 USC 151 to 169.

(7) Bidder's certificate. When bidding on a public contract, the bidder shall incorporate and make a part of the bidder's proposal for doing any work or labor or furnishing any material in or about any public work or contract of the municipality a sworn statement by the bidder, or if not an individual by one authorized, that the bidder or authorized person has examined and carefully prepared the proposal from the plans and specifications and has checked the same in detail before submitting the proposal or bid to the municipality. As a part of the proposal, the bidder also shall submit a list of the subcontractors the bidder proposes to contract with and the class of work to be performed by each. In order to qualify for inclusion in the bidder's list a subcontractor shall first submit a bid in writing, to the general contractor at least 48 hours prior to the time of the bid closing. The list may not be added to or altered without the written consent of the municipality. A proposal of a bidder is not invalid if any subcontractor and the class of work to be performed by the subcontractor has been omitted from a proposal; the omission shall be considered inadvertent or the bidder will perform the work personally.

(8) Settlement of disputes; defaults. Whenever there is a dispute between a contractor or surety or the municipality as to whether there is compliance with the provisions of a public contract as to the hours of labor, wages, residence, character and classification of workers employed by the contractor, the determination of the municipality is final. If a violation of these provisions occurs, the municipality may declare the contract in default and request the surety to perform or relet upon advertisement the remaining portion of the public contract.

(9) Estimates and release of funds. (a) Notwithstanding sub. (1)(as), in this subsection, “municipality” does not include the department of transportation.

(b) As the work progresses under a contract involving $1,000 or more for the construction, execution, repair, remodeling or improvement of a public work or building or for the furnishing of supplies or materials, regardless of whether proposals for

the contract are required to be advertised by law, the municipality, from time to time, shall grant to the contractor an estimate of the amount and proportionate value of the work done, which entitles the contractor to receive the amount of the estimate, less the retainage, from the proper fund. The retainage shall be an amount equal to not more than 5 percent of the estimate until 50 percent of the work has been completed. At 50 percent completion, further partial payments shall be made in full to the contractor and no additional amounts may be retained unless the architect or engineer certifies that the job is not proceeding satisfactorily, but amounts previously retained shall not be paid to the contractor. At 50 percent completion or any time after 50 percent completion when the progress of the work is not satisfactory, additional amounts may be retained but the total retainage may not be more than 10 percent of the value of the work completed. Upon substantial completion of the work, an amount retained may be paid to the contractor. When the work has been substantially completed except for work which cannot be completed because of weather conditions, lack of materials or other reasons which in the judgment of the municipality are valid reasons for noncompletion, the municipality may make additional payments, retaining at all times an amount sufficient to cover the estimated cost of the work still to be completed or may pay out the entire amount retained and receive from the contractor guarantees in the form of a bond or other collateral sufficient to ensure completion of the job. For the purposes of this section, estimates may include any fabricated or manufactured materials and components specified, previously paid for by the contractor and delivered to the work or properly stored and suitable for incorporation in the work embraced in the contract.

(11) Limitation on performance of private construction work by political subdivisions. (a) In this subsection, "construction project" means a road, sewer, water, stormwater, wastewater, grading, parking lot, or other infrastructure-related project or the provision of construction-related services for such a project.

(b) Except for work ancillary to replacing a utility-side water service line, as defined in s. 196.372(1)(c), containing lead that is performed with the consent of a private property owner and that does not involve replacing the customer-side water service line, as defined in s. 196.372(1)(a), containing lead, a political subdivision may not use its own workforce to perform a construction project for which a private person is financially responsible.

(12) Public building plan information. (a) In this subsection:

1. "Public building plan information" means construction plans, designs, specifications, and related materials for construction work undertaken, or proposed to be undertaken, by a municipality pursuant to a public contract.

2. "Public plan room" means a nonprofit organization that gathers and makes available to the public for inspection and copying public building plan information.

(b) Notwithstanding s. 19.35(3), if a municipality receives a request for public building plan information from a public plan room, the municipality shall provide the requested information by electronic copy, and without charging a fee, if all of the following apply:

1. The public building plan information relates to a structure or building constructed, or proposed to be constructed, by a municipality.

2. The public plan room allows the public to register and inspect or copy the public building plan information that it obtains under this subsection without charging a fee.

(c) A municipality shall provide the requested information under par. (b) even if the municipality contracts with another person to assist the municipality with public contracts, related construction projects, or the management and storage of public building plan information.

Credits

<<For credits, see Historical Note field.>>

Notes of Decisions (60)

W. S. A. 66.0901, WI ST 66.0901
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter X. Planning, Housing and Transportation

W.S.A. 66.1001

66.1001. Comprehensive planning

Currentness

(1) Definitions. In this section:

(a) "Comprehensive plan" means a guide to the physical, social, and economic development of a local governmental unit that is one of the following:

1. For a county, a development plan that is prepared or amended under s. 59.69(2) or (3).

2. For a city, village, or town, a master plan that is adopted or amended under s. 62.23(2) or (3).

3. For a regional planning commission, a master plan that is adopted or amended under s. 66.0309(8), (9) or (10).

(am) "Consistent with" means furthers or does not contradict the objectives, goals, and policies contained in the comprehensive plan.

(b) "Local governmental unit" means a city, village, town, county or regional planning commission that may adopt, prepare or amend a comprehensive plan.

(c) "Political subdivision" means a city, village, town, or county that may adopt, prepare, or amend a comprehensive plan.

(2) Contents of a comprehensive plan. A comprehensive plan shall contain all of the following elements:

(a) *Issues and opportunities element.* Background information on the local governmental unit and a statement of overall objectives, policies, goals and programs of the local governmental unit to guide the future development and redevelopment of the local governmental unit over a 20-year planning period. Background information shall include population, household and employment forecasts that the local governmental unit uses in developing its comprehensive plan, and demographic trends, age distribution, educational levels, income levels and employment characteristics that exist within the local governmental unit.

(b) *Housing element.* A compilation of objectives, policies, goals, maps and programs of the local governmental unit to provide an adequate housing supply that meets existing and forecasted housing demand in the local governmental unit. The element shall assess the age, structural, value and occupancy characteristics of the local governmental unit's housing stock. The element shall also identify specific policies and programs that promote the development of housing for residents of the local governmental unit and provide a range of housing choices that meet the needs of persons of all income levels and of all age groups and persons with special needs, policies and programs that promote the availability of land for the development or redevelopment of low-income and moderate-income housing, and policies and programs to maintain or rehabilitate the local governmental unit's existing housing stock.

(c) *Transportation element*. A compilation of objectives, policies, goals, maps and programs to guide the future development of the various modes of transportation, including highways, transit, transportation systems for persons with disabilities, bicycles, electric scooters, electric personal assistive mobility devices, walking, railroads, air transportation, trucking and water transportation. The element shall compare the local governmental unit's objectives, policies, goals and programs to state and regional transportation plans. The element shall also identify highways within the local governmental unit by function and incorporate state, regional and other applicable transportation plans, including transportation corridor plans, county highway functional and jurisdictional studies, urban area and rural area transportation plans, airport master plans and rail plans that apply in the local governmental unit.

(d) *Utilities and community facilities element.* A compilation of objectives, policies, goals, maps and programs to guide the future development of utilities and community facilities in the local governmental unit such as sanitary sewer service, storm water management, water supply, solid waste disposal, on-site wastewater treatment technologies, recycling facilities, parks, telecommunications facilities, power-generating plants and transmission lines, cemeteries, health care facilities, child care facilities and other public facilities, such as police, fire and rescue facilities, libraries, schools and other governmental facilities. The element shall describe the location, use and capacity of existing public utilities and community facilities that serve the local governmental unit, shall include an approximate timetable that forecasts the need in the local governmental unit to expand or rehabilitate existing utilities and facilities or to create new utilities and facilities and shall assess future needs for government services in the local governmental unit that are related to such utilities and facilities.

(e) *Agricultural, natural and cultural resources element.* A compilation of objectives, policies, goals, maps and programs for the conservation, and promotion of the effective management, of natural resources such as groundwater, forests, productive agricultural areas, environmentally sensitive areas, threatened and endangered species, stream corridors, surface water, floodplains, wetlands, wildlife habitat, metallic and nonmetallic mineral resources consistent with zoning limitations under s. 295.20(2), parks, open spaces, historical and cultural resources, community design, recreational resources and other natural resources.

(f) *Economic development element.* A compilation of objectives, policies, goals, maps and programs to promote the stabilization, retention or expansion, of the economic base and quality employment opportunities in the local governmental unit, including an analysis of the labor force and economic base of the local governmental unit. The element shall assess categories or particular types of new businesses and industries that are desired by the local governmental unit. The element shall assess the local governmental unit's strengths and weaknesses with respect to attracting and retaining businesses and industries, and shall designate an adequate number of sites for such businesses and industries. The element shall also evaluate and promote the use of environmentally contaminated sites for commercial or industrial uses. The element shall also identify county, regional and state economic development programs that apply to the local governmental unit.

(g) *Intergovernmental cooperation element.* A compilation of objectives, policies, goals, maps, and programs for joint planning and decision making with other jurisdictions, including school districts, drainage districts, and adjacent local governmental

units, for siting and building public facilities and sharing public services. The element shall analyze the relationship of the local governmental unit to school districts, drainage districts, and adjacent local governmental units, and to the region, the state and other governmental units. The element shall consider, to the greatest extent possible, the maps and plans of any military base or installation, with at least 200 assigned military personnel or that contains at least 2,000 acres, with which the local governmental unit shares common territory. The element shall incorporate any plans or agreements to which the local governmental unit is a party under s. 66.0301, 66.0307 or 66.0309. The element shall identify existing or potential conflicts between the local governmental unit and other governmental units that are specified in this paragraph and describe processes to resolve such conflicts.

(h) *Land-use element.* A compilation of objectives, policies, goals, maps and programs to guide the future development and redevelopment of public and private property. The element shall contain a listing of the amount, type, intensity and net density of existing uses of land in the local governmental unit, such as agricultural, residential, commercial, industrial and other public and private uses. The element shall analyze trends in the supply, demand and price of land, opportunities for redevelopment and existing and potential land-use conflicts. The element shall contain projections, based on the background information specified in par. (a), for 20 years, in 5-year increments, of future residential, agricultural, commercial and industrial land uses including the assumptions of net densities or other spatial assumptions upon which the projections are based. The element shall also include a series of maps that shows current land uses and future land uses that indicate productive agricultural soils, natural limitations for building site development, floodplains, wetlands and other environmentally sensitive lands, the boundaries of areas to which services of public utilities and community facilities, as those terms are used in par. (d), will be provided in the future, consistent with the timetable described in par. (d), and the general location of future land uses by net density or other classifications.

(i) *Implementation element.* A compilation of programs and specific actions to be completed in a stated sequence, including proposed changes to any applicable zoning ordinances, official maps, or subdivision ordinances, to implement the objectives, policies, plans and programs contained in pars. (a) to (h). The element shall describe how each of the elements of the comprehensive plan will be integrated and made consistent with the other elements of the comprehensive plan, and shall include a mechanism to measure the local governmental unit's progress toward achieving all aspects of the comprehensive plan. The element shall include a process for updating the comprehensive plan. A comprehensive plan under this subsection shall be updated no less than once every 10 years.

(2m) Effect of enactment of a comprehensive plan, consistency requirements. (a) The enactment of a comprehensive plan by ordinance does not make the comprehensive plan by itself a regulation.

(b) A conditional use permit that may be issued by a political subdivision does not need to be consistent with the political subdivision's comprehensive plan.

(3) Ordinances that must be consistent with comprehensive plans. Except as provided in sub. (3m), beginning on January 1, 2010, if a local governmental unit enacts or amends any of the following ordinances, the ordinance shall be consistent with that local governmental unit's comprehensive plan:

(g) Official mapping ordinances enacted or amended under s. 62.23(6).

(h) Local subdivision ordinances enacted or amended under s. 236.45 or 236.46.

(j) County zoning ordinances enacted or amended under s. 59.69.

(k) City or village zoning ordinances enacted or amended under s. 62.23(7).

(L) Town zoning ordinances enacted or amended under s. 60.61 or 60.62.

(q) Shorelands or wetlands in shorelands zoning ordinances enacted or amended under s. 59.692, 61.351, 61.353, 62.231, or 62.233.

(3m) Delay of consistency requirement. (a) If a local governmental unit has not adopted a comprehensive plan before January 1, 2010, the local governmental unit is exempt from the requirement under sub. (3) if any of the following applies:

1. The local governmental unit has applied for but has not received a comprehensive planning grant under s. 16.965(2), and the local governmental unit adopts a resolution stating that the local governmental unit will adopt a comprehensive plan that will take effect no later than January 1, 2012.

2. The local governmental unit has received a comprehensive planning grant under s. 16.965(2) and has been granted an extension of time under s. 16.965(5) to complete comprehensive planning.

(b) The exemption under par. (a) shall continue until the following dates:

1. For a local governmental unit exempt under par. (a) 1., January 1, 2012.

2. For a local governmental unit exempt under par. (a) 2., the date on which the extension of time granted under s. 16.965(5) expires.

(4) Procedures for adopting comprehensive plans. A local governmental unit shall comply with all of the following before its comprehensive plan may take effect:

(a) The governing body of a local governmental unit shall adopt written procedures that are designed to foster public participation, including open discussion, communication programs, information services, and public meetings for which advance notice has been provided, in every stage of the preparation of a comprehensive plan. The written procedures shall provide for wide distribution of proposed, alternative, or amended elements of a comprehensive plan and shall provide an opportunity for written comments on the plan to be submitted by members of the public to the governing body and for the governing body to respond to such written comments. The written procedures shall describe the methods the governing body of a local governmental unit will use to distribute proposed, alternative, or amended elements of a comprehensive plan to owners of property, or to persons who have a leasehold interest in property pursuant to which the persons may extract nonmetallic mineral resources in or on property, in which the allowable use or intensity of use of the property is changed by the comprehensive plan.

(b) The plan commission or other body of a local governmental unit that is authorized to prepare or amend a comprehensive plan may recommend the adoption or amendment of a comprehensive plan only by adopting a resolution by a majority vote of the entire commission. The vote shall be recorded in the official minutes of the plan commission or other body. The resolution shall refer to maps and other descriptive materials that relate to one or more elements of a comprehensive plan. One copy of an adopted comprehensive plan, or of an amendment to such a plan, shall be sent to all of the following:

1. Every governmental body that is located in whole or in part within the boundaries of the local governmental unit.

2. The clerk of every local governmental unit that is adjacent to the local governmental unit that is the subject of the plan that is adopted or amended as described in par. (b)(intro.).

4. After September 1, 2005, the department of administration.

5. The regional planning commission in which the local governmental unit is located.

6. The public library that serves the area in which the local governmental unit is located.

(c) No comprehensive plan that is recommended for adoption or amendment under par. (b) may take effect until the political subdivision enacts an ordinance or the regional planning commission adopts a resolution that adopts the plan or amendment. The political subdivision may not enact an ordinance or the regional planning commission may not adopt a resolution under this paragraph unless the comprehensive plan contains all of the elements specified in sub. (2). An ordinance may be enacted or a resolution may be adopted under this paragraph only by a majority vote of the members-elect, as defined in s. 59.001(2m), of the governing body. One copy of a comprehensive plan enacted or adopted under this paragraph shall be sent to all of the entities specified under par. (b).

(d) No political subdivision may enact an ordinance or no regional planning commission may adopt a resolution under par. (c) unless the political subdivision or regional planning commission holds at least one public hearing at which the proposed ordinance or resolution is discussed. That hearing must be preceded by a class 1 notice under ch. 985 that is published at least 30 days before the hearing is held. The political subdivision or regional planning commission may also provide notice of the hearing by any other means it considers appropriate. The class 1 notice shall contain at least the following information:

1. The date, time and place of the hearing.

2. A summary, which may include a map, of the proposed comprehensive plan or amendment to such a plan.

3. The name of an individual employed by the local governmental unit who may provide additional information regarding the proposed ordinance.

4. Information relating to where and when the proposed comprehensive plan or amendment to such a plan may be inspected before the hearing, and how a copy of the plan or amendment may be obtained.

(e) At least 30 days before the hearing described in par. (d) is held, a local governmental unit shall provide written notice to all of the following:

1. An operator who has obtained, or made application for, a permit that is described under s. 295.12(3)(d).

2. A person who has registered a marketable nonmetallic mineral deposit under s. 295.20.

3. Any other property owner or leaseholder who has an interest in property pursuant to which the person may extract nonmetallic mineral resources, if the property owner or leaseholder requests in writing that the local governmental unit provide the property owner or leaseholder notice of the hearing described in par. (d).

(f) A political subdivision shall maintain a list of persons who submit a written or electronic request to receive notice of any proposed ordinance, described under par. (c), that affects the allowable use of the property owned by the person. Annually, the political subdivision shall inform residents of the political subdivision that they may add their names to the list. The political subdivision may satisfy this requirement to provide such information by any of the following means: publishing a 1st class notice under ch. 985; publishing on the political subdivision's Internet site; 1st class mail; or including the information in a mailing that is sent to all property owners. At least 30 days before the hearing described in par. (d) is held a political subdivision shall provide written notice, including a copy or summary of the proposed ordinance, to all such persons whose property, the allowable use of which, may be affected by the proposed ordinance. The notice shall be by mail or in any reasonable form that is agreed to by the person and the political subdivision, including electronic mail, voice mail, or text message. The political subdivision may charge each person on the list who receives a notice by 1st class mail a fee that does not exceed the approximate cost of providing the notice to the person.

(5) Applicability of a regional planning commission's plan. A regional planning commission's comprehensive plan is only advisory in its applicability to a political subdivision and a political subdivision's comprehensive plan.

(6) Comprehensive plan may take effect. Notwithstanding sub. (4), a comprehensive plan, or an amendment of a comprehensive plan, may take effect even if a local governmental unit fails to provide the notice that is required under sub. (4) (e) or (f), unless the local governmental unit intentionally fails to provide the notice.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (5)

W. S. A. 66.1001, WI ST 66.1001
Current through 2023 Act 272, published April 10, 2024.

End of Document

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter XI. Development

W.S.A. 66.1101

66.1101. Promotion of industry; industrial sites

Currentness

(1) It is declared to be the policy of the state to encourage and promote the development of industry to provide greater employment opportunities and to broaden the state's tax base to relieve the tax burden of residents and home owners. It is recognized that the availability of suitable sites is a prime factor in influencing the location of industry but that existing available sites may be encroached upon by the development of other uses unless protected from encroachment by purchase and reservation. It is further recognized that cities, villages and towns have broad power to act for the commercial benefit and the health, safety and public welfare of the public. However, to implement that power, legislation authorizing borrowing is necessary. It is, therefore, the policy of the state to authorize cities, villages and towns to borrow for the reservation and development of industrial sites, and the expenditure of funds for that purpose is determined to be a public purpose.

(2) For financing purposes, the purchase, reservation and development of industrial sites undertaken by a city, village or town is a public utility within the meaning of s. 66.0621. In financing under that section, rentals and fees are considered to be revenue. Any indebtedness created under this section shall not be included in arriving at the constitutional debt limitation.

(3) Sites purchased for industrial development under this section or under any other authority may be developed by the city, village or town by the installation of utilities and roadways but not by the construction of buildings or structures. The sites may be sold or leased for industrial purposes but only for a fair consideration to be determined by the governing body.

Credits
<<For credits, see Historical Note field.>>

W. S. A. 66.1101, WI ST 66.1101
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter XII. Housing Authorities

W.S.A. 66.1201

66.1201. Housing authorities

Currentness

(1) Short title. Sections 66.1201 to 66.1211 may be referred to as the "Housing Authorities Law".

(2) Finding and declaration of necessity. It is declared that there exist in the state insanitary or unsafe dwelling accommodations and that persons of low income are forced to reside in insanitary or unsafe accommodations; that within the state there is a shortage of safe or sanitary dwelling accommodations available at rents which persons of low income can afford and that these persons are forced to occupy overcrowded and congested dwelling accommodations; that the conditions described in this subsection cause an increase in and spread of disease and crime and constitute a menace to the health, safety, morals and welfare of the residents of the state and impair economic values; that these conditions necessitate excessive and disproportionate expenditures of public funds for crime prevention and punishment, public health and safety, fire and accident protection, and other public services and facilities; that these slum areas cannot be cleared, nor can the shortage of safe and sanitary dwellings for persons of low income be relieved, through the operation of private enterprise, and that the construction of housing projects for persons of low income would, therefore, not be competitive with private enterprise; that the clearance, replanning and reconstruction of the areas in which insanitary or unsafe housing conditions exist and the providing of safe and sanitary dwelling accommodations for persons of low income are public uses and purposes for which public money may be spent and private property acquired and are governmental functions of state concern; that it is in the public interest that work on these projects be commenced as soon as possible in order to relieve unemployment which now constitutes an emergency; and the necessity in the public interest for the provisions of this section, is declared as a matter of legislative determination.

(2m) Discrimination. Persons otherwise entitled to any right, benefit, facility, or privilege under ss. 66.1201 to 66.1211 may not be denied the right, benefit, facility, or privilege in any manner for any purpose nor be discriminated against because of sex, race, color, creed, sexual orientation, status as a victim of domestic abuse, sexual assault, or stalking, as defined in s. 106.50(1m)(u), or national origin.

(3) Definitions. In ss. 66.1201 to 66.1211, unless a different meaning clearly appears from the context:

(a) "Area of operation" includes the city for which a housing authority is created, the area within 5 miles of the territorial boundaries of the city but not beyond the county limits of the county in which the city is located and the area within the limits of the city unless the city annexes the area of operation. "Area of operation" does not include any area which lies within the territorial boundaries of any city for which another housing authority is created by this section.

(b) “Authority” or “housing authority” means any of the public corporations established pursuant to sub. (4).

(c) “Bonds” means any bonds, interim certificates, notes, debentures or other obligations of the authority issued pursuant to ss. 66.1201 to 66.1211.

(cm) “City clerk” and “mayor” mean the clerk and mayor, respectively, of the city or the officers of the city charged with the duties customarily imposed on the clerk and mayor, respectively.

(d) “Commissioner” means one of the members of an authority appointed in accordance with ss. 66.1201 to 66.1211.

(e) “Community facilities” includes real and personal property, and buildings and equipment for recreational or social assemblies, for educational, health or welfare purposes and necessary utilities, when designed primarily for the benefit and use of the housing authority or the occupants of the dwelling accommodations, or for both.

(f) “Contract” means any agreement of an authority with or for the benefit of an obligee whether contained in a resolution, trust indenture, mortgage, lease, bond or other instrument.

(g) “Council” means the common council or other body charged with governing a city.

(h) “Federal government” includes the United States of America and any agency or instrumentality, corporate or otherwise, of the United States of America.

(i) “Government” includes the state and federal governments and any subdivision, agency or instrumentality, corporate or otherwise, of either of them.

(j) “Housing projects” includes all real and personal property, building and improvements, and community facilities acquired or constructed pursuant to a single plan either to demolish, clear, remove, alter or repair insanitary or unsafe housing or to provide safe and sanitary dwelling accommodations for persons of low income, or both. “Housing projects” includes the planning of buildings and improvements, the acquisition of property, the demolition of existing structures, the construction, reconstruction, alteration and repair of the improvements and all other related work.

(js) “Mixed development” means all real and personal property, buildings and improvements, and community facilities acquired, rehabilitated, or constructed pursuant to a single plan to revitalize, redevelop, or transfer one or more properties into a mixed-use or mixed-income development primarily to serve persons of low income or persons of low income and persons of moderate income with housing, commercial, and neighborhood amenities or other support services. “Mixed development” includes the planning of buildings and improvements, the acquisition of property, the demolition of existing structures, the construction, reconstruction, alteration, and repair of the improvements, and all other related work.

(k) “Mortgage” includes deeds of trust, mortgages, building and loan contracts, land contracts or other instruments conveying real or personal property as security for bonds and conferring a right to foreclose and cause a sale of the real property or personal property.

(L) "Obligee of the authority" or "obligee" includes any bondholder, trustee or trustees for any bondholders, any lessor demising property to the authority used in connection with a housing project or any assignee of the lessor's interest or any part of the lessor's interest, and the federal government, when it is a party to any contract with the authority.

(m) "Persons of low income" means persons or families who lack the amount of income necessary, as determined by the authority undertaking the housing project, to enable them, without financial assistance, to live in decent, safe and sanitary dwellings, without overcrowding.

(mg) "Persons of moderate income" means persons or families who qualify as having moderate income, as determined by the authority. The authority may not consider a household to be a person of moderate income if the household's income exceeds 120 percent of the median income for the area, unless an applicable guideline or regulation of the federal department of housing and urban development permits the household to qualify as having moderate income.

(n) "Real property" includes lands, lands under water, structures, and any easements, franchises and incorporeal hereditaments and every estate and right in an estate, legal and equitable, including terms for years and liens by way of judgment, mortgage or otherwise.

(o) "Slum" means any area where dwellings predominate which, by reason of dilapidation, overcrowding, faulty arrangement or design, lack of ventilation, light or sanitary facilities, or any combination of these factors, are detrimental to safety, health and morals.

(p) "State public body" means any city, town, village, county, municipal corporation, commission, district, authority, other subdivision or public body of the state.

(q) "Trust indenture" includes instruments pledging the revenues of real or personal properties.

(4) Creation of housing authorities. (a) When a council declares by resolution that there is need for an authority to function in the city, a public body corporate and politic then exists in the city and shall be known as the "housing authority" of the city. The authority may then transact business and exercise any powers granted to it under this section.

(b) The council shall adopt a resolution declaring that there is need for a housing authority in the city if the council finds that insanitary or unsafe inhabited dwelling accommodations exist in the city or that there is a shortage of safe or sanitary dwelling accommodations in the city available to persons of low income at rentals they can afford. In determining whether dwelling accommodations are unsafe or insanitary the council may take into consideration the degree of overcrowding, the percentage of land coverage, the light, air, space and access available to the inhabitants of the dwelling accommodations, the size and arrangement of the rooms, the sanitary facilities, and the extent to which conditions exist in the buildings which endanger life or property by fire or other causes.

(c) In any suit, action or proceeding involving the validity or enforcement of or relating to any contract of the authority, the authority shall be conclusively deemed to have become established and authorized to transact business and exercise its powers under this section upon proof of the adoption of a resolution by the council declaring the need for the authority. The resolution

is sufficient if it declares that there is a need for an authority and finds that either or both of the conditions described in par. (b) exist in the city. A copy of the resolution duly certified by the city clerk is admissible evidence in any suit, action or proceeding.

(5) Appointment, qualifications and tenure of commissioners. (a) When the council adopts a resolution under sub. (4), it shall promptly notify the mayor. Upon receiving the notice, the mayor shall, with the confirmation of the council, appoint 5 persons as commissioners of the authority, except that the mayor of a 1st class city that has created a housing authority before May 5, 1994, shall appoint 7 commissioners, at least 2 of whom shall be residents of a housing project acquired or constructed by the authority. No commissioner may be connected in any official capacity with any political party nor may more than 2 be officers of the city in which the authority is created. The powers of each authority shall be vested in the commissioners of the authority.

(b) The first 5 commissioners who are first appointed shall be designated by the mayor to serve for terms of 1, 2, 3, 4 and 5 years respectively from the date of their appointment and the 2 additional commissioners appointed by the mayor of a 1st class city under par. (a) shall be first appointed to terms of 3 and 5 years respectively. Thereafter, the term of office shall be 5 years. A commissioner shall hold office until his or her successor has been appointed and has qualified. Vacancies shall be filled for the unexpired term in the same manner as other appointments. Three commissioners constitute a quorum, except that in an authority with 7 commissioners, 4 commissioners constitute a quorum. The mayor shall file with the city clerk a certificate of the appointment or reappointment of any commissioner and the certificate is conclusive evidence of the proper appointment of that commissioner if that commissioner has been confirmed under this paragraph and has taken and filed the official oath before entering office. The council of a city may pay commissioners a per diem and mileage and other necessary expenses incurred in the discharge of their duties at rates established by the council.

(c) When the office of the first chairperson of the authority becomes vacant, the authority shall select a chairperson from among its members. An authority shall select from among its members a vice chairperson, and it may employ a secretary, who shall be executive director, technical experts and other officers, agents and employees, permanent and temporary and shall determine their qualifications, duties and compensation. An authority may call upon the city attorney or chief law officer of the city for legal services. An authority may delegate to one or more of its agents or employees powers or duties of the authority.

(6) Duty of the authority and its commissioners. The authority and its commissioners shall comply or cause compliance strictly with all provisions of ss. 66.1201 to 66.1211, with the laws of the state and with any contract of the authority.

(7) Interested commissioners or employees. No commissioner or employee of an authority may acquire any direct or indirect interest in any housing project or in any property included in any project or have any direct or indirect interest in any contract for insurance, materials or services to be furnished or used in connection with any housing project. If a commissioner or employee of an authority owns or controls a direct or indirect interest in any property included in any housing project, that person shall immediately disclose the interest in writing to the authority and the disclosure shall be entered upon the minutes of the authority. Failure to so disclose the interest constitutes misconduct in office.

(8) Removal of commissioners. For inefficiency or neglect of duty or misconduct in office, a commissioner of an authority may be removed by the mayor, but a commissioner may be removed only after having been given a copy of the charges at least 10 days before the hearing on the charges and an opportunity to be heard in person or by counsel. If a commissioner is removed, a record of the proceedings, together with the charges and findings, shall be filed in the office of the city clerk. To the extent applicable, the provisions of s. 17.16 relating to removal for cause apply to any removal.

(9) Powers of authority. An authority is a public body and a body corporate and politic, exercising public powers, and has all the powers necessary or convenient to carry out and effectuate the purposes and provisions of ss. 66.1201 to 66.1211, including the following powers in addition to others granted in this section:

(a) Within its area of operation to prepare, carry out, acquire, lease and operate housing projects approved by the council; to provide for the construction, reconstruction, improvement, alteration or repair of any housing project or any part of a housing project.

(am) On any property wholly or partially owned by a housing authority before October 1, 2021, and within its area of operation to prepare, carry out, acquire, lease, and operate mixed developments; and to provide for the construction, reconstruction, improvement, alteration, or repair of any mixed development or any part of a mixed development. This paragraph applies only to a housing authority created by a 1st class city.

(b) To take over by purchase, lease or otherwise any housing project undertaken by any government and located within the area of operation of the authority when approved by the council; to purchase, lease, obtain options upon, acquire by gift, grant, bequest, devise, or otherwise, any real or personal property or any interest in the real or personal property.

(c) To act as agent for any government in connection with the acquisition, construction, operation or management of a housing project or any part of a housing project.

(d) To arrange or contract for the furnishing of services, privileges, works, or facilities for, or in connection with, a housing project or the occupants of a housing project.

(e) To lease or rent any dwellings, houses, accommodations, lands, buildings, structures or facilities embraced in any housing project and, subject to the limitations contained in this section, to establish and revise the rents or charges for the housing project.

(f) Within its area of operation to investigate into living, dwelling and housing conditions and into the means and methods of improving those conditions; and to engage in research and studies on the subject of housing.

(h) To acquire by eminent domain any real property, including improvements and fixtures on the real property.

(i) To own, hold, clear and improve property, to insure or provide for the insurance of the property or operations of the authority against any risks, to procure insurance or guarantees from the federal government of the payment of any debts or parts of debts secured by mortgages made or held by the authority on any property included in any housing project.

(j) To contract for the sale of, and to sell, any part or all of the interest in real estate acquired and to execute contracts of sale and conveyances as the authority considers desirable.

(k) In connection with any loan, to agree to limitations upon its right to dispose of any housing project or part of a housing project.

(L) In connection with any loan by a government, to agree to limitations upon the exercise of any powers conferred upon the authority by ss. 66.1201 to 66.1211.

(m) To invest any funds held in reserve or sinking funds, or any funds not required for immediate disbursement, in property or securities in which savings banks may legally invest funds subject to their control.

(n) To sue and be sued, to have a seal and to alter the same at pleasure, to have perpetual succession, to make and execute contracts and other instruments necessary or convenient to the exercise of the powers of the authority.

(o) To make and amend and repeal bylaws, rules and regulations not inconsistent with ss. 66.1201 to 66.1211, to carry into effect the powers and purposes of the authority.

(p) To exercise all or any part or combination of powers granted in this section. No provisions of law with respect to the acquisition or disposition of property by other public bodies are applicable to an authority unless otherwise provided.

(q) To execute bonds, notes, debentures or other evidences of indebtedness which, when executed by a housing authority, are not a debt or charge against any city, county, state or any other governmental authority, other than against the authority itself and its available property, income or other assets in accordance with the terms of an evidence of indebtedness and of this section, and no individual liability exists for any official act done by any member of the authority. No authority may levy any tax or assessment.

(r) To provide by all means available under ss. 66.1201 to 66.1211 housing projects for veterans and their families regardless of their income. The projects are not subject to the limitations of s. 66.1205.

(s) Notwithstanding the provisions of any law, to acquire sites; to prepare, carry out, acquire, lease, construct and operate housing projects to provide temporary dwelling accommodations for families regardless of income who are displaced under ss. 66.1201 to 66.1331; to further slum clearance, urban redevelopment and blight elimination; and to provide temporary dwelling accommodations for families displaced by reason of any street widening, expressway or other public works project causing the demolition of dwellings.

(t) To participate in an employee retirement or pension system of the city which has declared the need for the authority and to expend funds of the authority for this purpose.

(u) To join or cooperate with one or more authorities in the exercise, either jointly or otherwise, of any of their powers for the purpose of financing, including the issuance of bonds, notes or other obligations and giving security for these obligations, planning, undertaking, owning, constructing, operating or contracting with respect to a housing project located within the area of operation of any one or more of the authorities. For this purpose an authority may by resolution prescribe and authorize any other housing authority, joining or cooperating with it, to act on its behalf with respect to any powers, as its agent or otherwise, in the name of the authority joining or cooperating or in its own name.

(v) To establish a procedure for preserving records of the authority by the use of microfilm, another reproductive device, optical imaging, or electronic formatting if authorized under s. 19.21(4)(c). The procedure shall assure that copies of records that are

open to public inspection continue to be available to members of the public requesting them. A photographic reproduction of a record or copy of a record generated from optical disc or electronic storage is deemed the same as an original record for all purposes if it meets the applicable standards established in ss. 16.61 and 16.612.

(w) To exercise any powers of a redevelopment authority operating under s. 66.1333 if done in concert with a redevelopment authority under a contract under s. 66.0301.

(x) To, within its area of operation, either by itself or with the department of veterans affairs, undertake and carry out studies and analyses of veterans housing needs and meeting those needs and make the study results available to the public, including the building, housing and supply industries.

(10) Eminent domain. (a) The authority may acquire by eminent domain any real property, including fixtures and improvements, which it deems necessary to carry out the purposes of ss. 66.1201 to 66.1211 after the adoption by it of a resolution declaring that the acquisition of the property described in the resolution is in the public interest and necessary for public use. The authority may exercise the power of eminent domain pursuant to ch. 32 or pursuant to any other applicable statutory provisions.

(b) At any time at or after the filing for condemnation, and before the entry of final judgment, the authority may file with the clerk of the court in which the petition is filed a declaration of taking signed by the duly authorized officer or agent of the authority declaring that all or any part of the property described in the petition is to be taken for the use of the authority. The declaration of taking is sufficient if it sets forth all of the following:

1. A description of the property.

2. A statement of the estate or interest in the property being taken.

3. A statement of the sum of money estimated by the authority to be just compensation for the property taken, which sum shall be not less than the last assessed valuation for tax purposes of the estate or interest in the property to be taken.

(c) From the filing of the declaration of taking under par. (b) and the deposit in court of the amount of the estimated compensation stated in the declaration, title to the property specified in the declaration vests in the authority and the property is condemned and taken for the use of the authority and the right to just compensation for the property vests in the persons entitled to the compensation. Upon the filing of the declaration of taking the court shall designate a day not exceeding 30 days after the filing, except upon good cause shown, on which the person in possession shall surrender possession to the authority.

(d) The ultimate amount of compensation vests in the manner provided by law. If the amount vested exceeds the amount deposited in court by the authority, the court shall enter judgment against the authority in the amount of the deficiency together with interest at the rate of 6 percent per year on the deficiency from the date of the vesting of title to the date of the entry of the final judgment subject to abatement for use, income, rents or profits derived from the property by the owner subsequent to the vesting of title in the authority. The court shall order the authority to deposit the amount of the deficiency in court.

(e) At any time before the vesting of title of property in the authority the authority may withdraw or dismiss its petition with respect to any of the property described in the petition.

(f) Upon vesting of title to any property in the authority, all the right, title and interest of all persons having an interest in, or lien upon, the property are divested immediately and these persons are entitled only to receive compensation for the property.

(g) Except as provided in this subsection with reference to the declaration of taking, the proceedings shall be as provided by law for condemnation, and the deposit in court of the amount estimated by the authority upon a declaration of taking shall be disbursed as provided by law for an award in condemnation proceedings.

(h) Property already devoted to a public use may be acquired, provided that no property belonging to any municipality or to any government may be acquired without its consent and that no property belonging to a public utility corporation may be acquired without the approval of the public service commission or other officer or tribunal, if any, having regulatory power over the public utility corporation.

(i) If a housing project or mixed development involves federal financial assistance, the duration of replacement housing payments to displaced tenants under the relocation plan is as provided under 42 USC 4624. This paragraph applies only to a project or development on a property wholly or partially owned before October 1, 2021, by a housing authority created by a 1st class city.

(11) Acquisition of land for government. The authority may acquire, by purchase or by the exercise of its power of eminent domain under sub. (10), any property, real or personal, for any housing project being constructed or operated by a government. The authority upon such terms and conditions, with or without consideration, as it shall determine, may convey title or deliver possession of property so acquired or purchased to the government for use in connection with a housing project.

(12) Zoning and building laws. All housing projects of an authority shall be subject to the planning, zoning, sanitary and building laws, ordinances and regulations applicable to the locality in which the housing project is situated.

(13) Types of bonds. (a)1. An authority may issue any bonds for its corporate purposes, including bonds on which the principal and interest are payable by any of the following methods:

a. Exclusively from the income and revenues of the housing project financed with the proceeds of the bonds, or with those proceeds together with a grant from the federal government in aid of the project.

b. Exclusively from the income and revenues of certain designated housing projects whether or not they were financed in whole or in part with the proceeds of the bonds.

c. From its revenues generally.

2. Any of the bonds under subd. 1. may be additionally secured by a pledge of any revenues or, subject to the limitations imposed under pars. (b) and (c), a mortgage of any housing project, projects or other property of the authority.

(b) Neither the commissioners of the authority nor any person executing the bonds is liable personally on the bonds by reason of their issuance.

(c) The bonds and other obligations of the authority are not a debt of any municipality located within its boundaries or of the state and this fact shall be stated on their face. Neither the state nor any municipality is liable for the bonds or other obligations, nor are they payable out of any funds or properties other than those of the authority.

(14) Form and sale of bonds. (a) Bonds of an authority shall be authorized by its resolution and may be issued in one or more series and shall bear any date, mature at any time, bear interest at any rate, be in any denomination, be in the form of coupon bonds or of bonds registered under s. 67.09, carry any conversion or registration privileges, have any rank or priority, be executed in any manner, be payable in any medium of payment, at any place, and be subject to any terms of redemption, with or without premium, that the resolution, its trust indenture or mortgage may provide. Any bond reciting in substance that it has been issued by an authority to aid in financing a housing project to provide dwelling accommodations for persons of low income shall be conclusively deemed, in any suit, action or proceeding involving the validity or enforceability of the bond or the security for the bond, to have been issued for such a housing project. Bonds of an authority are issued for an essential public and governmental purpose and are public instrumentalities and, together with interest and income, are exempt from taxes.

(b) The bonds may be sold at public or private sale as the authority provides. The bonds may be sold at any price determined by the authority.

(c) The bonds shall be executed as provided in s. 67.08(1).

(d) The authority may purchase, out of available funds, any bonds issued by it at a price not more than the principal amount of the bonds and the accrued interest. Bonds payable exclusively from the revenues of a designated project or projects shall be purchased only out of any revenues available for that purpose. All bonds so purchased shall be canceled. This paragraph does not apply to the redemption of bonds.

(e) Any provision of any law to the contrary notwithstanding, any bonds, interim certificates, or other obligations issued pursuant to ss. 66.1201 to 66.1211 are fully negotiable.

(15) Provisions of bonds, trust indentures, and mortgages. In connection with the issuance of bonds or the incurring of any obligation under a lease and in order to secure the payment of bonds or obligations, the authority may:

(a) Pledge by resolution, trust indenture, mortgage, subject to the limitations in this subsection, or other contract any of its rents, fees, or revenues.

(b) Covenant against mortgaging any of its property or against permitting any lien on its property.

(c) Covenant with respect to limitations on its right to sell, lease or otherwise dispose of any housing project or any part of a housing project, or with respect to limitations on its right to undertake additional housing projects.

(d) Covenant against pledging any of its rents, fees and revenues or against permitting any lien on its rents, fees and revenues.

(e) Provide for the release of property, rents, fees and revenues from any pledge or mortgage, and reserve rights and powers in, or the right to dispose of, property which is subject to a pledge or mortgage.

(f) Covenant as to the bonds to be issued pursuant to any resolution, trust indenture, mortgage or other instrument and as to the issuance of bonds in escrow or otherwise, and as to the use and disposition of the proceeds of the bonds.

(g) Provide for the terms, form, registration, exchange, execution and authentication of bonds.

(h) Provide for the replacement of lost, destroyed or mutilated bonds.

(i) Covenant that the authority warrants the title to the premises.

(j) Covenant as to the rents and fees to be charged, the amount to be raised each year or other period of time by rents, fees and other revenues and as to the use and disposition to be made of the revenues.

(k) Covenant as to the use of any of its property.

(L) Create special funds which segregate all of the following:

1. The proceeds of any loan or grant or both.

2. The rents, fees and revenues of a housing project.

3. Any moneys held for the payment of the costs of operations and maintenance of any housing projects or as a reserve for the meeting of contingencies in the operation and maintenance of housing projects.

4. Any moneys held for the payment of the principal and interest on its bonds or the sums due under its leases or as a reserve for the payments.

5. Any moneys held for any other reserves or contingencies.

(Lm) Covenant as to the use and disposal of the moneys held in funds created under par. (L).

(m) Redeem the bonds, covenant for their redemption and provide the terms and conditions of the bonds.

(n) Covenant against extending the time for the payment of its bonds or interest on the bonds by any means.

(o) Prescribe the procedure, if any, by which the terms of any contract with bondholders may be amended or abrogated, the amount of bonds the holders of which must consent to a contract amendment or abrogation and the manner in which consent may be given.

(p) Covenant as to property maintenance, replacement and insurance and the use and disposition of insurance moneys.

(q) Vest in an obligee of the authority, if the authority fails to observe or perform any covenant on its part to be kept or performed, the right to cure any default and to advance any moneys necessary for that purpose. The moneys advanced may be made an additional obligation of the authority with such interest, security and priority as may be provided in any trust indenture, mortgage, lease or contract of the authority.

(r) Covenant and prescribe as to the events of default and terms and conditions upon which any of its bonds shall become or may be declared due before maturity and as to the terms and conditions upon which the declaration and its consequences may be waived.

(s) Covenant as to the rights, liabilities, powers and duties arising upon the breach by it of any covenant, condition or obligation.

(t) Covenant to surrender possession of all or any part of any housing project upon the happening of a default, as defined in the contract, and to vest in an obligee the right to take possession and to use, operate, manage and control housing projects, and to collect and receive all rents, fees and revenues arising from the housing projects in the same manner as the authority itself might do and to dispose of the moneys collected in accordance with the agreement of the authority with the obligee.

(u) Vest in a trust the right to enforce any covenant made to secure, to pay, or in relation to the bonds, to provide for the powers and duties of a trustee, to limit liabilities of a trustee and to provide the terms and conditions upon which the trustee or the bondholders or any proportion of them may enforce any covenant.

(v) Make covenants other than the covenants that are authorized in this subsection.

(w) Execute all instruments that are necessary or convenient in the exercise of its powers or in the performance of its covenants or duties.

(x) Make covenants and do any act necessary or convenient in order to secure its bonds, or, in the absolute discretion of the authority, that tend to make the bonds more marketable. An authority may not mortgage any of its property except as provided in sub. (16).

(16) Power to mortgage when project financed with aid of government. (a) In this subsection, “government” includes the Wisconsin Housing and Economic Development Authority.

(b) In connection with any project financed in whole or in part, or otherwise aided by a government, whether through a donation of money or property, a loan, the insurance or guarantee of a loan, or otherwise, the authority may do any of the following:

1. Mortgage its property.

2. Grant security interests in its property.

3. Issue its note or other obligation as may be required by the government.

(17) Remedies of an obligee of authority. An obligee of the authority, subject to its contract, may do any of the following:

(a) By mandamus, suit, action or proceeding, all of which may be joined in one action, compel the authority and its commissioners, officers, agents or employees to perform every term, provision and covenant contained in any contract of the authority, and require the carrying out of any covenants and agreements of the authority and the fulfillment of all duties imposed upon the authority by ss. 66.1201 to 66.1211.

(b) By suit, action or proceeding enjoin any unlawful acts or things, or the violation of any of the rights of the obligee of the authority.

(c) By suit, action or proceeding cause possession of any housing project or any part of a housing project to be surrendered to any obligee having the right to possession pursuant to any contract of the authority.

(18) Additional remedies conferrable by mortgage or trust indenture. Any authority may by its trust indenture, mortgage, lease or other contract confer upon any obligee holding or representing a specified amount in bonds, lease or other obligations, the right upon the happening of an "event of default" as defined in the instrument:

(a) By suit, action or proceeding obtain the appointment of a receiver of any housing project of the authority or any part of a housing project. Upon appointment, a receiver may enter and take possession of the housing project or any part of the housing project and operate and maintain it, and collect and receive all fees, rents, revenues or other charges arising in the same manner as the authority itself might do. The receiver shall keep the moneys in a separate account or accounts and apply the moneys in accordance with the obligations of the authority as a court directs.

(b) By suit, action or proceeding require the authority and its commissioners to account as if it and they were the trustees of an express trust.

(19) Remedies cumulative. All the rights and remedies in this section are in addition to all other rights and remedies that may be conferred upon an obligee of the authority by law or by any contract with the authority.

(20) Subordination of mortgage to agreement with government. The authority may agree in any mortgage made by it that the mortgage is subordinate to a contract for the supervision by a government of the operation and maintenance of the mortgaged

property and the construction of improvements on the mortgaged property. A purchaser at a sale of the property of an authority pursuant to a foreclosure of a mortgage or any other remedy in connection with the foreclosure shall obtain title subject to the contract.

(21) Contracts with federal government. In addition to the powers conferred upon the authority by other provisions of ss. 66.1201 to 66.1211, the authority may borrow money or accept grants from the federal government for any housing project that the authority may undertake, take over any land acquired by the federal government for the construction or operation of a housing project, take over or lease or manage any housing project constructed or owned by the federal government, and to these ends, enter into any contracts, mortgages, trust indentures, leases or other agreements that the federal government may require including agreements that the federal government may supervise and approve the construction, maintenance and operation of the housing project. A council may take any action necessary to secure the financial aid and the cooperation of the federal government in the undertaking, construction, maintenance and operation of any housing project which the authority may undertake.

(22) Tax exemption and payments in lieu of taxes. The property of an authority is public property used for essential public and governmental purposes and the property and an authority are exempt from all taxes of the state or any state public body, except that the city in which a project or projects are located may fix a sum to be paid annually in lieu of taxes by the authority for the services, improvements, or facilities furnished to the property of the authority by the city. The amount paid in lieu of taxes may not exceed the amount that would be levied as the annual tax of the city upon the project. Property of an authority includes property in which an authority operating within a 1st class city or an entity in which an authority operating within a 1st class city holds an ownership interest holds a partial ownership interest if the property is held for any of the following purposes:

(a) As part of a financing or equity plan that includes state or federal tax credits, financing, funding, or rent subsidy.

(b) A purpose related to the conversion of a housing project to a rental or housing assistance program under a contract with the federal government.

(23) Reports. The authority shall at least once a year file with the mayor of the city a report of its activities for the preceding year.

(24) Bids. (a) When a housing authority has the approval of the council for any project authorized under sub. (9)(a) or (b), the authority shall complete and approve plans, specifications, and conditions for carrying out the project, and shall advertise by publishing a class 2 notice, under ch. 985, for bids for all work which the authority must do by contract. The authority is not required to submit for bidding any contract in an amount of $25,000 or less or, if the contract is for a project on a property wholly or partially owned before October 1, 2021, by a housing authority created by a 1st class city, $50,000 or less, but if the estimated cost of the contract, except a contract for a project on a property wholly or partially owned before October 1, 2021, by an authority created by a 1st class city, is between $10,000 and $25,000, the authority shall give a class 2 notice, under ch. 985, of the proposed work before the contract is entered into. A contract subject to bidding shall be awarded to the lowest qualified and competent bidder. Section 66.0901 applies to the bidding.

(ag) As an alternative to the advertising and bidding procedure under par. (a), an authority may contract under any purchase procedure authorized for the authority by the federal government.

(am) The authority may reject any bid required under par. (a).

(b) An authority may contract for the acquisition of a housing project without submitting the contract for bids as required by par. (a) if all of the following apply:

1. The contract provides for undertaking of the housing project on land not owned at the time of the contract by the authority except the contract may provide for undertaking of the housing project on land acquired and owned by a community development authority for the purpose of ss. 66.1105, 66.1301 to 66.1329, 66.1331 or 66.1333 if the community development authority is proceeding under this paragraph as provided by s. 66.1335(4).

2. The contract provides for conveyance or lease of the project to the authority after completion of the project.

3. The authority invites developers to submit proposals to provide a completed project and evaluates proposals according to site, cost, design, the developer's experience and other criteria specified by the authority.

(25) Liquidation and disposal of housing projects. (a) In any city or village the council or village board by resolution or ordinance, or the electors by referendum under s. 9.20, may require the authority to liquidate and dispose of a project held and operated under ss. 66.1201 to 66.1211 or 66.1331.

(b) If liquidation and disposal of a project is provided for under par. (a) the housing authority or other designated agency shall sell the project to the highest bidder after public advertisement, or transfer it to any state public body authorized by law to acquire the project. No project may be sold for less than its fair market value as determined by a board of 3 licensed appraisers appointed by the council or village board.

(c) The arrangements for the liquidation and disposal of a project shall provide for the payment and retirement of all outstanding obligations in connection with the project, together with interest on the obligations and any premiums prescribed for the redemption of any bonds, notes or other obligations before maturity.

(d) Any proceeds remaining after payment of the obligations under par. (c) shall be distributed in accordance with the federal law applicable at the time of the liquidation and disposal of the project. If no federal law is applicable to the liquidation and disposal of the project all remaining proceeds shall be paid to the city or village.

(e) If the highest bid received is insufficient for the payment of all obligations set forth in par. (c) the project shall not be sold unless the city or village provides sufficient additional funds to discharge the obligations.

(f) In order to carry out this subsection an authority or other designated agency shall exercise any option available to it for the payment and redemption of outstanding obligations set forth in par. (c) before maturity, if the city or village provides funds for payment and redemption.

(g) No actions taken under this subsection shall affect or diminish the rights of any bondholders or other obligees of the authority.

(h) In this subsection, “outstanding obligations” or “obligations” includes bonds, notes or evidences of indebtedness, as well as aids, grants, contributions or loans made by or received from any federal, state or local political government or agency.

(26) Dissolution of housing authority. Any housing authority may be dissolved upon adoption of an ordinance or resolution by the council or village board concerned declaring that the need for the authority no longer exists, that all projects under the authority's jurisdiction have been disposed of, that there are no outstanding obligations or contracts and that no further business remains to be transacted by the authority.

Credits

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Notes of Decisions (23)

W. S. A. 66.1201, WI ST 66.1201
Current through 2023 Act 272, published April 10, 2024.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Wisconsin Statutes Annotated
Municipalities (Ch. 59 to 68)
Chapter 66. General Municipality Law (Refs & Annos)
Subchapter XIII. Urban Redevelopment and Renewal

W.S.A. 66.1301

66.1301. Urban redevelopment

Currentness

(1) Short title. Sections 66.1301 to 66.1329 may be referred to as the "Urban Redevelopment Law".

(2) Finding and declaration of necessity. It is declared that in the cities of the state substandard and insanitary areas exist which have resulted from inadequate planning, excessive land coverage, lack of proper light, air and open space, defective design and arrangement of buildings, lack of proper sanitary facilities, and the existence of buildings, which, by reason of age, obsolescence, inadequate or outmoded design, or physical deterioration have become economic or social liabilities, or both. These conditions are prevalent in areas where substandard, insanitary, outworn or outmoded industrial, commercial or residential buildings prevail. These conditions impair the economic value of large areas, infecting them with economic blight, and these areas are characterized by depreciated values, impaired investments, and reduced capacity to pay taxes. These conditions are chiefly in areas which are so subdivided into small parcels in divided ownerships and frequently with defective titles, that their assembly for purposes of clearance, replanning, rehabilitation and reconstruction is difficult and costly. The existence of these conditions and the failure to clear, replan, rehabilitate or reconstruct these areas results in a loss of population by the areas and further deterioration, accompanied by added costs to the communities for creation of new public facilities and services elsewhere. It is difficult and uneconomic for individual owners independently to undertake to remedy these conditions. It is desirable to encourage owners of property or holders of claims on property in these areas to join together and with outsiders in corporate groups for the purpose of the clearance, replanning, rehabilitation and reconstruction of these areas by joint action. It is necessary to create, with proper safeguards, inducements and opportunities for the employment of private investment and equity capital in the clearance, replanning, rehabilitation and reconstruction of these areas. These conditions require the employment of capital on an investment rather than a speculative basis, allowing however the widest latitude in the amortization of any indebtedness created. These conditions further require the acquisition at fair prices of adequate areas, the gradual clearance of the areas through demolition of existing obsolete, inadequate, unsafe and insanitary buildings and the redevelopment of the areas under proper supervision with appropriate planning, land use and construction policies. The clearance, replanning, rehabilitation and reconstruction of these areas on a large scale basis are necessary for the public welfare. The clearance, replanning, reconstruction and rehabilitation of these areas are public uses and purposes for which private property may be acquired. Substandard and insanitary areas constitute a menace to the health, safety, morals, welfare and reasonable comfort of the citizens of the state. These conditions require the aid of redevelopment corporations for the purpose of attaining the ends recited in this subsection. The protection and promotion of the health, safety, morals, welfare and reasonable comfort of the citizens of the state are matters of public concern. Sections 66.1301 to 66.1329 are in the public interest.

(2m) Discrimination. Persons entitled to any right, benefit, facility, or privilege under ss. 66.1301 to 66.1329 may not be denied the right, benefit, facility, or privilege in any manner for any purpose nor be discriminated against because of sex, race, color,

creed, sexual orientation, status as a victim of domestic abuse, sexual assault, or stalking, as defined in s. 106.50(1m)(u), or national origin.

(3) Definitions. In ss. 66.1301 to 66.1329, unless a different intent clearly appears from the context:

(a) "Area" means a portion of a city which its planning commission finds to be substandard or insanitary, so that the clearance, replanning, rehabilitation or reconstruction of that portion is necessary or advisable to effectuate the public purposes declared in sub. (2). "Area" includes buildings or improvements not in themselves substandard or insanitary, and real property, whether improved or unimproved, the inclusion of which is considered necessary for the effective clearance, replanning, reconstruction or rehabilitation of the area of which the buildings, improvements or real property form a part and includes vacant land which is in such proximity to other land or structures that the economic value of the other land or structures is impaired.

(d) "Development" means a specific work, repair or improvement to put into effect a development plan and includes the real property, buildings and improvements owned, constructed, managed or operated by a redevelopment corporation.

(e) "Development area" means that portion of an area to which a development plan is applicable.

(f) "Development cost" means the amount determined by the planning commission to be the actual cost of the development or of the part of the development for which the determination is made. "Development cost" includes, among other costs, all of the following:

1. The reasonable costs of planning the development, including preliminary studies and surveys, neighborhood planning, architectural and engineering services and legal and incorporation expense.

2. The actual cost, if any, of alleviating hardship to families occupying dwelling accommodations in the development area where hardship results from the execution of the development plan.

3. The reasonable costs of financing the development, including carrying charges during construction.

4. Working capital in an amount not exceeding 5 percent of development cost.

5. The actual cost of the real property included in the development, of demolition of existing structures and of utilities, landscaping and roadways.

6. The amount of special assessments subsequently paid.

7. The actual cost of construction, equipment and furnishing of buildings and improvements, including architectural, engineering and builder's fees.

8. The actual cost of reconstruction, rehabilitation, remodeling or initial repair of existing buildings and improvements.

9. Reasonable management costs until the development is ready for use.

10. The actual cost of improving that portion of the development area which is to remain as open space, together with additions to development cost that equal the actual cost of additions to or changes in the development in accordance with the original development plan or after approved changes in or amendments to the development plan.

(g) "Development plan" means a plan for the redevelopment of all or any part of an area, and includes any amendments that are approved in accordance with the requirements of s. 66.1305(1).

(h) "Local governing body" means a common council, council, commission or other board or body vested by the charter of a city or other law with jurisdiction to adopt or enact ordinances or local laws.

(n) "Mortgage" means a mortgage, trust indenture, deed of trust, building and loan contract or other instrument creating a lien on real property, and the indebtedness secured by each of them.

(o) "Neighborhood unit" means a primarily residential district having the facilities necessary for well-rounded family living, such as schools, parks, playgrounds, parking areas and local shopping districts.

(p) "Planning commission" means the official bureau, board, commission or agency of a city that is authorized to prepare, adopt, amend or modify a master plan for the development of the city.

(q) "Real property" includes lands, buildings, improvements, land under water, waterfront property, and any easements, franchises and hereditaments, corporeal or incorporeal, and every estate, interest, privilege, easement, franchise and right in or appurtenant to the real property, legal or equitable, including rights-of-way, terms for years and liens, charges, or encumbrances by mortgage, judgment or otherwise.

(r) "Redevelopment" means the clearance, replanning, reconstruction or rehabilitation of an area or part of an area, and the provision of industrial, commercial, residential or public structures or spaces as may be appropriate, including recreational and other facilities incidental or appurtenant to the structures or spaces.

(s) "Redevelopment corporation" means a corporation carrying out a redevelopment plan under ss. 66.1301 to 66.1329.

Credits
<<For credits, see Historical Note field.>>

Notes of Decisions (2)

W. S. A. 66.1301, WI ST 66.1301
Current through 2023 Act 272, published April 10, 2024.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COMMONWEALTH OF PENNSYLVANIA, et al.,

Plaintiffs,

v.

ELISABETH D. DEVOS, in her official capacity as Secretary of Education, et al.,

Defendants,

and

FOUNDATION FOR INDIVIDUAL RIGHTS IN EDUCATION, *et al*,

Intervenor-Defendants,

and

STATE OF TEXAS,

[Proposed] Intervenor-Defendant.

Case No. 20-cv-01468-CJN

MEMORANDUM IN SUPPORT OF TEXAS' PARTIALLY OPPOSED

MOTION TO INTERVENE

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The State of Texas ("Texas") moves to intervene in defense of the Department of Education's ("the Department") Final Rule addressing Title IX obligations, which took effect on August 14, 2020.[1] At the start of this suit, Texas' interests were aligned with the Department. On January 20, however, President elect Joe Biden will assume office and redirect the Department's policy regarding Title IX. The President elect has condemned the Final Rule, calling it "a green light to ignore sexual violence" and promising to bring it to a "quick end." *The Biden Agenda for Women*, JOEBIDEN.COM, https://joebiden.com/womens-agenda/ (last visited Jan. 15, 2021). In light of this sea change, Texas can no longer rely on the Department to adequately represent its interests in defending the Final Rule.

BACKGROUND

During the Obama Administration, the Department issued its misguided 2011 Dear Colleague Letter[2] and 2014 Questions and Answers on Title IX Sexual Violence ("2014 Question and Answers").[3] Although neither underwent notice and comment rulemaking, the two guidance documents put recipients in a no-win situation where either conforming or failing to conform to the guidance documents would expose them to significant risk of litigation.[4] The President-elect played a key role in the development and implementation of the Obama Administration's policies

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[1] *Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance*, 85 Fed. Reg. 30,026 (May 19, 2020).

[2] Russlynn Ali, OCR, U.S. Dept. of Educ., Dear Colleague Letter: Sexual Violence (Apr. 4, 2011), http://www2.ed.gov/about/offices/list/ocr/letters/colleague-201104.pdf.

[3] U.S. Dept. of Educ., *Questions and Answers on Title IX and Sexual Violence* (Apr. 24, 2014), https://www2.ed.gov/about/offices/list/ocr/docs/qa-201404-title-ix.pdf.

[4] *See*, *e.g.*, Taylor Mooney, *How Betsy DeVos plans to change the rules for handling sexual misconduct on campus*, CBS NEWS (Nov. 24, 2019) ("Prior to 2011, the number of lawsuits filed against universities for failing to provide due process in Title IX cases averaged one per year. It is expected there will be over 100 such lawsuits filed in 2019 alone."), https://www.cbsnews.com/news/title-ix-sexual-misconduct-on-campus-trump-administration-changing-obama-rules-cbsn-documentary/.

on sexual harassment,[5] including the changes the administration advanced regarding Title IX. The President-elect, in fact, stood as the Obama Administration's spokesperson for the Dear Colleague Letter, announcing its publication to students at the University of New Hampshire in Durham. *See* Press Release, U.S. Dept. of Educ., *Vice President Biden Announces New Administration Effort to Help Nation's Schools Address Sexual Violence* (Apr. 4, 2011), https://www.ed.gov/news/press-releases/vice-president-biden-announces-new-administration-effort-help-nations-schools-ad.

In response to growing criticism, the Department rescinded the Dear Colleague Letter and the 2014 Questions and Answers in 2017.[6] It soon became apparent, however, that the withdrawal could not repair the damage caused by the two guidance documents on its own, as there was significant confusion regarding recipients' obligations to combat sexual harassment. On May 19, 2020, therefore, the Department issued the Final Rule that is the subject of this action. The Final Rule, for the first time, clearly demarcated the outer boundaries of federal fund recipients' obligations under Title IX with respect to sexual harassment. It thereby reduced their risk of liability and resolved the dilemma of how to enforce Title IX without sacrificing the rights of either the victims of sexual harassment or the accused.

At the time this lawsuit commenced, the Department understood and respected the detrimental impact that the Obama Administration's misguided guidance documents had on common providers of education like Texas. That will all change on January 20, 2021 when the President-elect is inaugurated into office. The President-elect has not altered his opinion about

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[5] Unless otherwise stated, the term "sexual harassment" encompasses all forms of sexual harassment, including sexual violence and sexual assault. Likewise, unless otherwise stated, the term, "academic institutions" encompasses all entities covered by the new Final Rule issued by the Department, including schools, colleges, and universities, both primary and secondary.

[6] *See* Candice Jackson, OCR, U.S. Dept. of Educ., Dear Colleague Letter (Sept. 9, 2017), https://www2.ed.gov/about/offices/list/ocr/letters/colleague-title-ix-201709.pdf.

Title IX policy since advocacy of the Dear Colleague Letter. He has announced his intent to advance the same objectives for Title IX as he did during the Obama Administration, which means curtailing, if not repealing outright, the reforms contained in the Final Rule. *See The Biden Plan To End Violence Against Women*, JOEBIDEN.COM, https://joebiden.com/vawa/ (last visited Jan. 15, 2021). To that end, the President-elect has promised his supporters that the Department under his administration will put a "quick end" to the Final Rule. *The Biden Agenda for Women*, JOEBIDEN.COM, https://joebiden.com/womens-agenda/ (last visited Jan. 15, 2021). As head of the executive branch, the incoming President will have authority over the Department. His objectives will inform the Department's approach to Title IX, up to and including the Department's defense of the Final Rule and the resolution of this lawsuit. Texas therefore files this motion to intervene.

LEGAL STANDARD

The Federal Rules provide two mechanisms for third-party intervention in a lawsuit: intervention of right under Federal Rule of Civil Procedure 24(a) and permissive intervention under Rule 24(b). For intervention of right to apply, the movant must demonstrate that: (1) the motion is timely; (2) the movant has a legally protected interest in the action; (3) the action must threaten to impair that interest; and (4) the movant's interest is not adequately represented by the existing parties. *See United States v. Facebook, Inc.*, 456 F. Supp. 3d 105, 108 (D.D.C. 2020). "[T]he inquiry" into these factors "is a flexible one, which focuses on the particular facts and circumstances surrounding each application." *Edwards v. City of Houston*, 78 F.3d 983, 999 (5th Cir. 1996). Accordingly, "intervention of right must be measured by a practical rather than technical yardstick." *Facebook*, 456 F. Supp. 3d at 108.

To qualify for permissive intervention, the movant must show: (1) an independent ground for subject matter jurisdiction; (2) a timely motion; and (3) a claim or defense that has a question

of law or fact in common with the main action. *Facebook*, 456 F. Supp. 3d at 108. "As its name would suggest, permissive intervention is an inherently discretionary enterprise." *E.E.O.C. v. Nat'l Children's Ctr., Inc.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998). The D.C. Circuit has adopted "a liberal application in favor of permitting intervention." *Nuesse v. Camp*, 385 F.2d 694, 702 (D.C. Cir. 1967). A liberal approach to intervention is especially appropriate "where the subject matter of the lawsuit is of great public interest, the intervenor has a real stake in the outcome and the intervention may well assist the court in its determination through . . . the framing of issues." *Daggett v. Comm'n on Gov't Ethics*, 172 F.3d 104, 116–17 (1st Cir. 1999) (Lynch, J., concurring).

Texas meets the requirements for both intervention as of right and permissive intervention.

ARGUMENT

I. The Court should grant intervention as of right.

A. Texas' motion is timely.

In light of the impending change of Administrations, Texas moves to intervene in defense of the Final Rule. The motion is timely because it was filed close in time to the change in circumstances requiring intervention: President-elect Biden's inauguration on January 20. *See Smoke v. Norton*, 252 F.3d 468, 471 (D.C. Cir. 2001) (judging a motion to intervene timely because it was filed when "the potential inadequacy of representation came into existence").

The timeliness of a motion to intervene is "judged in consideration of all the circumstances." *Id.* (quoting *United States v. AT&T*, 642 F.2d 1285, 1295 (D.C. Cir. 1980)). Though the "time elapsed since the inception of the suit is relevant, measuring the length of time passed is not in itself the determinative test," *Roane v. Leonhart*, 741 F.3d 147, 151 (D.C. Cir. 2014) (internal citations omitted), "particularly where intervention is sought as of right." *Hodgson v. United Mine Workers of Am.*, 473 F.2d 118, 129 (D.C. Cir. 1972). Rather, "[t]he crucial date for

assessing the timeliness of a motion to intervene is when proposed intervenors should have been aware that their interests would not be adequately protected by the existing parties." *Smith v. Marsh*, 194 F.3d 1045, 1052 (9th Cir. 1999).

During the Trump Administration, Texas had no reason to intervene. Like Texas, the previous administration defended the Final Rule as an effective means of combating sexual harassment without sacrificing either clarity or constitutional liberties. The President-elect, however, has expressed open and adamant hostility to the Final Rule, necessitating Texas' intervention if it is to protect its interests. *See infra* at I.D; *see also W. Energy All. v. Zinke*, 877 F.3d 1157, 1169 (10th Cir. 2017) (holding that "the change in the Administration raises the possibility of 'divergence of interest' or a 'shift' during litigation"). The Department will cease adequately representing Texas' interests only after January 20, 2021 when the new administration takes over and begins implementing its own policies. This is not an occasion where a non-party sat on its rights. Texas has actively monitored the present action from the beginning and exhibited proper diligence in bringing its motion.

Further, the timing of Texas' motion does not prejudice any of the existing parties. As this Court previously held, courts "do not require timeliness for its own sake." *100Reporters LLC v. U.S. Dep't of Justice*, 307 F.R.D. 269, 275 (D.D.C. 2014) (quoting *Roane,* 741 F.3d at 151); *see Ute Indian Tribe of Uintah & Ouray Indian Reservation v. U.S. Dep't of the Interior*, 1:18-CV-00547 (CJN), 2020 WL 1465886, at *1 (D.D.C. Feb. 5, 2020) ("[T]he timeliness requirement was not designed to penalize prospective intervenors for failing to act promptly."). The requirement is instead "aimed primarily at preventing potential intervenors from unduly disrupting litigation, to the unfair detriment of the existing parties." Thus, "in assessing timeliness," the court must weigh "whether any delay in seeking intervention unfairly disadvantaged the original parties."

100Reporters, 307 F.R.D. at 275 (citing *Roane*, 741 F.3d at 151); *see* 7C Charles Alan Wright, *et al.*, Fed. Prac. & Proc. § 1916 (3d ed.) ("The most important consideration in deciding whether a motion for intervention is untimely is whether the delay in moving for intervention will prejudice the existing parties to the case.").

This case is still in its relatively early stages. The Department has not yet filed its answer. *See*, *e.g.*, *Wash. All. of Tech. Workers v. U.S. Dep't of Homeland Sec.*, 395 F. Supp. 3d 1, 19 (D.D.C. 2019) (deeming intervention timely after positively noting that defendant failed to file answer even though the case commenced three years ago); *Forest Cty. Potawatomi Cmty. v. United States*, 317 F.R.D. 6, 13 (D.D.C. 2016) (ruling intervention timely nine months after litigation commenced because it was filed before any of the defendants had filed an answer). And while the parties have started filing dispositive motions over the past month, Texas' addition will not disrupt or delay the parties' schedule or force the parties to assume additional work. Texas adopts, as its own, the arguments that the Department makes in its cross-motion for summary judgment and its brief opposing Plaintiff States' motion for summary judgment – both of which will be filed before January 20, 2021. Texas merely seeks the opportunity to defend these arguments after the Biden Administration assumes office and the Department is no longer able to adequately represent Texas' interests. Texas also agrees to abide by the schedule the parties negotiated. *See Cayuga Nation v. Zinke*, 324 F.R.D. 277, 284 (D.D.C. 2018) (requiring that intervening party submits non-cumulative arguments and complies with scheduling order). Texas' intervention therefore will have minimum impact on the original parties. If anything, Texas' addition will avert a potential disruption to the case should the federal government withdraw its support of the Final Rule and refuse to defend it. The motion is timely.

B. Texas has significant protectable interests directly affected by this litigation.

As a provider of public education, Texas has clear and substantial interests at stake in this action. Indeed, its interests are the "mirror-image" of Plaintiff States' interests. While the Plaintiff States allege that they "are being injured by the [Final Rule]," Texas "w[ould] be injured by [the Final Rule's] invalidation." *Builders Ass'n of Greater Chi. v. City of Chicago*, 170 F.R.D. 435, 440 (N.D. Ill. 1996).

Like Plaintiff States, Texas "administers a system of primary and secondary public education that is funded by both state and federal money." ECF 102 ¶ 274; *see also* Tex. Educ. Agency, 2020 *Comprehensive Biennial Report on Texas Public Schools* at 297 (Dec. 4, 2020) (reporting that Texas received $5.3 billion dollars for K-12 education), https://tea.texas.gov/sites/default/files/comp_annual_biennial_2020.pdf. The Texas Constitution charges the Texas Legislature "to establish and make suitable provision for the support and maintenance of an efficient system of public free schools." Tex. Const. art. VII, § 1. Pursuant to this charge, Texas funds, regulates, and oversees the second largest system of K–12 public education in the nation, serving over 5.4 million students across 1,200 school districts. Tex. Educ. Agency, *Enrollment in Texas Public Schools 2019-20* at 1 (Aug. 12, 2020), https://tea.texas.gov/sites/default/files/enroll_2019-20.pdf.

Texas also funds, supports, and administers a robust network of higher education—same as Plaintiff States. *See* ECF 102 ¶ 277. Texas is home to 119 public postsecondary institutions, including 37 universities and 82 two-year colleges and technical schools. *See* Tex. Higher Educ. Coordinating Bd., *2020 Texas Public Higher Education Almanac* at 28, 47 (Sept. 28, 2020), https://reportcenter.highered.texas.gov/agency-publication/almanac/2020-texas-public-higher-education-almanac/. While most states have just one or two public university systems, Texas has six. The largest of these systems—the University of Texas—has 14 separate locations that educate

approximately 240,000 students each year. *See About The University of Texas System*, THE UNIVERSITY OF TEXAS SYSTEM, https://www.utsystem.edu/about (last visited Jan. 15, 2021). All told, the State's entire network of higher education enrolled just shy of 1.7 million students in 2019. *See* Tex. Higher. Educ. Coordinating Bd., at 13.

Because Texas "receives federal funding from the Department for primary and secondary education, [Texas] and its public primary and secondary education systems are subject to" the Final Rule. ECF 102 ¶ 276. Likewise, "[e]ach of the institutions in [Texas's] systems of higher education receives federal funding and, as a result, is subject to the Rule" as well. ECF 102 ¶ 279. This means that Texas and its academic institutions have an obligation to investigate and enforce alleged violations of Title IX. Texas is intensely interested in the Final Rule as a result.

First, the Final Rule clarified the definition of sexual harassment as well as the conditions that must be met before a recipient's obligations under Title IX are activated. Invalidating the Final Rule would create uncertainty, harming the Texas institutions regulated under Title IX. *See infra* Part I.C. Earlier guidance had caused a great deal of uncertainty regarding recipients' legal responsibilities under Title IX.[7] Recipients did not know how to comply with the new mandates or whether failure to do so would incur legal consequences. *See* Janet Napolitano, *"Only Yes Means Yes": An Essay on University Policies Regarding Sexual Violence and Sexual Assault*, 33 YALE L. & POL'Y REV. 387, 394–395 (2015).

[7] The Task Force on Federal Regulation of Higher Education specifically identified the Dear Colleague Letter and 2014 Question and Answers as guidance documents that were meant to eliminate uncertainty but only led to more confusion. *See Recalibrating Regulation of Colleges and Universities* at 14 (Feb. 12, 2015), *available at* https://www.acenet.edu/Documents/Higher-Education-Regulations-Task-Force-Report.pdf.

In an abundance of caution, many academic institutions, including those funded by Texas, elected to revise their policies to cover a greater range of conduct and make it easier for administrators to arrive at a determination of guilt. *See Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020) (describing the pressure universities faced as a result of the Dear Colleague Letter). But that led to litigation. Hundreds of lawsuits have been filed since the Dear Colleague Letter was issued—a sizeable number of which academic institutions lost or settled. *See* Jonathan Taylor, Milestone: 600+ Title IX/Due Process Lawsuits in Behalf of Accused Students, Title IX for All (Apr. 1, 2020), https://www.titleixforall.com/milestone-600-title-ix-due-process-lawsuits-in-behalf-of-accused-students.

Second, the Final Rule reduced Texas' risk of liability. While previous guidance had supported an improperly broad view of Title IX liability, the Final Rule fixed those issues. By confining Title IX liability to proper limits set by statute, the Final Rule benefits Texas. If it were invalidated, Texas institutions would be subject to litigation expenses, which, in turn, would lead to higher compliance costs and diversion of resources.

In short, earlier guidance put Texas institutions between a rock and a hard place. Not following the guidance would risk federal enforcement actions, but following the guidance would lead to lawsuits, litigation expenses, and ultimately monetary settlements. *Id.*; *see also* Greta Anderson, *More Title IX Lawsuits by Accusers and Accused*, INSIDER HIGHER ED (Oct. 3, 2019), https://www.insidehighered.com/news/2019/10/03/students-look-federal-courts-challenge-title-ix-proceedings (describing the "high cost of addressing sexual misconduct. . . a lose-lose situation for universities"). The Final Rule, by contrast, resolves the dilemma. It provides clear guidance limiting Texas' liability and reducing expected litigation expenses.

These interests support intervention. If Plaintiff States' systems of public education give them standing to challenge the Final Rule, then Texas' system similarly gives it a protectable interest sufficient for intervention. *See Indep. Petrochemical Corp. v. Aetna Cas. & Sur. Co.*, 105 F.R.D. 106, 109 (D.D.C. 1985) (explaining that the court follows a "liberal formulation of the 'interest' test," which is more forgiving than the interest necessary to initiate a lawsuit); *Nuesse,* 385 F.2d at 700 (describing the purpose of the interest test as "involving as many apparently concerned persons as is compatible with efficiency and due process").

C. Disposition of this action may impair or impede Texas' ability to protect its interests.

As explained above, the Final Rule provides important benefits to Texas, its schools, and its citizens. It both limits the scope of potential Title IX liability and also provides clarity that helps schools follow the law. But Plaintiffs ask this Court to deprive Texas of those benefits by vacating the Final Rule. *See* ECF 102 § 14. Those "practical consequences" are more than sufficient to show impairment of Texas' interests. *Nat. Res. Def. Council v. Costle*, 561 F.2d 904, 909 (D.C. Cir. 1977). When a movant benefits from a regulation, invalidation of that regulation would necessarily impair the movant's interests. *See, e.g.*, *Wash. All. of Tech. Workers v. U.S. Dep't of Homeland Sec.*, 395 F. Supp. 3d 1, 20 (D.D.C. 2019); *Waterkeeper All., Inc. v. Wheeler*, 330 F.R.D. 1, 8 (D.D.C. 2018); *Envtl. Def. Fund, Inc. v. Costle*, 79 F.R.D. 235, 242 (D.D.C. 1978), *aff'd*, (D.C. Cir. July 31, 1978).

"[R]elegat[ion] to the status of amicus curiae" would not enable Texas to protect their interests in this case and "is not an adequate substitute for participation as a party." *Nuesse*, 385 F.2d at 704 n.10. In such a scenario, no party would provide a comprehensive defense of the Final Rule to the Court. Texas would not be able to file motions or appeal if necessary. *Id.* Although Texas acted as amicus curiae earlier in the proceeding, it did so when the Department adequately

represented Texas' interests and Texas was merely supplementing the Department's arguments. For the reasons stated below, those interests will diverge on January 20, 2021. *See infra* Part I.D. Texas will likely be the sole party then defending the Final Rule in its entirety, making it essential that its arguments be part of the Court's deliberations. "Participation by [Texas] as amicus curiae is not sufficient to protect against these practical impairments." *Feller v. Brock*, 802 F.2d 722, 730 (4th Cir. 1986). Texas should be granted intervenor status.

D. The parties no longer adequately represent Texas' interests.

Rule 24(a)'s inadequate representation requirement is "not onerous." *Fund For Animals, Inc. v. Norton*, 322 F.3d 728, 735 (D.C. Cir. 2003) (citing *Dimond v. District of Columbia*, 792 F.2d 179, 192 (D.C. Cir. 1986)). "[T]he burden of making that showing should be treated as minimal." *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972). Movants "ordinarily should be allowed to intervene unless it is clear that the party will provide adequate representation for the absentee." *United States v. Am. Tel. & Tel. Co.*, 642 F.2d 1285, 1293 (D.C. Cir. 1980); *see also Smuck v. Hobson*, 408 F.2d 175, 181 (D.C. Cir. 1969) (holding that the burden is on the parties opposing intervention to demonstrate that existing representation is adequate). After January 20, neither the Department nor the current Intervenor-Defendants will adequately represent Texas' interests.

1. The incoming administration is hostile to the Rule and Texas' interests.

As an initial matter, "the change in the Administration raises 'the possibility of divergence of interest' or a 'shift' during litigation." *W. Energy All*, 877 F.3d at 1169. This possibility, on its own, satisfies Rule 24(a)'s requirement of inadequate representation. *See Forest Cty. Potawatomi Cmty.*, 317 F.R.D. at 11 (stating that all movant need show is "a *possibility* that its interests may not be adequately represented absent intervention") (emphasis added). However, in addition to the

general uncertainty surrounding a change of party in the White House, the President-elect has repeatedly (and erroneously) asserted that the Final Rule is "a green light to ignore sexual violence." *The Biden Agenda for Women*, JOEBIDEN.COM, https://joebiden.com/womens-agenda/ (last visited Jan. 15, 2021). Promising to put a "quick end" to the Final Rule, he plans to "restore [earlier] Title IX guidance for colleges, including the 2011 Dear Colleague Letter."[8] *Id*; *The Biden Plan To End Violence Against Women*, JOEBIDEN.COM, https://joebiden.com/vawa/ (last visited Jan. 15, 2021). These statements are evidence of an unavoidable, fundamental divide between Texas and the Department under the President-elect's incoming administration. Texas cannot trust that the Department will serve as an adequate representative going forward.

2. Existing intervenors do not have the same interests as Texas.

Earlier in the proceedings, the Court permitted the intervention of three non-profits dedicated to promoting free speech and due process on college campuses. Although these organizations support the Final Rule, they represent "different interest[s]" than Texas. *Fund For Animals*, 322 F.3d at 737 (holding "that interests need not be wholly adverse" for representation to be inadequate). The Intervenor-Defendants advocate on behalf of students, alumni, and faculty, many of whom were subject to Title IX proceedings. Texas, in contrast, is a provider of public education, for which it and its associated academic institutions receive federal funds. Thus, whereas Intervenor-Defendants represent individuals whose rights may have been violated as a result of a Title IX action, Texas represents institutions subject to Title IX.

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[8] The President-elect offered similar remarks in a statement he and his campaign released following the Department's announcement of the Final Rule, whereby he promised the Final Rule would "be put to a quick end in January 2021." Joe Biden, *Statement on the Trump Administration Rule to Undermine Title IX and Campus Safety* (May 6, 2020), https://medium.com/@JoeBiden/statement-by-vice-president-joe-biden-on-the-trump-administration-rule-to-undermine-title-ix-and-e5dbc545daa.

The differences between Texas and Intervenor-Defendants do not end there. As sovereign, Texas has an independent duty to provide "a quality education that enables [students] to achieve their potential and fully participate now and in the future in the social, economic, and educational opportunities of our state and nation." TEX. EDUC. CODE § 4.001. In doing so, Texas must respect the rights of students suffering from sexual harassment as well as those accused of misconduct. The Intervenor-Defendants, as private parties, are not subject to the same tensions. *Cf. Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 539 (1972) (concluding that government cannot adequately represent private parties because it is also entrusted with protecting vital public interests).

Because of these differences, Texas and the Intervenor-Defendants have adopted distinct legal positions, which has significant implications for the resolution of this case. Texas takes a position similar to the one advanced by the Department prior to the change in administration: namely, it emphasizes that the Final Rule is consistent with federal statutes that form the basis of Plaintiff States' suit. The Intervenor-Defendants, on the other hand, contend that the Constitution mandates many of the provisions in the Final Rule notwithstanding what is authorized by federal statute.

The Intervenor-Defendants explained in their motion to intervene that courts, including the D.C. Circuit, "look skeptically on government entities serving as adequate advocates for private parties." ECF 27 at 12 (quoting *Crossroads Grassroots Policy Strategies v. Fed. Election Comm'n*, 788 F.3d 312, 321 (D.C. Cir. 2015)). This is because governments often serve "numerous complex and conflicting interests" that have the potential to affect their approach to litigation. *Commonwealth of Pennsylvania v. President of the United States of Am.*, 888 F.3d 52, 61 (3d Cir. 2018) (citing *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 973 (3d Cir. 1998)). The same logic

applies here, just in reverse. As private parties, the Intervenor-Defendants lack the complex and competing duties and concerns that define Texas' interest in Plaintiff States' challenge to the Final Rule.

II. In the alternative, the Court should permit permissive intervention.

Texas satisfies all the requisites for permissive intervention. *See New Hampshire v. Holder*, 293 F.R.D. 1, 8 (D.D.C. 2013) (requiring movant to show an independent ground for subject matter jurisdiction, a timely motion, and claim or defense that has a question of law or fact in common with the main action). The Court should exercise its "wide latitude" and permit Texas to intervene in this action even if Texas does not qualify for intervention as of right. *Sault Ste. Marie Tribe of Chippewa Indians v. Bernhardt*, 331 F.R.D. 5, 9 (D.D.C. 2019).

First, Texas has an independent ground for subject matter jurisdiction, as the action raises a federal question. *See* 7C Charles Alan Wright, *et al.*, Fed. Prac. & Proc. Civ. § 1917 (3d ed.) ("[T]he need for independent jurisdictional grounds is almost entirely a problem of diversity litigation. In federal-question cases there should be no problem of jurisdiction with regard to an intervening defendant nor is there any problem when one seeking to intervene as a plaintiff relies on the same federal statute as does the original plaintiff.").

Second, Texas' motion is timely. As explained above, the need for intervention arises on January 20, so Texas has not delayed, much less prejudiced any existing parties. *See supra* Part I.A.

Third, Texas' position in support of the Final Rule involves common questions of law and fact. *Nat'l Children's Ctr.,* 146 F.3d at 1047 (noting courts in this jurisdiction "afforded this requirement considerable breadth"). Both "the main action" and Texas' defense center on whether the Final Rule is consistent with Title IX and the Administrative Procedures Act. Fed. R. Civ. P.

24(b)(1)(B). Those common questions of law and fact are sufficient for permissive intervention. *See Weinberg v. Barry*, 604 F. Supp. 390, 392 n.1 (D.D.C. 1985).

Finally, the Court should exercise its discretion to permit intervention because Texas offers a unique, important perspective that is currently absent from the proceeding. *See Humane Soc. of U.S. v. Clark*, 109 F.R.D. 518, 521 (D.D.C. 1985) (judging it appropriate "[i]n light of the 'scope and complexity of plaintiffs' challenge,'" to have absent interests "directly represented"). Like Plaintiff States, Texas is a common provider of education, whose schools, universities, and other academic programing are subject to Title IX. But unlike Plaintiff States, Texas believes that the Final Rule will not only facilitate enforcement of Title IX but also discourage unconstitutional practices that have violated the rights of individuals accused of misconduct. *See Envtl. Def. Fund, Inc. v. Costle*, 79 F.R.D. 235, 244 (D.D.C. 1978), *aff'd*, (D.C. Cir. July 31, 1978) (considering whether movant will "supplement the position already taken by the other parties").

Texas can provide a broad-based defense of the Final Rule, enabling the Court to fully assess its validity through adversarial proceedings, despite the new Administration's change of position on the merits. *Clark*, 109 F.R.D. at 521 (granting intervention because movant showed "willingness and ability to contribute to the full development of the factual and legal issues presented").

CONCLUSION

For the foregoing reasons, the State of Texas respectfully requests that the Court grant its motion to intervene as a matter of right under Rule 24(a) or, in the alterative, for permissive intervention under Rule 24(b).

Date: January 19, 2021

KEN PAXTON
Attorney General of Texas

BRENT WEBSTER
First Assistant Attorney General

Respectfully submitted.

PATRICK K. SWEETEN
Associate Deputy for Special Litigation
Texas State Bar No. 00798537

WILLIAM T. THOMPSON
Special Counsel
Texas State Bar No. 24088531

/s/ Kathleen T. Hunker
KATHLEEN T. HUNKER
Special Counsel
Texas State Bar No. 24118415

OFFICE OF THE ATTORNEY GENERAL
P.O. Box 12548 (MC-009)
Austin, Texas 78711-2548
Tel.: (512) 936-1414
Fax: (512) 936-0545
patrick.sweeten@oag.texas.gov
kathleen.hunker@oag.texas.gov
will.thompson@oag.texas.gov


KeyCite Yellow Flag - Negative Treatment
Unconstitutional or Preempted Validity Called into Doubt by Purl v. United States Department of Health and Human Services, N.D.Tex., Dec. 22, 2024


KeyCite Yellow Flag - Negative Treatment
Proposed Regulation

Code of Federal Regulations
Title 45. Public Welfare
Subtitle A. Department of Health and Human Services (Refs & Annos)
Subchapter C. Administrative Data Standards and Related Requirements (Refs & Annos)
Part 160. General Administrative Requirements (Refs & Annos)
Subpart A. General Provisions

45 C.F.R. § 160.103

§ 160.103 Definitions.

Currentness

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d–1320d–4, 1320d–7, 1320d–8, and 1320d–9;

(2) Section 264 of Pub.L. 104–191;

(3) Sections 13400–13424 of Public Law 111–5; or

(4) This subchapter.

ALJ means Administrative Law Judge.

ANSI stands for the American National Standards Institute.

Business associate:

(1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) Business associate includes:

(i) A Health Information Organization, E–prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) Business associate does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of § 164.504(f) of this subchapter apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Civil money penalty or penalty means the amount determined under § 160.404 of this part and includes the plural of these terms.

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

Compliance date means the date by which a covered entity or business associate must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Disclosure means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing with identifying numbers in tax returns, statements, and other required documents.

Electronic media means:

(1) Electronic storage material on which data is or may be recorded electronically, including, for example, devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card;

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet, extranet or intranet, leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media if the information being exchanged did not exist in electronic form immediately before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of protected health information as specified in this section.

Employer is defined as it is in 26 U.S.C. 3401(d).

Family member means, with respect to an individual:

(1) A dependent (as such term is defined in 45 CFR 144.103), of the individual; or

(2) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).

(i) First-degree relatives include parents, spouses, siblings, and children.

(ii) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(iii) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(iv) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

Genetic information means:

(1) Subject to paragraphs (2) and (3) of this definition, with respect to an individual, information about:

(i) The individual's genetic tests;

(ii) The genetic tests of family members of the individual;

(iii) The manifestation of a disease or disorder in family members of such individual; or

(iv) Any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(2) Any reference in this subchapter to genetic information concerning an individual or family member of an individual shall include the genetic information of:

(i) A fetus carried by the individual or family member who is a pregnant woman; and

(ii) Any embryo legally held by an individual or family member utilizing an assisted reproductive technology.

(3) Genetic information excludes information about the sex or age of any individual.

Genetic services means:

(1) A genetic test;

(2) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(3) Genetic education.

Genetic test means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. Genetic test does not include an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition.

Group health plan (also see definition of health plan in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg–91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. Health care includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, including genetic information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg–91(b)(2) and used in the definition of health plan in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg–91(b)(3) and used in the definition of health plan in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(1) Health plan includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.

(vi) The Voluntary Prescription Drug Benefit Program under Part D of title XVIII of the Act, 42 U.S.C. 1395w–101 through 1395w–152.

(vii) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(viii) An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.

(ix) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(x) The health care program for uniformed services under title 10 of the United States Code.

(xi) The veterans health care program under 38 U.S.C. chapter 17.

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.

(xv) The Medicare Advantage program under Part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(2) Health plan excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg–91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)–(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Manifestation or manifested means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this subchapter, a disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on genetic information.

Modify or modification refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Person means a natural person (meaning a human being who is born alive), trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) Protected health information excludes individually identifiable health information:

(i) In education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) In records described at 20 U.S.C. 1232g(a)(4)(B)(iv);

(iii) In employment records held by a covered entity in its role as employer; and

(iv) Regarding a person who has been deceased for more than 50 years.

Public health, as used in the terms “public health surveillance,” “public health investigation,” and “public health intervention,” means population-level activities to prevent disease in and promote the health of populations. Such activities include identifying, monitoring, preventing, or mitigating ongoing or prospective threats to the health or safety of a population, which may involve the collection of protected health information. But such activities do not include those with any of the following purposes:

(1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating health care.

(3) To identify any person for any of the activities described at paragraphs (1) or (2) of this definition.

Reproductive health care means health care, as defined in this section, that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes. This definition shall not be construed to set forth a standard of care for or regulate what constitutes clinically appropriate reproductive health care.

Respondent means a covered entity or business associate upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services, or practices:

(i) Classification of components;

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of protected health information.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, State means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Subcontractor means a person to whom a business associate delegates a function, activity, or service, other than in the capacity of a member of the workforce of such business associate.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Health care electronic funds transfers (EFT) and remittance advice.

(12) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Violation or violate means, as the context may require, failure to comply with an administrative simplification provision.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity or business associate, is under the direct control of such covered entity or business associate, whether or not they are paid by the covered entity or business associate.

Credits

[67 FR 38019, May 31, 2002; 67 FR 53266, Aug. 14, 2002; 68 FR 8374, Feb. 20, 2003; 71 FR 8424, Feb. 16, 2006; 76 FR 40495, July 8, 2011; 77 FR 1589, Jan. 10, 2012; 78 FR 5687, Jan. 25, 2013; 79 FR 36432, June 27, 2014; 89 FR 33062, April 26, 2024]

SOURCE: 65 FR 50365, Aug. 17, 2000; 65 FR 82798, Dec. 28, 2000; 66 FR 12434, Feb. 26, 2001; 68 FR 18901, April 17, 2003; 71 FR 8424, Feb. 16, 2006; 74 FR 42767, Aug. 24, 2009; 74 FR 56130, Oct. 30, 2009; 76 FR 40495, July 8, 2011; 78 FR 5687, Jan. 25, 2013, unless otherwise noted.

AUTHORITY: 42 U.S.C. 1302(a); 42 U.S.C. 1320d–1320d–9; sec. 264, Pub.L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)); 5 U.S.C. 552; secs. 13400–13424, Pub.L. 111–5, 123 Stat. 258–279; and sec. 1104 of Pub.L. 111–148, 124 Stat. 146–154.

Notes of Decisions (31)

Current through January 13, 2025, 90 FR 2871. Some sections may be more current. See credits for details.

End of Document

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 7. Social Security (Refs & Annos)
Subchapter XI. General Provisions, Peer Review, and Administrative Simplification (Refs & Annos)
Part C. Administrative Simplification

42 U.S.C.A. § 1320d-5

§ 1320d-5. General penalty for failure to comply with requirements and standards

Currentness

(a) General penalty

(1) In general

Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part--

(A) in the case of a violation of such provision in which it is established that the person did not know (and by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

(B) in the case of a violation of such provision in which it is established that the violation was due to reasonable cause and not to willful neglect, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

(C) in the case of a violation of such provision in which it is established that the violation was due to willful neglect--

(i) if the violation is corrected as described in subsection (b)(3)(A), [1] a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.

(2) Procedures

The provisions of section 1320a-7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1320a-7a of this title.

(3) Tiers of penalties described

For purposes of paragraph (1), with respect to a violation by a person of a provision of this part--

(A) the amount described in this subparagraph is $100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $25,000;

(B) the amount described in this subparagraph is $1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $100,000;

(C) the amount described in this subparagraph is $10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $250,000; and

(D) the amount described in this subparagraph is $50,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $1,500,000.

(b) Limitations

(1) Offenses otherwise punishable

No penalty may be imposed under subsection (a) and no damages obtained under subsection (d) with respect to an act if a penalty has been imposed under section 1320d-6 of this title with respect to such act.

(2) Failures due to reasonable cause

(A) In general

Except as provided in subparagraph (B) or subsection (a)(1)(C), no penalty may be imposed under subsection (a) and no damages obtained under subsection (d) if the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty or damages knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

(B) Extension of period

(i) No penalty

With respect to the imposition of a penalty by the Secretary under subsection (a), the period referred to in subparagraph (A) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) Assistance

If the Secretary determines that a person failed to comply because the person was unable to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A). Such assistance shall be provided in any manner determined appropriate by the Secretary.

(3) Reduction

In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) and any damages under subsection (d) that is[2] not entirely waived under paragraph (3)[3] may be waived to the extent that the payment of such penalty[4] would be excessive relative to the compliance failure involved.

(c) Noncompliance due to willful neglect

(1) In general

A violation of a provision of this part due to willful neglect is a violation for which the Secretary is required to impose a penalty under subsection (a)(1).

(2) Required investigation

For purposes of paragraph (1), the Secretary shall formally investigate any complaint of a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicate such a possible violation due to willful neglect.

(d) Enforcement by State attorneys general

(1) Civil action

Except as provided in subsection (b), in any case in which the attorney general of a State has reason to believe that an interest of one or more of the residents of that State has been or is threatened or adversely affected by any person who violates a provision of this part, the attorney general of the State, as parens patriae, may bring a civil action on behalf of such residents of the State in a district court of the United States of appropriate jurisdiction--

(A) to enjoin further such violation by the defendant; or

(B) to obtain damages on behalf of such residents of the State, in an amount equal to the amount determined under paragraph (2).

(2) Statutory damages

(A) In general

For purposes of paragraph (1)(B), the amount determined under this paragraph is the amount calculated by multiplying the number of violations by up to $100. For purposes of the preceding sentence, in the case of a continuing violation, the number of violations shall be determined consistent with the HIPAA privacy regulations (as defined in section 1320d-9(b)(3) of this title) for violations of subsection (a).

(B) Limitation

The total amount of damages imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.

(C) Reduction of damages

In assessing damages under subparagraph (A), the court may consider the factors the Secretary may consider in determining the amount of a civil money penalty under subsection (a) under the HIPAA privacy regulations.

(3) Attorney fees

In the case of any successful action under paragraph (1), the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State.

(4) Notice to Secretary

The State shall serve prior written notice of any action under paragraph (1) upon the Secretary and provide the Secretary with a copy of its complaint, except in any case in which such prior notice is not feasible, in which case the State shall serve such notice immediately upon instituting such action. The Secretary shall have the right--

(A) to intervene in the action;

(B) upon so intervening, to be heard on all matters arising therein; and

(C) to file petitions for appeal.

(5) Construction

For purposes of bringing any civil action under paragraph (1), nothing in this section shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State.

(6) Venue; service of process

(A) Venue

Any action brought under paragraph (1) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of Title 28.

(B) Service of process

In an action brought under paragraph (1), process may be served in any district in which the defendant--

(i) is an inhabitant; or

(ii) maintains a physical place of business.

(7) Limitation on State action while Federal action is pending

If the Secretary has instituted an action against a person under subsection (a) with respect to a specific violation of this part, no State attorney general may bring an action under this subsection against the person with respect to such violation during the pendency of that action.

(8) Application of CMP statute of limitation

A civil action may not be instituted with respect to a violation of this part unless an action to impose a civil money penalty may be instituted under subsection (a) with respect to such violation consistent with the second sentence of section 1320a-7a(c)(1) of this title.

(e) Allowing continued use of corrective action

Nothing in this section shall be construed as preventing the Office for Civil Rights of the Department of Health and Human Services from continuing, in its discretion, to use corrective action without a penalty in cases where the person did not know (and by exercising reasonable diligence would not have known) of the violation involved.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XI, § 1176, as added Pub.L. 104-191, Title II, § 262(a), Aug. 21, 1996, 110 Stat. 2028; amended Pub.L. 111-5, Div. A, Title XIII, § 13410(a)(1), (d)(1) to (3), (e)(1), (2), (f), Feb. 17, 2009, 123 Stat. 271 to 276.)

Notes of Decisions (12)

Footnotes

1 So in original. Probably should be "(b)(2)(A)".

2 So in original. Probably should be "are".

3 So in original. Probably should be "(2)".

4 So in original. The words "or damages" probably should appear after "penalty".

42 U.S.C.A. § 1320d-5, 42 USCA § 1320d-5
Current through P.L. 118-158. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 7. Social Security (Refs & Annos)
Subchapter XI. General Provisions, Peer Review, and Administrative Simplification (Refs & Annos)
Part C. Administrative Simplification

42 U.S.C.A. § 1320d-6

§ 1320d-6. Wrongful disclosure of individually identifiable health information

Currentness

(a) Offense

A person who knowingly and in violation of this part--

(1) uses or causes to be used a unique health identifier;

(2) obtains individually identifiable health information relating to an individual; or

(3) discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b). For purposes of the previous sentence, a person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1320d-9(b)(3) of this title) and the individual obtained or disclosed such information without authorization.

(b) Penalties

A person described in subsection (a) shall--

(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and

(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

CREDIT(S)

(Aug. 14, 1935, c. 531, Title XI, § 1177, as added Pub.L. 104-191, Title II, § 262(a), Aug. 21, 1996, 110 Stat. 2029; amended Pub.L. 111-5, Div. A, Title XIII, § 13409, Feb. 17, 2009, 123 Stat. 271.)

Notes of Decisions (36)

42 U.S.C.A. § 1320d-6, 42 USCA § 1320d-6
Current through P.L. 118-158. Some statute sections may be more current, see credits for details.

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Opinion 1.1.1 Patient-Physician Relationships

The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.

A patient-physician relationship exists when a physician serves a patient's medical needs. Generally, the relationship is entered into by mutual consent between physician and patient (or surrogate).

However, in certain circumstances a limited patient-physician relationship may be created without the patient's (or surrogate's) explicit agreement. Such circumstances include:

(a) When a physician provides emergency care or provides care at the request of the patient's treating physician. In these circumstances, the patient's (or surrogate's) agreement to the relationship is implicit.

(b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.

(c) When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists.

AMA Principles of Medical Ethics: I,II,IV,VIII

Background report(s):

CEJA Report 3-A-16, Modernized *Code of Medical Ethics*

CEJA Report 1-A-01, The Patient-Physician Relationship

CEJA Report 3-A-16 Modernized Code of Medical Ethics

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(b) When a physician provides medically appropriate care for a prisoner under court order, in keeping with ethics guidance on court-initiated treatment.

(c) When a physician examines a patient in the context of an independent medical examination, in keeping with ethics guidance. In such situations, a limited patient-physician relationship exists. [new guidance cross-references guidance in Opinion 1.2.6]

AMA Principles of Medical Ethics: I,II,IV,VIII

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 1-A-01

Subject: The Patient-Physician Relationship

Presented by: Herbert Rakatansky, MD, Chair

Presented to: Reference Committee on Amendments to Constitution and Bylaws (William J. Mangold, Jr., MD, Chair)

Introduction

At the center of the history of the American Medical Association lies its *Code of Medical Ethics*. The original *Code* of 1847 promulgated an ethic that emphasized conduct rather than character. It was premised on the understanding that the very nature of the physician's responsibility consisted of caring for the sick and that this was a responsibility owed by all physicians to all patients.[1] Also, building upon the Hippocratic tradition, physicians were called upon to hold a sense of ethical obligation that rose above considerations of personal advancement.[2] According to one commentator, "the central moral commitment of the code was its dedication to something other than the physician's self-interest, that something being the primacy of the welfare of the patient."[3]

The current *Code*'s focus on the relationship between physician and patient is exemplified by the *Fundamental Elements of the Patient-Physician Relationship* issued in 1990.[4] In particular, physicians are to foster this partnership by providing information and allowing for autonomous decision-making, acting respectfully and in a timely manner, preserving confidentiality, ensuring continuity of care, and facilitating access to care. Despite this list of features of the relationship patients can expect from physicians and which physicians must strive to fulfill, the very nature of the patient-physician relationship remains unexamined.

The patient-physician relationship, which is at the heart of the AMA's *Code of Medical Ethics*, is the focus of this report.

Conceptualizing the patient-physician relationship

According to one medical ethicist, there is no single characterization that can properly do justice to the patient-physician relationship "given the complexity of professional styles, patient expectations and values, and contexts in which the relationship is established."[5] For example, patients treated for chronic diseases may have long-established relationships with their physicians, or may be interacting with a specialist for a single consult.

Irrespective of the circumstances of the encounter between patient and physician, medical ethicists have characterized it in terms of a moral activity. This has been found to arise from the condition that brings patients into contact with physicians, namely illness. "Healing is sought for concerns that go to the root of human existence: fears of death, deformity, and disability."[6] Patients have been described in terms of their vulnerability, and consequently exploitable state,

* Reports of the Council on Ethical and Judicial Affairs are assigned to the Reference Committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

and their dependence on the medical expertise and the compassion of physicians. In order to maintain good health or to secure the treatments that will alleviate their ills, patients, or surrogate decision-makers on their behalf, agree to enter into relationships with physicians. At times, the agreement to enter into a relationship is implied, such as when a patient is unconscious and in need of emergency care, or when physicians provide a specific service at the request of the treating physician (e.g. the services of a pathologist). Physicians also agree to enter the relationship; either directly, as agents, or by previous contractual arrangements to treat a group of patients. The relationship, therefore, is established by mutual agreement. In some rare instances, such as legally mandated treatment as described in Opinion 2.065, "Court-Initiated Treatments in Criminal Cases,"[7] treatment may be provided by a physician even though a patient has not consented to entering into a relationship. In such circumstances, physicians remain bound by the same obligations.

Once the relationship has been established, patients should be confident that they are receiving the best medical care their physicians can provide, uncompromised by external factors. However, the medical profession currently finds itself amidst tensions between physicians' altruistic covenant to provide needed medical care to patients and the market ethos of profit-making.[8]

Ethical obligations of physicians

Trust is central to the patient-physician relationship. Physicians provide specialized knowledge and expert skills that are relied upon by patients. Physicians also hold considerable control over medical resources used for the benefit of patients.

Many ethicists have emphasized the obligation of fidelity that is owed whenever the physician establishes a relationship with the patient.[9] One important manifestation of this obligation of fidelity is the ethical obligation not to abandon a patient, which would undermine physicians' trustworthiness. CEJA Opinion 8.115, "Termination of the Physician-Patient Relationship" embodies this obligation to ensure continuity of care. Viewed from a different perspective, medicine is an act of "profession" whereby physicians promise to use their knowledge to help and to heal.[10]

The patient-physician relationship is held to high standards of conduct, as embodied in the *Code of Medical Ethics*. This characterization of the patient-physician relationship differs significantly from the contractual view of the relationship in which patients seek care and physicians provide it.[11] Ethically, it would be insufficient to view health care as an ordinary service and to allow care that patients request from physicians to be governed by the maxim "let the buyer beware."

However, much of the current health care delivery system operates according to the dynamics of the market. According to many participants in this system, profit-making is a legitimate goal and financial incentives are important tools in controlling health care resources. This reality confers even greater importance onto the principal feature of the patient-physician relationship, which require that patients' interests be given priority. Therefore, external factors that may result in compromising medical judgment deserve careful examination.

Conflicts of interest

Many ethicists have long argued that some effacement of self-interest is morally obligatory for physicians.[8] This notion is captured throughout the *Code of Medical Ethics*.

Conflicts between physicians' and patients' interests

Physicians' self-interest that may conflict with the interests of patients is addressed in unambiguous terms in Opinion 8.03, "Conflicts of Interest: Guidelines," which states that "Under no circumstances may physicians place their own financial interests above the welfare of their patients (…) If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit."

More troubling in this era of managed care are some of the methods used to accomplish cost containment. Specifically, various risk-bearing arrangements that affect physicians' incomes according to their use of health care resources may lead to limitations that could be harmful to patients. In Opinion 8.054, "Financial Incentives and the Practice of Medicine," physicians are advised to evaluate financial incentives included in managed care contracts to ensure that quality of patient care is not compromised by placing physicians' payments at excessive risk or by setting unrealistic expectations for utilization. The Opinion also recommends that large financial incentives should be limited in order to prevent physicians' personal financial concerns from creating a conflict with their role as individual patient advocates.

Conflicts between individual patients and patient populations

Managed care's use of financial incentives to influence physicians' decision-making also has led to a shift from patient-focused medicine to population-based medicine. In order to stay within budgetary limits, physicians are urged, often through financial and other incentives, to consider the impact of the decisions they make on an entire group of patients, rather than on a single patient. Physicians who allow such incentives to color medical judgement become primarily agents of the health plan rather than of individual patients.[12] It would seem more likely that patients' trust in physicians will be best preserved if those who are ill can expect their physicians to be advocates for optimal care and not just some minimal standard.[12] However, systemic budgetary constraints may in fact prevent patients from obtaining access to the optimal level of care necessary to treat a condition. Faced with such prospects, patients must find allies who will assist them in gaining access to the resources needed to treat their condition. In an earlier report,[13] the Council clearly identified that physicians have a duty of patient advocacy that should not be altered by the system of health care delivery, and that requires physicians to advocate for any care they believe will materially benefit their patients.

Conclusion

The medical profession must strive to preserve the trust patients hold in their physicians. It cannot abandon ethical standards to economic forces. As individual physicians advocate for the care their individual patients require, so must the medical profession advocate for access to care for all. Individual physicians must work to forge strong alliances with their own patients, and the medical profession with the public, to preserve the integrity of the profession.

Recommendations

The Council recommends that the following be adopted and the remainder of the report be filed:

> The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between patient and physician is based on trust and gives rise to physicians'

ethical obligations to place patients' welfare above their own self-interest and above obligations to other groups, and to advocate for their patients' welfare.

A patient-physician relationship is generally created by mutual agreement between physician and patient (or surrogate). In some instances the agreement is implied, such as in emergency care or when physicians provide services at the request of the treating physician. In rare instances, treatment without consent may be provided under court order (see Opinion 2.065). Nevertheless, the physician's obligations to the patient remain intact.

Within the patient-physician relationship, a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount.

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AMA *Code of Medical Ethics*

3.1.1 Privacy in Health Care

Protecting information gathered in association with the care of the patient is a core value in health care. However, respecting patient privacy in other forms is also fundamental, as an expression of respect for patient autonomy and a prerequisite for trust.

Patient privacy encompasses a number of aspects, including personal space (physical privacy), personal data (informational privacy), personal choices including cultural and religious affiliations (decisional privacy), and personal relationships with family members and other intimates (associational privacy).

Physicians must seek to protect patient privacy in all settings to the greatest extent possible and should:

(a) Minimize intrusion on privacy when the patient's privacy must be balanced against other factors.

(b) Inform the patient when there has been a significant infringement on privacy of which the patient would otherwise not be aware.

(c) Be mindful that individual patients may have special concerns about privacy in any or all of these areas.

(d) Be transparent with any inquiry about existing privacy safeguards for patient data but acknowledge that anonymity cannot be guaranteed and that breaches can occur notwithstanding best data safety practices.

AMA Principles of Medical Ethics: I,IV

POLITICO

HEALTH CARE

Anti-abortion groups have 2 asks. RFK Jr. is listening.

Their support could make or break whether Senate confirms Kennedy for Trump's Cabinet.

Abortion opponents — concerned about Robert F. Kennedy's past comments supporting abortion access — have two major asks. | Rebecca Noble/Getty Images

By **MEGAN MESSERLY**, **ALICE MIRANDA OLLSTEIN** and **ADAM CANCRYN**
11/20/2024 12:00 PM EST

Robert F. Kennedy Jr. is on a mission to win over skeptical anti-abortion groups and their allies on Capitol Hill.

It could make or break whether the soon-to-be GOP-controlled Senate confirms him to serve as President-elect Donald Trump's Health and Human Services secretary.

Abortion opponents — concerned about Kennedy's past comments supporting abortion access — have two major asks: that he appoint an anti-abortion stalwart to a senior position in HHS and that he promise privately to them and publicly during his confirmation hearing to restore anti-abortion policies from the first Trump administration, according to four anti-abortion advocates

And Kennedy, according to a fifth person close to the Trump transition, is open to their entreaties.

The negotiations come amid growing recognition from Kennedy's inner circle and the broader Trump transition team that he needs to appease anti-abortion groups and those alarmed by his views on vaccines to secure the 50 votes needed for Senate confirmation. Trump's health secretary will play a key role in shaping abortion access, including through access to abortion pills, making the decision pivotal to anti-abortion advocates.

Kennedy, those close to him say, is chiefly focused on shaping the nation's public health and food policies. And because he has little personal interest in abortion policies, there's acknowledgment his confirmation could hinge on putting someone alongside him who does.

"He's all over the place on this issue," said one of the anti-abortion advocates.

Sen. James Lankford (R-Okla.), a prominent opponent of abortion who sits on the Senate Finance Committee, which will be responsible for advancing the nomination to a floor vote, has already made clear that he plans to press Kennedy on abortion-related issues.

"I have a lot of life questions," Lankford told POLITICO. "I want to know if the second Trump administration will have the same life perspective at HHS that the first one did. … They were very, very good about all the different issues."

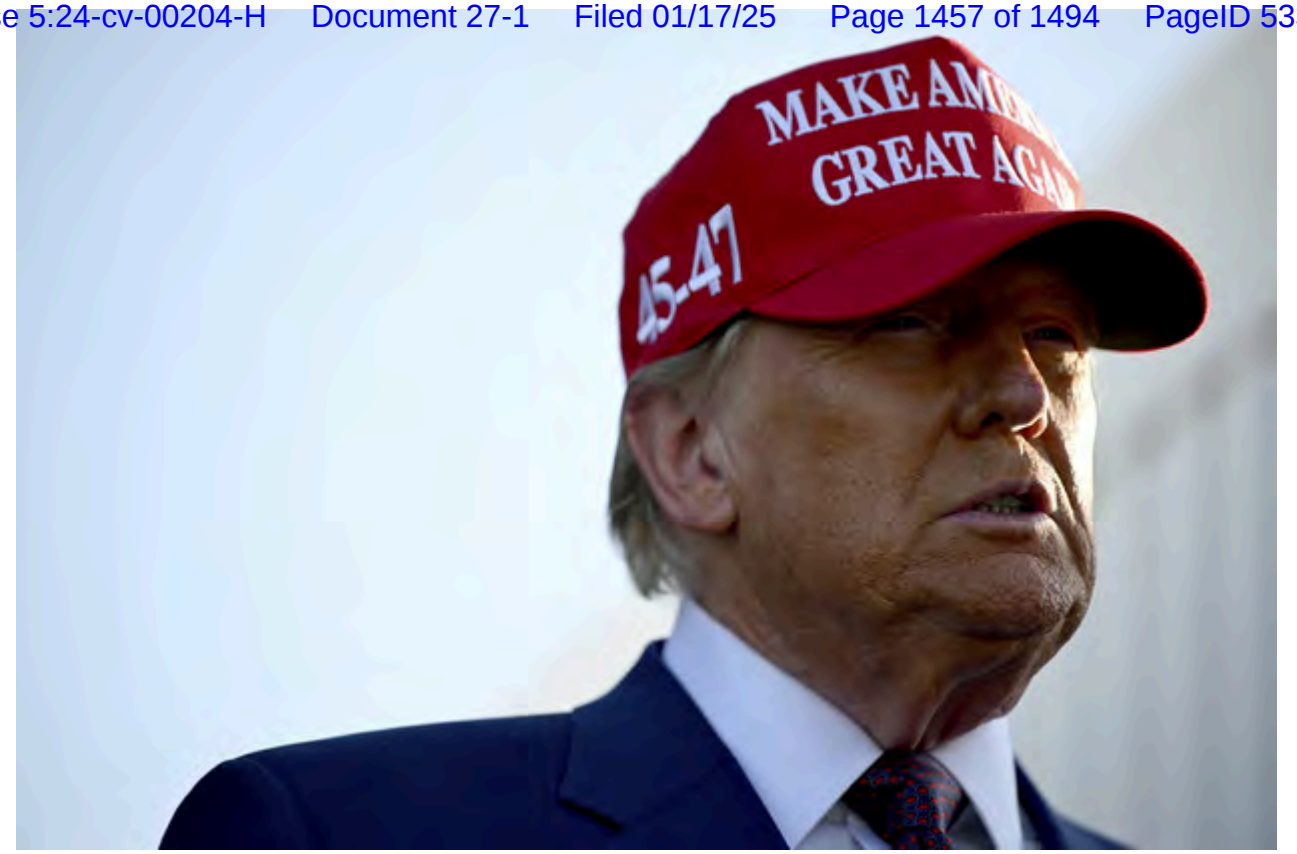
A spokesperson for the Trump transition did not immediately respond to a request for comment.

Among those anti-abortion advocates pushing for the senior HHS post are Roger Severino, director of HHS' Office for Civil Rights during the first Trump administration, and Eric Hargan, former deputy HHS secretary during the last administration. Neither responded to requests for comment.

At a minimum, anti-abortion groups want to see the Trump administration rescind the policies Biden implemented that expanded abortion access, such as the update to HIPAA privacy rules to cover abortions, as well as FDA rules making abortion pills available by mail and at retail pharmacies.

"We eagerly anticipate the day when the abortion pill is recognized for the evil it is and prohibited, and we encourage the President-elect to, at a minimum, swiftly reverse these changes made by the Biden administration," Brent Leatherwood, president of the Ethics and Religious Liberty Commission, the political arm of the Southern Baptist Convention, wrote in a recent memo to the Trump transition team outlining several of those policy priorities.

The advocates are also demanding the return of several Trump-era abortion rules, including the so-called Mexico City policy that blocked federal funding for international non-governmental organizations that provide or offer counseling on abortions, anti-abortion restrictions on federal family-planning clinics and a federal ban on discriminating against health care entities that refuse to cover abortion services or refer patients for the procedure when taxpayer dollars are involved.



Kennedy took a host of contradictory positions on abortion during his presidential campaign, which he suspended in July before endorsing President-elect Donald Trump. | Pool photo by Brandon Bell

"The accomplishments from President Trump's first term become the baseline for the second term," Susan B. Anthony Pro-Life America argued in its own memo, shared with POLITICO. "However, in order to even get to the baseline, there is much that must be undone from the Biden-Harris regime, which worked tirelessly to promote abortion in every nook and cranny of the federal government."

Kennedy took a host of contradictory positions on abortion during his presidential campaign, which he suspended in July before endorsing Trump. He said "every abortion is a tragedy" — but also that he identifies as "pro-choice" and believes "it is always the woman's right to choose." He hired an anti-abortion activist to his campaign and called for a national ban on abortion after 15 weeks of pregnancy and then reversed himself on that position.

The group Students for Life of America is less critical of Kennedy's abortion

The group's chief policy strategist, Kristi Hamrick, argued that the shift back in May is a sign that "he is someone who will listen" to their movement going

forward.

"When faced with evidence, he changed his views," she said. "How intelligent, refreshing and unlike so many in the health care space."

The group is also betting that Kennedy's environmental background will make him amenable to their pitch that abortion pills pose a threat to the U.S. water supply, and they are working to set up a meeting with him to make their case on cutting off patient access to the drugs.

Still, Students for Life is part of the chorus pushing for Severino — the lead author of Project 2025's health care chapter — to hold a prominent role at HHS, with Hamrick calling him "someone who knows just how corrupt and biased the agency is and who has ideas to fix it."

"They need to balance the HHS ticket with experience" due to Kennedy's lack of familiarity with government bureaucracy and federal funding streams, she said, adding that they trust someone who worked for years at the agency, like Severino, to make sure all of the Biden-era programs expanding access to abortion are rolled back.

Ben Leonard contributed to this report.

FILED UNDER: ABORTION, ROBERT F. KENNEDY JR., DONALD TRUMP,

Trump's HHS nominee Robert F. Kennedy Jr. reassures pro-life senators with policy plans

Robert F. Kennedy Jr., President-elect Donald Trump's nominee to be secretary of Health and Human Services, arrives for meetings at the Hart Senate Office Building on Capitol Hill on Dec. 16, 2024, in Washington, D.C. | Credit: Chip Somodevilla/Getty Images

By Tyler Arnold

Washington, D.C. Newsroom, Dec 18, 2024 / 17:50 pm

Robert F. Kennedy Jr. is reassuring Republican senators that he will back certain pro-life policies if the Senate confirms him to lead the U.S. Department of Health and Human Services (HHS).

In November, U.S. President-elect Donald Trump **nominated Kennedy** to serve as the United States secretary of the HHS, a position that requires Senate confirmation. HHS oversees 10 agencies, including the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC).

Kennedy is a former Democrat. He **ran for president** as an independent in 2024 before **dropping out** and **endorsing Trump**.

Although Kennedy has supported legal abortion for his entire public career, he told pro-life senators in closed-door meetings that he would oppose taxpayer funds for abortion domestically and abroad and restore conscience protections.

"Today I got to sit down with [Kennedy] — we had a substantive discussion about American health care … [and] a good discussion, at length, about pro-life policies at HHS," Sen. Josh Hawley, R-Missouri, said in **a series of posts on X**.

According to Hawley, Kennedy told him that, if confirmed, he would reinstate **the Mexico City Policy**, which ends federal funding for overseas organizations that promote abortion. Trump reinstated the Mexico City Policy during his first term and said in **an October interview with EWTN News** that he would consider doing so again in a second term.

Hawley said Kennedy's plans include "ending taxpayer funding for abortions domestically" and "reinstating the bar on Title X funds going to organizations that promote abortion." He said that Kennedy also "pledged to reinstate conscience protections for health care providers."

Sen. Tommy Tuberville, R-Alabama, told reporters that he and Kennedy also talked about abortion, saying: "The big thing about abortion is that he's telling everybody … whatever President Trump [supports], I'm going to back him 100%."

"Basically, [Kennedy] and President Trump have sat down and talked about it and both of them came to an agreement," Tuberville said. "Roe v. Wade is gone, [abortion has] gone back to the states. Let the people vote on it."

Sen. Markwayne Mullin, R-Oklahoma, **told reporters** that Kennedy told him he "serves the will of the [incoming] president of the United States and he'll be pushing his policies forward."

"[Kennedy's] first thing is [that] we have too many abortions," Mullin said. "... His follow up to that is [that he is] serving at the will of the president of the United States. ... I think that should clear up that question for anyone."

Sen. Tim Scott, R-South Carolina, said **in a post on X** that he also spoke with Kennedy about abortion.

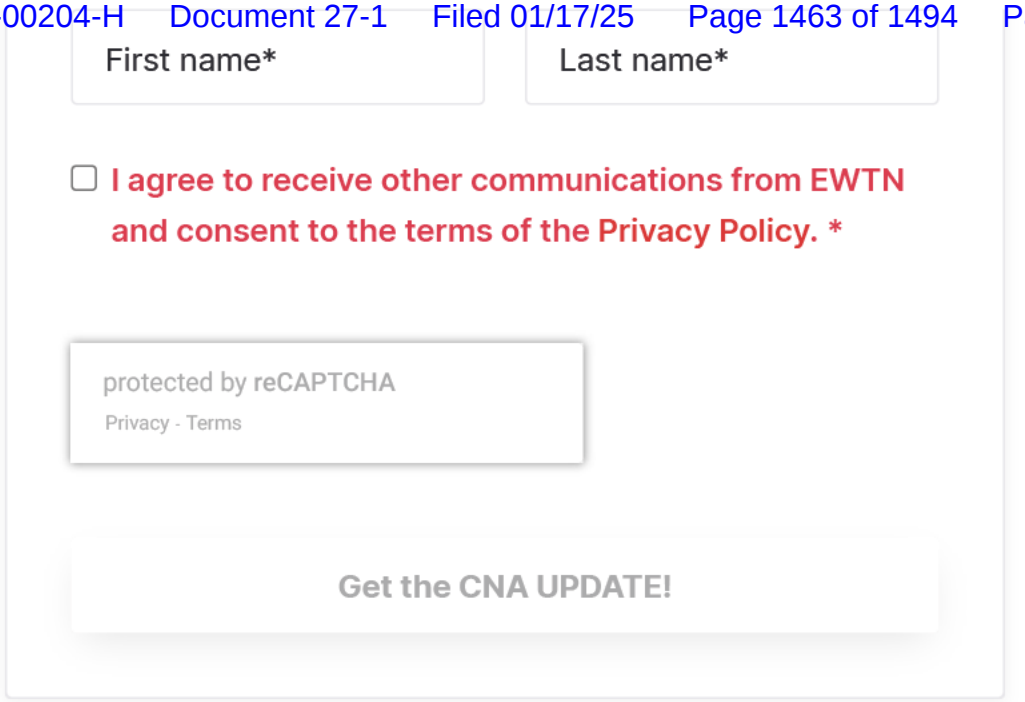
"I had a productive discussion with Robert F. Kennedy Jr. this evening about the future of our nation's health care system, preventing taxpayer-funded abortion, and Americans' long-term well-being," Scott said.

During his independent presidential campaign, Kennedy **first endorsed** abortion in all stages of pregnancy, including late-term abortion. He later **retracted that position** and said he would back restrictions at the point of fetal viability.

Kennedy also said during his campaign that **he would support** a "massive subsidized day care initiative" to reduce abortion without limiting legal access.

No word on chemical abortions

(Story continues below)



Tuberville, however, said that he did not speak with Kennedy about chemical abortions, which are regulated by the FDA. Trump himself **has said he will not** restrict access to **the abortion pill mifepristone**. Chemical abortions account for about half of all abortions in the country.

The FDA first approved mifepristone to be used in chemical abortions in 2000. Under current law, the drug is approved to abort an unborn child up to 10 weeks' gestation, at which point the child has a fetal heartbeat, early brain activity, and partially developed eyes, lips, and nostrils.

Mifepristone kills the child by blocking the hormone progesterone, which cuts off the supply of oxygen and nutrients. A second pill, misoprostol, is taken between 24 to 48 hours after mifepristone to induce contractions meant to expel the child's body from the mother, essentially inducing labor.

Pro-life advocates **have been urging** the incoming administration to restrict abortion drugs. Many activists have argued that the executive branch could prohibit the delivery of abortion drugs in the mail by **enforcing the Comstock Act** — a plan that has not been embraced by Trump.

Tags: Catholic News, President Donald Trump, HHS - Department of Health and Human Services, Abortion in the United States, Robert F. Kennedy Jr., Pro-Life News

Tyler Arnold is a staff reporter for Catholic News Agency, based in EWTN News' Washington Bureau. He previously worked at The Center Square and has been published in a variety of outlets, including The Associated Press, National Review, The American Conservative, and The Federalist.

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Photograph by Philip Montgomery for TIME

POLITICS DONALD TRUMP

How Far Trump Would Go

ERIC CORTELLESSA / PALM BEACH, FLA. @EricCortellessa | April 30, 2024

In exclusive interviews, the former President lays out a second-term agenda that would reshape America and its role in the world.

This feature was published in April 2024.

Donald Trump thinks he's identified a crucial mistake of his first term: He was too nice.

We've been talking for more than an hour on April 12 at his fever-dream palace in Palm Beach. Aides lurk around the perimeter of a gilded dining room overlooking the manicured lawn. When one nudges me to wrap up the interview, I bring up the many former Cabinet officials who refuse to endorse Trump this time. Some have publicly warned that he poses a danger to the Republic. Why should voters trust you, I ask, when some of the people who observed you most closely do not?

As always, Trump punches back, denigrating his former top advisers. But beneath the typical torrent of invective, there is a larger lesson he has taken away. "I let them quit because I have a heart. I don't want to embarrass anybody," Trump says. "I don't think I'll do that again. From now on, I'll fire."

Six months from the 2024 presidential election, Trump is better positioned to win the White House than at any point in either of his previous campaigns. He leads Joe Biden by slim margins in most polls, including in several of the seven swing states likely to determine the outcome. But I had not come to ask about the election, the disgrace that followed the last one, or how he has become the first former—and perhaps future—American President to face a criminal trial. I wanted to know what Trump would do if he wins a second term, to hear his vision for the nation, in his own words.

Photograph by Philip Montgomery for TIME

The former President, at Mar-a-Lago on April 12, is rallying the right at home and seeking common cause with autocratic leaders abroad.

What emerged in two interviews with Trump, and conversations with more than a dozen of his closest advisers and confidants, were the outlines of an imperial presidency that would reshape America and its role in the world. To carry out a deportation operation designed to remove more than 11 million people from the country, Trump told me, he would be willing to build migrant detention camps and deploy the U.S. military, both at the border and inland. He would let red states monitor women's pregnancies and prosecute those who violate abortion bans. He would, at his personal discretion, withhold funds appropriated by Congress, according to top advisers. He would be willing to fire a U.S. Attorney who doesn't carry out his order to prosecute someone, breaking with a tradition of independent law enforcement that dates from America's founding. He is weighing pardons for every one of his supporters accused of attacking the U.S. Capitol on Jan. 6, 2021, more than 800 of whom have pleaded guilty or been convicted by a jury. He might not come to the aid of an attacked ally in Europe or Asia if he felt that country wasn't paying enough for its own defense. He would gut the U.S. civil service, deploy the National Guard to American cities as he sees fit, close the White House pandemic-preparedness office, and staff his Administration with acolytes who back his false assertion that the 2020 election was stolen.

Trump remains the same guy, with the same goals and grievances. But in person, if anything, he appears more assertive and confident. "When I first got to Washington, I knew very few people," he says. "I had to rely on people." Now he is in charge. The arranged marriage with the timorous Republican Party stalwarts is over; the old guard is vanquished, and the people who remain are his people. Trump would enter a second term backed by a slew of policy shops staffed by loyalists who have drawn up detailed plans in service of his agenda, which would concentrate the powers of the state in the hands of a man whose appetite for power appears all but insatiable. "I don't think it's a big mystery what his agenda would be," says his close adviser Kellyanne Conway. "But I think people will be surprised at the alacrity with which he will take action."

- **The 7 States That Will Decide the Election**
- **A Guide to Kamala Harris' Views on Abortion, the Economy, and More**
- **See the Most Memorable Looks From the Republican National Convention**
- **How Far Trump Would Go**
- **Read the Full Transcripts of Donald Trump's Interviews With TIME**

The courts, the Constitution, and a Congress of unknown composition would all have a say in whether Trump's objectives come to pass. The machinery of Washington has a range of defenses: leaks to a free press, whistle-blower protections, the oversight of inspectors general. The same deficiencies of temperament and judgment that hindered him in the past remain present. If he wins, Trump would be a lame duck—contrary to the suggestions of some supporters, he tells TIME he would not seek to overturn or ignore the Constitution's prohibition on a third term. Public opinion would also be a powerful

check. Amid a popular outcry, Trump was forced to scale back some of his most draconian first-term initiatives, including the policy of separating migrant families. As George Orwell wrote in 1945, the ability of governments to carry out their designs "depends on the general temper in the country."

Every election is billed as a national turning point. This time that rings true. To supporters, the prospect of Trump 2.0, unconstrained and backed by a disciplined movement of true believers, offers revolutionary promise. To much of the rest of the nation and the world, it represents an alarming risk. A second Trump term could bring "the end of our democracy," says presidential historian Douglas Brinkley, "and the birth of a new kind of authoritarian presidential order."

Trump steps onto the patio at Mar-a-Lago near dusk. The well-heeled crowd eating Wagyu steaks and grilled branzino pauses to applaud as he takes his seat. On this gorgeous evening, the club is a MAGA mecca. Billionaire donor Steve Wynn is here. So is Speaker of the House Mike Johnson, who is dining with the former President after a joint press conference proposing legislation to prevent noncitizens from voting. Their voting in federal elections is already illegal, and extremely rare, but remains a Trumpian fixation that the embattled Speaker appeared happy to co-sign in exchange for the political cover that standing with Trump provides.

At the moment, though, Trump's attention is elsewhere. With an index finger, he swipes through an iPad on the table to curate the restaurant's soundtrack. The playlist veers from Sinead O'Connor to James Brown to *The Phantom of the Opera*. And there's a uniquely Trump choice: a rendition of "The Star-Spangled Banner" sung by a choir of defendants imprisoned for attacking the U.S. Capitol on Jan. 6, interspersed with a recording of Trump reciting the Pledge of Allegiance. This has become a staple of his rallies, converting the ultimate symbol of national unity into a weapon of factional devotion.

The spectacle picks up where his first term left off. The events of Jan. 6, during which a pro-Trump mob attacked the center of American democracy in an effort to subvert the peaceful transfer of power, was a profound stain on his legacy. Trump has sought to recast an insurrectionist riot as an act of patriotism. "I call them the J-6 patriots," he says. When I ask whether he would consider pardoning every one of them, he says, "Yes, absolutely." As Trump faces dozens of felony charges, including for election interference, conspiracy to defraud the United States, willful retention of national-security secrets, and falsifying business records to conceal hush-money payments, he has tried to turn legal peril into a badge of honor.

In a second term, Trump's influence on American democracy would extend far beyond pardoning powers. Allies are laying the groundwork to restructure the presidency in line with a doctrine called the unitary executive theory, which holds that many of the

constraints imposed on the White House by legislators and the courts should be swept away in favor of a more powerful Commander in Chief.

Read More: *Fact-Checking What Donald Trump Said In His Interviews With TIME*

Nowhere would that power be more momentous than at the Department of Justice. Since the nation's earliest days, Presidents have generally kept a respectful distance from Senate-confirmed law-enforcement officials to avoid exploiting for personal ends their enormous ability to curtail Americans' freedoms. But Trump, burned in his first term by multiple investigations directed by his own appointees, is ever more vocal about imposing his will directly on the department and its far-flung investigators and prosecutors.

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In our Mar-a-Lago interview, Trump says he might fire U.S. Attorneys who refuse his orders to prosecute someone: "It would depend on the situation." He's told supporters he would seek retribution against his enemies in a second term. Would that include Fani Willis, the Atlanta-area district attorney who charged him with election interference, or Alvin Bragg, the Manhattan DA in the Stormy Daniels case, who Trump has previously said should be prosecuted? Trump demurs but offers no promises. "No, I don't want to do that," he says, before adding, "We're gonna look at a lot of things. What they've done is a terrible thing."

Trump has also vowed to appoint a "real special prosecutor" to go after Biden. "I wouldn't want to hurt Biden," he tells me. "I have too much respect for the office." Seconds later, though, he suggests Biden's fate may be tied to an upcoming Supreme Court ruling on whether Presidents can face criminal prosecution for acts committed in office. "If they said that a President doesn't get immunity," says Trump, "then Biden, I am sure, will be prosecuted for all of his crimes." (Biden has not been charged with any, and a House Republican effort to impeach him has failed to unearth evidence of any crimes or misdemeanors, high or low.)

Read More: *Trump Says 'Anti-White Feeling' Is a Problem in the U.S.*

Such moves would be potentially catastrophic for the credibility of American law enforcement, scholars and former Justice Department leaders from both parties say. "If he ordered an improper prosecution, I would expect any respectable U.S. Attorney to say no," says Michael McConnell, a former U.S. appellate judge appointed by President George W. Bush. "If the President fired the U.S. Attorney, it would be an enormous firestorm." McConnell, now a Stanford law professor, says the dismissal could have a cascading effect similar to the Saturday Night Massacre, when President Richard Nixon ordered top DOJ officials to remove the special counsel investigating Watergate. Presidents have the constitutional right to fire U.S. Attorneys, and typically replace their predecessors' appointees upon taking office. But discharging one specifically for refusing a President's order would be all but unprecedented.

Trump's radical designs for presidential power would be felt throughout the country. A main focus is the southern border. Trump says he plans to sign orders to reinstall many of the same policies from his first term, such as the Remain in Mexico program, which requires that non-Mexican asylum seekers be sent south of the border until their court dates, and Title 42, which allows border officials to expel migrants without letting them apply for asylum. Advisers say he plans to cite record border crossings and fentanyl- and child-trafficking as justification for reimposing the emergency measures. He would direct federal funding to resume construction of the border wall, likely by allocating money from the military budget without congressional approval. The capstone of this program, advisers say, would be a massive deportation operation that would target millions of people. Trump made similar pledges in his first term, but says he plans to be more aggressive in a second. "People need to be deported," says Tom Homan, a top Trump adviser and former acting head of Immigration and Customs Enforcement. "No one should be off the table."

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For an operation of that scale, Trump says he would rely mostly on the National Guard to round up and remove undocumented migrants throughout the country. "If they weren't able to, then I'd use [other parts of] the military," he says. When I ask if that means he would override the Posse Comitatus Act—an 1878 law that prohibits the use of military force on civilians—Trump seems unmoved by the weight of the statute. "Well, these aren't civilians," he says. "These are people that aren't legally in our country." He would also seek help from local police and says he would deny funding for jurisdictions that decline to adopt his policies. "There's a possibility that some won't want to participate," Trump says, "and they won't partake in the riches."

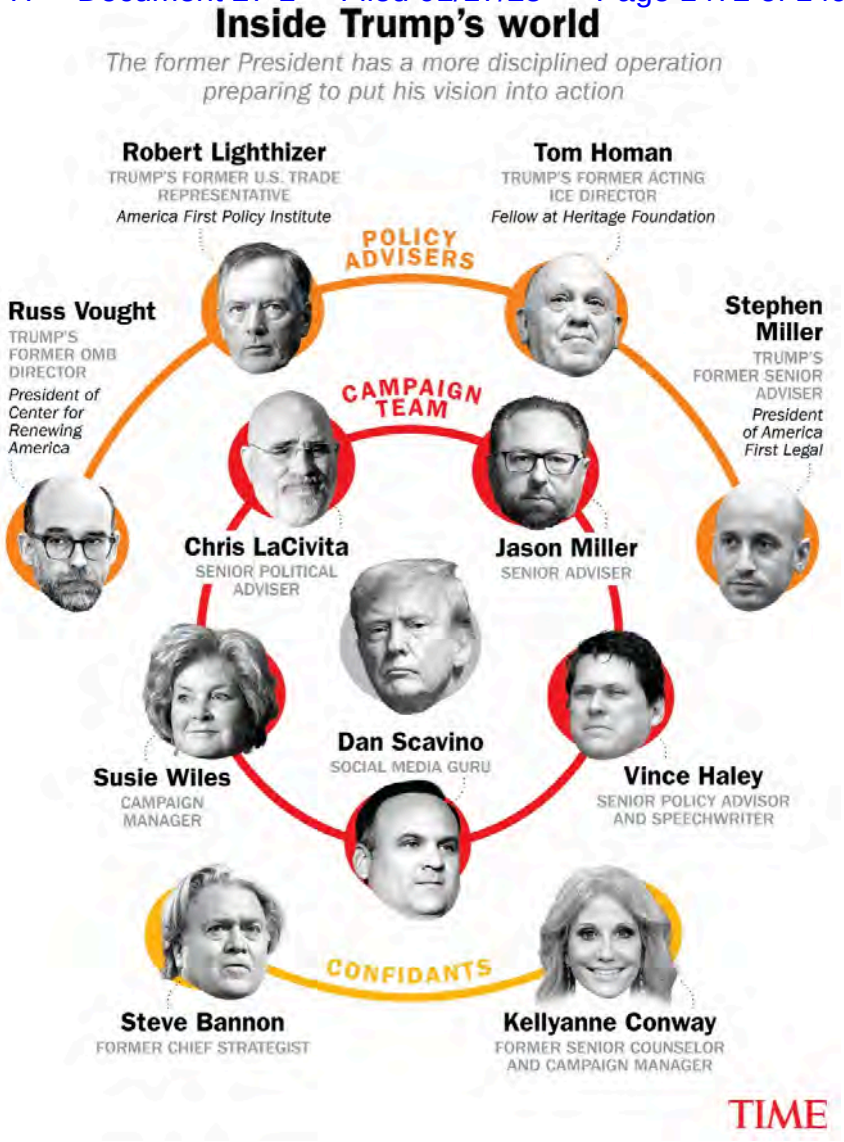
As President, Trump nominated three Supreme Court Justices who voted to overturn *Roe v. Wade,* and he claims credit for his role in ending a constitutional right to an abortion. At the same time, he has sought to defuse a potent campaign issue for the Democrats by saying he wouldn't sign a federal ban. In our interview at Mar-a-Lago, he declines to commit to vetoing any additional federal restrictions if they came to his desk. More than 20 states now have full or partial abortion bans, and Trump says those policies should be left to the states to do what they want, including monitoring women's pregnancies. "I think they might do that," he says. When I ask whether he would be comfortable with states prosecuting women for having abortions beyond the point the laws permit, he says, "It's irrelevant whether I'm comfortable or not. It's totally irrelevant, because the states are going to make those decisions." President Biden has said he would fight state anti-abortion measures in court and with regulation.

Trump's allies don't plan to be passive on abortion if he returns to power. The Heritage Foundation has called for enforcement of a 19th century statute that would outlaw the mailing of abortion pills. The Republican Study Committee (RSC), which includes more than 80% of the House GOP conference, included in its 2025 budget proposal the Life at Conception Act, which says the right to life extends to "the moment of fertilization." I ask

Trump if he would veto that bill if it came to his desk. "I don't have to do anything about vetoes," Trump says, "because we now have it back in the states."

Presidents typically have a narrow window to pass major legislation. Trump's team is eyeing two bills to kick off a second term: a border-security and immigration package, and an extension of his 2017 tax cuts. Many of the latter's provisions expire early in 2025: the tax cuts on individual income brackets, 100% business expensing, the doubling of the estate-tax deduction. Trump is planning to intensify his protectionist agenda, telling me he's considering a tariff of more than 10% on all imports, and perhaps even a 100% tariff on some Chinese goods. Trump says the tariffs will liberate the U.S. economy from being at the mercy of foreign manufacturing and spur an industrial renaissance in the U.S. When I point out that independent analysts estimate Trump's first term tariffs on thousands of products, including steel and aluminum, solar panels, and washing machines, may have cost the U.S. $316 billion and more than 300,000 jobs, by one account, he dismisses these experts out of hand. His advisers argue that the average yearly inflation rate in his first term—under 2%—is evidence that his tariffs won't raise prices.

Since leaving office, Trump has tried to engineer a caucus of the compliant, clearing primary fields in Senate and House races. His hope is that GOP majorities replete with MAGA diehards could rubber-stamp his legislative agenda and nominees. Representative Jim Banks of Indiana, a former RSC chairman and the GOP nominee for the state's open Senate seat, recalls an August 2022 RSC planning meeting with Trump at his residence in Bedminster, N.J. As the group arrived, Banks recalls, news broke that Mar-a-Lago had been raided by the FBI. Banks was sure the meeting would be canceled. Moments later, Trump walked through the doors, defiant and pledging to run again. "I need allies there when I'm elected," Banks recalls Trump saying. The difference in a second Trump term, Banks says now, "is he's going to have the backup in Congress that he didn't have before."



Trump's intention to remake America's relations abroad may be just as consequential. Since its founding, the U.S. has sought to build and sustain alliances based on the shared values of political and economic freedom. Trump takes a much more transactional approach to international relations than his predecessors, expressing disdain for what he views as free-riding friends and appreciation for authoritarian leaders like President Xi Jinping of China, Prime Minister Viktor Orban of Hungary, or former President Jair Bolsonaro of Brazil.

That's one reason America's traditional allies were horrified when Trump recently said at a campaign rally that Russia could "do whatever the hell they want" to a NATO country he believes doesn't spend enough on collective defense. That wasn't idle bluster, Trump tells me. "If you're not going to pay, then you're on your own," he says. Trump has long said the alliance is ripping the U.S. off. Former NATO Secretary-General Jens Stoltenberg credited Trump's first-term threat to pull out of the alliance with spurring other members to add more than $100 billion to their defense budgets.

But an insecure NATO is as likely to accrue to Russia's benefit as it is to America's. President Vladimir Putin's 2022 invasion of Ukraine looks to many in Europe and the U.S. like a test of his broader vision to reconstruct the Soviet empire. Under Biden and a bipartisan Congress, the U.S. has sent more than $100 billion to Ukraine to defend itself. It's unlikely Trump would extend the same support to Kyiv. After Orban visited Mar-a-Lago in March, he said Trump "wouldn't give a penny" to Ukraine. "I wouldn't give unless Europe starts equalizing," Trump hedges in our interview. "If Europe is not going

to pay, why should we pay? They're much more greatly affected. We have an ocean in between us. They don't." (E.U. nations have given more than $100 billion in aid to Ukraine as well.)

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Trump has historically been reluctant to criticize or confront Putin. He sided with the Russian autocrat over his own intelligence community when it asserted that Russia interfered in the 2016 election. Even now, Trump uses Putin as a foil for his own political purposes. When I asked Trump why he has not called for the release of *Wall Street Journal* reporter Evan Gershkovich, who has been unjustly held on spurious charges in a Moscow prison for a year, Trump says, "I guess because I have so many other things I'm working on." Gershkovich should be freed, he adds, but he doubts it will happen before the election. "The reporter should be released and he will be released," Trump tells me. "I don't know if he's going to be released under Biden. I would get him released."

America's Asian allies, like its European ones, may be on their own under Trump. Taiwan's Foreign Minister recently said aid to Ukraine was critical in deterring Xi from invading the island. Communist China's leaders "have to understand that things like that can't come easy," Trump says, but he declines to say whether he would come to Taiwan's defense.

Trump is less cryptic on current U.S. troop deployments in Asia. If South Korea doesn't pay more to support U.S. troops there to deter Kim Jong Un's increasingly belligerent regime to the north, Trump suggests the U.S. could withdraw its forces. "We have 40,000 troops that are in a precarious position," he tells TIME. (The number is actually 28,500.) "Which doesn't make any sense. Why would we defend somebody? And we're talking about a very wealthy country."

Transactional isolationism may be the main strain of Trump's foreign policy, but there are limits. Trump says he would join Israel's side in a confrontation with Iran. "If they attack Israel, yes, we would be there," he tells me. He says he has come around to the now widespread belief in Israel that a Palestinian state existing side by side in peace is increasingly unlikely. "There was a time when I thought two-state could work," he says. "Now I think two-state is going to be very, very tough."

Yet even his support for Israel is not absolute. He's criticized Israel's handling of its war against Hamas, which has killed more than 30,000 Palestinians in Gaza, and has called for the nation to "get it over with." When I ask whether he would consider withholding U.S. military aid to Israel to push it toward winding down the war, he doesn't say yes, but he doesn't rule it out, either. He is sharply critical of Israeli Prime Minister Benjamin Netanyahu, once a close ally. "I had a bad experience with Bibi," Trump says. In his telling, a January 2020 U.S. operation to assassinate a top Iranian general was supposed to be a joint attack until Netanyahu backed out at the last moment. "That was something I never forgot," he says. He blames Netanyahu for failing to prevent the Oct. 7 attack, when Hamas militants infiltrated southern Israel and killed nearly 1,200 people amid acts of brutality including burning entire families alive and raping women and girls. "It happened on his watch," Trump says.

On the second day of Trump's New York trial on April 17, I stand behind the packed counter of the Sanaa Convenience Store on 139th Street and Broadway, waiting for Trump to drop in for a postcourt campaign stop. He chose the bodega for its history. In 2022, one of the store's clerks fatally stabbed a customer who attacked him. Bragg, the Manhattan DA, charged the clerk with second-degree murder. (The charges were later dropped amid public outrage over video footage that appeared to show the clerk acting in self-defense.) A baseball bat behind the counter alludes to lingering security concerns. When Trump arrives, he asks the store's co-owner, Maad Ahmed, a Yemeni immigrant, about safety. "You should be allowed to have a gun," Trump tells Ahmed. "If you had a gun, you'd never get robbed."

On the campaign trail, Trump uses crime as a cudgel, painting urban America as a savage hell-scape even though violent crime has declined in recent years, with homicides

sinking 6% in 2022 and 15% in 2023, according to the FBI. When I point this out, Trump tells me he thinks the data, which is collected by state and local police departments, is rigged. "It's a lie," he says. He has pledged to send the National Guard into cities struggling with crime in a second term—possibly without the request of governors—and plans to approve Justice Department grants only to cities that adopt his preferred policing methods like stop-and-frisk.

To critics, Trump's preoccupation with crime is a racial dog whistle. In polls, large numbers of his supporters have expressed the view that antiwhite racism now represents a greater problem in the U.S. than the systemic racism that has long afflicted Black Americans. When I ask if he agrees, Trump does not dispute this position. "There is a definite antiwhite feeling in the country," he tells TIME, "and that can't be allowed either." In a second term, advisers say, a Trump Administration would rescind Biden's Executive Orders designed to boost diversity and racial equity.

Trump's ability to campaign for the White House in the midst of an unprecedented criminal trial is the product of a more professional campaign operation that has avoided the infighting that plagued past versions. "He has a very disciplined team around him," says Representative Elise Stefanik of New York. "That is an indicator of how disciplined and focused a second term will be." That control now extends to the party writ large. In 2016, the GOP establishment, having failed to derail Trump's campaign, surrounded him with staff who sought to temper him. Today the party's permanent class have either devoted themselves to the gospel of MAGA or given up. Trump has cleaned house at the Republican National Committee, installing handpicked leaders—including his daughter-in-law—who have reportedly imposed loyalty tests on prospective job applicants, asking whether they believe the false assertion that the 2020 election was stolen. (The RNC has denied there is a litmus test.) Trump tells me he would have trouble hiring anyone who admits Biden won: "I wouldn't feel good about it."

Policy groups are creating a government-in-waiting full of true believers. The Heritage Foundation's Project 2025 has drawn up plans for legislation and Executive Orders as it trains prospective personnel for a second Trump term. The Center for Renewing America, led by Russell Vought, Trump's former director of the Office of Management and Budget, is dedicated to disempowering the so-called administrative state, the collection of bureaucrats with the power to control everything from drug-safety determinations to the contents of school lunches. The America First Policy Institute is a research haven of pro-Trump right-wing populists. America First Legal, led by Trump's immigration adviser Stephen Miller, is mounting court battles against the Biden Administration.

The goal of these groups is to put Trump's vision into action on day one. "The President never had a policy process that was designed to give him what he actually wanted and campaigned on," says Vought. "[We are] sorting through the legal authorities, the mechanics, and providing the momentum for a future Administration." That includes a

litany of boundary-pushing right-wing policies, including slashing Department of Justice funding and cutting climate and environmental regulations.

Read More: *Fact-Checking What Donald Trump Said in His 2024 Interviews With TIME*

Trump's campaign says he would be the final decision-maker on which policies suggested by these organizations would get implemented. But at the least, these advisers could form the front lines of a planned march against what Trump dubs the Deep State, marrying bureaucratic savvy to their leader's anti-bureaucratic zeal. One weapon in Trump's second-term "War on Washington" is a wonky one: restoring the power of impoundment, which allowed Presidents to withhold congressionally appropriated funds. Impoundment was a favorite maneuver of Nixon, who used his authority to freeze funding for subsidized housing and the Environmental Protection Agency. Trump and his allies plan to challenge a 1974 law that prohibits use of the measure, according to campaign policy advisers.

Another inside move is the enforcement of Schedule F, which allows the President to fire nonpolitical government officials and which Trump says he would embrace. "You have some people that are protected that shouldn't be protected," he says. A senior U.S. judge offers an example of how consequential such a move could be. Suppose there's another pandemic, and President Trump wants to push the use of an untested drug, much as he did with hydroxychloroquine during COVID-19. Under Schedule F, if the drug's medical reviewer at the Food and Drug Administration refuses to sign off on its use, Trump could fire them, and anyone else who doesn't approve it. The Trump team says the President needs the power to hold bureaucrats accountable to voters. "The mere mention of Schedule F," says Vought, "ensures that the bureaucracy moves in your direction."

It can be hard at times to discern Trump's true intentions. In his interviews with TIME, he often sidestepped questions or answered them in contradictory ways. There's no telling how his ego and self-destructive behavior might hinder his objectives. And for all his norm-breaking, there are lines he says he won't cross. When asked if he would comply with all orders upheld by the Supreme Court, Trump says he would.

But his policy preoccupations are clear and consistent. If Trump is able to carry out a fraction of his goals, the impact could prove as transformative as any presidency in more than a century. "He's in full war mode," says his former adviser and occasional confidant Stephen Bannon. Trump's sense of the state of the country is "quite apocalyptic," Bannon says. "That's where Trump's heart is. That's where his obsession is."

These obsessions could once again push the nation to the brink of crisis. Trump does not dismiss the possibility of political violence around the election. "If we don't win, you know, it depends," he tells TIME. "It always depends on the fairness of the election." When I ask what he meant when he baselessly claimed on Truth Social that a stolen election "allows for the termination of all rules, regulations and articles, even those

found in the Constitution," Trump responded by denying he had said it. He then complained about the "Biden-inspired" court case he faces in New York and suggested that the "fascists" in America's government were its greatest threat. "I think the enemy from within, in many cases, is much more dangerous for our country than the outside enemies of China, Russia, and various others," he tells me.

Toward the end of our conversation at Mar-a-Lago, I ask Trump to explain another troubling comment he made: that he wants to be dictator for a day. It came during a Fox News town hall with Sean Hannity, who gave Trump an opportunity to allay concerns that he would abuse power in office or seek retribution against political opponents. Trump said he would not be a dictator—"except for day one," he added. "I want to close the border, and I want to drill, drill, drill."

Trump says that the remark "was said in fun, in jest, sarcastically." He compares it to an infamous moment from the 2016 campaign, when he encouraged the Russians to hack and leak Hillary Clinton's emails. In Trump's mind, the media sensationalized those remarks too. But the Russians weren't joking: among many other efforts to influence the core exercise of American democracy that year, they hacked the Democratic National Committee's servers and disseminated its emails through WikiLeaks.

Whether or not he was kidding about bringing a tyrannical end to our 248-year experiment in democracy, I ask him, Don't you see why many Americans see such talk of dictatorship as contrary to our most cherished principles? Trump says no. Quite the opposite, he insists. "I think a lot of people like it." —*With reporting by Leslie Dickstein, Simmone Shah, and Julia Zorthian*

Congress of the United States
Washington, DC 20515

June 16, 2023

VIA Federal eRulemaking Portal

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Comments on Proposed Rule: HIPAA Privacy Rule To Support Reproductive Health Care Privacy, 88 FR 23506 (April 17, 2023), RIN: 0945-AA20, Docket No. 2023-07517

Dear Secretary Becerra:

We write to express our concern regarding the U.S. Department of Health and Human Services (HHS) proposed rule, "HIPAA Privacy Rule To Support Reproductive Health Care Privacy," 88 Fed. Reg. 23506 published on April 17, 2023 (the "Proposed Rule"), and to urge you to withdraw it immediately.

Abortion is not health care—it is a brutal act that destroys the life of an unborn child and hurts women. Congress did not authorize HHS to extend special provisions for abortion such as these under the guise of "health care." The Proposed Rule unlawfully thwarts the enforcement of compassionate laws protecting unborn children and their mothers, and directs health care providers to defy lawful court orders and search warrants.

The Proposed Rule creates special protections for abortion that limit cooperation with law enforcement, undermine the ability to report abuse, restrict the provision of public health information, and erase the humanity of unborn children. The Proposed Rule would interfere with valid state laws protecting life, arbitrarily permit abortionists to disclose protected health information (PHI) to defend themselves while silencing others, and unlawfully infringe on Congressional power.

The Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization* returned the power to regulate or prohibit abortion back to people and their elected representatives. Under the Proposed Rule, HHS attempts to undermine enforcement of Federal and State abortion laws, simply because this administration disagrees with the Court's decision.

As Members of Congress, we have a Constitutional interest in ensuring that in issuing regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), HHS does not exceed its Congressionally authorized power.

I. Summary of the Health Insurance Portability and Accountability Act of 1996

Enacted by Congress in 1996, HIPAA mandated the development of national standards to prevent PHI from being disclosed without the patient's consent.[1] As required under Title II of HIPAA, HHS developed

[1] Public Law 104-191.

the Privacy Rule to regulate the use and disclosure of PHI by covered health entities, including both health care providers and health plans.[2]

In certain circumstances, the HIPAA Privacy Rule permits, but does not require, covered entities to use and disclose PHI without authorization from the patient. These circumstances include the following:

- **Exception for law enforcement purposes:** A covered entity may disclose PHI to a law enforcement official for a law enforcement purpose, including complying with a subpoena, a court order, or a warrant.[3] It may provide PHI in specific criminal, civil, and administrative proceedings.

- **Exceptions for abuse:** A covered entity may report child abuse and neglect to the appropriate government authority authorized by law to receive these reports.[4] It may also disclose PHI about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority.[5]

- **Exception for serious and imminent threats to the health or safety of a person or the public:** A covered entity may disclose PHI if it believes the disclosure is necessary to prevent or lessen a serious or imminent threat to a person or to the public. [6]

- **Exception for public health data collection:** A covered entity may disclose PHI to a public health authority authorized by law to collect this information, including for the purpose of public health surveillance.[7]

II. Summary of Key Changes Made by the Proposed Rule

Definition of Reproductive Health Care

The HHS Proposed Rule creates an arbitrary and capricious new category for abortion under the umbrella of "reproductive health care," which is defined as "care, services, or supplies related to the reproductive health of the individual,".[8] The preamble to the Proposed Rule clarifies that this definition "applies broadly" and includes "non-prescription supplies" furnished either by a health care provider or an individual who is not a health care provider.[9] Under the Proposed Rule "seeking, obtaining, providing, or facilitating reproductive health care," such as abortion, broadly "includes, but is not limited to, any of the following: expressing interest in, inducing, using, performing, furnishing, paying for, disseminating information about, arranging, insuring, assisting, or otherwise taking action to engage in reproductive

[2] HIPAA Administrative Simplification. Regulation Text. 45 CFR Parts 160, 162, and 164 (Unofficial Version, as amended through March 26, 2013). https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/combined/hipaa-simplification-201303.pdf.
[3] 45 CRS § 164.512(f).
[4] Section 1178(b) of HIPAA [42 U.S.C. 1320d–7], 45 CFR § 164.512 (b)(1)(ii).
[5] 45 CFR § 164.512(c)(1)(i).
[6] 45 CFR § 164.512(j).
[7] 45 CFR § 164.512(b)(1)(i).
[8] Proposed 45 CFR § 160.103.
[9] 88 FR 23527.

health care; or attempting any of the same."[10] In addition to including performing surgical and chemical abortion, this definition would encompass actions like mailing abortion drugs, promoting abortion, illicitly transporting minors or victims of sexual abuse to undergo abortions, and providing equipment intended to induce abortions, to name only a few examples.

The Proposed Rule would systematically undercut pro-life state laws in order to give abortion special protection. As described below, the rule limits cooperation with law enforcement, restricts the provision of public health information, and strips unborn children from the scope of protections under the HIPAA Privacy Rule.

Changing the HIPAA Privacy Rule's Exception for Law Enforcement Purposes

The Proposed Rule amends the Privacy Rule to prohibit covered entities from cooperating with law enforcement or even following a court order by using or disclosing PHI "for a criminal, civil or administrative investigation into or proceeding against any person in connection with seeking, obtaining, providing, or facilitating" an abortion, or to identify any person for the purpose of initiating such an investigation or proceeding,[11] if one or more of following three conditions are met ("Rule of Applicability"):[12]

(1) the abortion is provided "outside of the state where the investigation or proceeding is authorized" and the abortion "is lawful in the state in which it is provided."

(2) the abortion is "protected, required, or authorized by Federal law, regardless of the state in which such health care is provided."

(3) the abortion is "provided in the state in which the investigation or proceeding is authorized" and the abortion "is permitted by the law of that state."

HHS states that the purpose of this proposed Rule of Applicability is to "limit the application of the prohibition to circumstances in which the care [the abortion] is lawful under the circumstances in which such health care is provided."[13] As explained further on, however, the Rule of Applicability is premised on dubious and untested legal arguments that displace vast swaths of State abortion laws and inhibit States in carrying out their legitimate interests in protecting unborn children.

Changing the HIPAA Exceptions for Abuse

This Proposed Rule interferes with, and exerts a chilling effect on, the investigation and reporting of child abuse and sexual abuse, protecting abusers instead of victims.

Consistent with Section 1178(b) of the Social Security Act (as added by HIPAA), the Privacy Rule allows covered entities to use or disclose PHI in reporting suspected child abuse or neglect to the appropriate government authority.[14] The Privacy Rule also allows for the disclosure of PHI to the appropriate

[10] Proposed 45 CFR § 164.502(a)(5)(iii)(B).
[11] Proposed 45 CFR § 164.502(a)(5)(iii)(A).
[12] Proposed 45 CFR § 164.502(a)(5)(iii)(C)(1),(2),(3).
[13] 88 FR 23530-23531.
[14] 45 CFR § 164.512(b)(1)(i).

government authority when the covered entity "reasonably believes [an individual] to be a victim of abuse, neglect, or domestic violence," subject to certain other requirements.[15]

Under the Proposed Rule, neither of these longstanding exceptions to protect victims of abuse would permit disclosures of PHI for investigating or prosecuting any individual for providing or facilitating an abortion (in the applicable circumstances) "when the report of abuse, neglect, or domestic violence is *based primarily* on the provision of reproductive health care" (emphasis added).[16] The broad definition of "reproductive health care" means this provision not only protects abortions sought or coerced by abusers to cover up their abuse, but also covers cases where the reporting is based on the administration of rape kits and medical treatment for victims of sexual assault. Consequently, the Proposed Rule would protect abusers and abortionists who turn a blind eye to them, while exerting a chilling effect on the reporting of child and sexual abuse and the ability of States to prosecute perpetrators of abuse.

HHS openly admits that it intends for this provision to protect abortionists rather than victims in a bid to override the will of pro-life States: "The Department is concerned that *recent state actions* may lead regulated entities to think that they are permitted to make such disclosures of PHI when they believe that persons who provide or facilitate access to reproductive health care are perpetrators of such crimes" (emphasis added).[17]

Changing the HIPAA Privacy Rule's Exception for Serious and Imminent Threats to the Health or Safety of a Person or the Public

The Privacy Rule allows a covered entity to disclose PHI when it is "necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public" and is "to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat."[18]

The Proposed Rule's redefinition limits the term "person" to a human being "who is born alive,"[19] wrongfully preventing the Privacy Rule's exception for a serious and imminent threat to the health or safety from applying to an unborn child. The use of this exception is appropriate for an unborn child because every pregnancy involves two patients, the unborn child and his or her mother. Both patients have their own DNA, sex, limbs, eye color, and heartbeat. Abortion is the most serious threat imaginable to the health and safety of the child in the womb.

Congress has recognized the unborn child explicitly in several laws, including the Unborn Victims of Violence Act,[20] the Emergency Medical Treatment and Active Labor Act (EMTALA),[21] and the National

[15] 45 CFR § 164.512(c)(1)(i).
[16] Proposed 45 CFR 164.152(c)(3)
[17] 88 FR 23519.
[18] 45 CFR § 164.512(j).
[19] Proposed 45 CFR § 160.103.
[20] 18 U.S.C. § 1841 (establishing a separate offense for unborn children who are killed or injured through the commission of certain Federal crimes).
[21] 42 U.S.C. §§ 1395w-22(d)(B)(i), 1395dd(c)(1)(A)(ii), (c)(2)(A), (e)(1)(A)(i),(B)(ii) (recognizing threats to the health of the unborn child as well as the mother).

Childhood Vaccine Injury Act.[22] HHS regulations governing the Child Health Insurance Program similarly recognize the unborn child.[23]

The preamble to the Proposed Rule wrongly cites the Born Alive Infants Protection Act to limit the scope of protections in the Privacy Rule for unborn human beings. That law rightfully recognizes that children born alive, even after failed abortions, are "persons" under Federal law. However, the law did not thereby state that unborn children were not "persons." In fact, to avoid this very misunderstanding, the law included a rule of construction that states: "Nothing in this section shall be construed to affirm, deny, expand, or contract any legal status or legal right applicable to any member of the species homo sapiens at any point prior to being `born alive' as defined in this section."[24] Therefore, HHS' use of this 2002 law exclude "unborn children" as persons is arbitrary and capricious.

Changing the HIPAA Exception for Public Health

As directed by Section 1178(b) of the Social Security Act (as added by HIPAA), the Privacy Rule allows covered entities to use or disclose PHI in matters related to public health surveillance. The Proposed Rule arbitrarily thwarts legitimate public health oversight of the abortion industry. Specifically, the rule redefines "public health," to exclude "uses and disclosures for the criminal, civil, or administrative investigation into or proceeding against a person in connection with obtaining, providing, or facilitating" an abortion.[25] In addition, the Administration also clarifies that it believes state laws requiring the disclosure of PHI for purposes such as criminal, civil, or administrative investigations related to abortion are preempted by HIPAA.[26] It also states that public health reporting activities, including categories like "disease or injury," "birth," or "death," will exclude information about abortion for purposes of HIPAA.[27]

III. Key Anti-Life Consequences of the Proposed Rule

The Proposed Rule Interferes with Valid State Laws Protecting Life

The Proposed Rule interferes with the administration and enforcement of valid State laws that regulate or prohibit abortion. This is by design and in response to *Dobbs*, as HHS itself admits the rule would "create a conflict" with "some state laws."[28] HHS states that, in the circumstances when the Proposed Rule applies, "the state lacks any substantial interest in seeking the disclosure"[29] and elsewhere describes states as lacking even a "legitimate interest."[30]

Such assertions run directly counter to the ruling of the Supreme Court in *Dobbs*, which made clear that "[a] law regulating abortion . . . is entitled to a 'strong presumption of validity.'"[31] This presumption "must be sustained if there is a rational basis on which the legislature could have thought that it would serve legitimate state interests." Such legitimate interests "include respect for and preservation of

[22] 42 U.S.C. §§ 300aa-11(b)(2),(f) (applying the maternal immunization provisions to recognize children who were in utero when their mothers received a vaccine as "persons" who received a vaccine).
[23] 42 CFR § 457.10 (permitting States to consider the unborn child a "targeted low-income child" by defining "child" to include "an individual" during "the period from conception to birth").
[24] 1 U.S.C. 8(c).
[25] Proposed 45 CFR § 160.103.
[26] 88 FR 23524.
[27] 88 FR 23524.
[28] 88 FR 23530.
[29] 88 FR 23522.
[30] 88 FR 23531.
[31] *Dobbs v. Jackson Women's Health Org*., 142 S. Ct. 2228, 2284 (2022)

prenatal life at all stages of development, … the protection of maternal health and safety; the elimination of particularly gruesome or barbaric medical procedures; the preservation of the integrity of the medical profession; the mitigation of fetal pain; and the prevention of discrimination on the basis of race, sex, or disability."[32]

The Proposed Rule would contradict the presumption of validity of State abortion laws and massively expand the power of the Federal bureaucracy to undermine them. HHS would be empowered to launch investigations or impose crippling fines on health providers for obeying state laws, complying with state court orders, or cooperating with law enforcement.

Despite HHS claim that the Proposed Rule only applies when abortion related activities are lawful,[33] the rule will hamper the ability of states and the Federal government to investigate and enforce valid and enforceable pro-life laws.

This result stems from how each of the three prongs of the proposed Rule of Applicability is drafted:

1. ***Under the first prong of the Rule of Applicability, States that protect life would be unable to obtain PHI from health care providers to investigate the provision, trafficking or shipping of abortion drugs, or otherwise performing or facilitating abortion if the action begins, ends, or otherwise is connected with activities that occur in a State where abortion is legal.***

   HHS explains that "[t]he proposal is not limited to circumstances in which the health care has not yet been obtained, provided, or facilitated. It also includes situations *where the health care is ongoing* or has been completed" (emphasis added).

   Below is a non-exhaustive list of examples of circumstances where the prohibitions of the Proposed Rule appear to apply:

   - An out-of-State (or international) abortionist or abortion drug trafficker uses telemedicine or the mail to prescribe or transport an abortion drug.[34]
   - An abortionist begins the process of a late-term abortion in a State where abortion on demand is legal and he or another abortionist completes it in a State where abortion is prohibited (or vice-versa).
   - A child is trafficked across State lines without the consent of a parent to obtain an abortion. (Idaho recently enacted a law to prevent this.)[35]
   - A victim of sexual abuse is transported across State lines from a pro-life State to a pro-abortion State to undergo an abortion and cover up the abuser's crimes.

   It is arbitrary and capricious for the Proposed Rule to allow pro-abortion States to extend the reach of their radical abortion policies into pro-life States, while inhibiting pro-life States in enforcing laws that seek to do the contrary.

[32] Ibid.
[33] 88 FR 23531.
[34] Ibid., Footnote 270 further suggests HHS intends to protect the illegal interstate shipping of abortion drugs by citing the Department of Justice Office of Legal Counsel's misguided memo that seeks reinterpret longstanding Federal laws prohibiting the mailing and interstate carriage of abortion drugs.
[35] Idaho House Bill 242 (2023) https://legislature.idaho.gov/sessioninfo/2023/legislation/h0242.

To the extent State laws on abortion involve novel interjurisdictional issues between the States, it is the role of the Federal Courts, not HHS to adjudicate any constitutional questions that may arise in this context. HHS does not have the authority to declare that a sweeping category of State laws that protect life should not receive the presumption of validity that they are entitled to under *Dobbs*.

2. ***Under the second prong of the Rule of Applicability, HHS baselessly asserts that Federal law authorizes or even requires abortions that are prohibited under state law.***
As an example, HHS cites the Department of Veterans Affairs (VA) interim final rule, which purports to authorize VA to provide abortions on demand even in defiance of State law.[36] HHS fails to acknowledge, however, that a 1992 Federal law expressly prohibits the VA from providing abortions.[37] Furthermore, under the Assimilative Crimes Act, it is a Federal crime to violate a State abortion law in a Federal enclave located within that State.[38] As a second example, HHS cites the Emergency Medical Treatment and Labor Act (EMTALA), which the Biden administration claims "requires" the performance of abortion when a woman's health is at risk, preempting State laws prohibiting elective abortions.[39] In reality, EMTALA explicitly recognizes the health of the unborn child alongside the mother's health.[40]

   We ask that HHS provide a complete list and justification of every Federal law it believes protects, requires, or authorizes abortion or abortion-related activities in violation of State law, and which State laws on abortion HHS believes are unenforceable by reason of Federal law.

3. ***Under the third prong of the Rule of Applicability, HHS prevents health care providers from disclosing PHI to law enforcement or a Court if the State has not made the abortion at issue unlawful.***
The Proposed Rule would have a chilling effect on the ability of States to enforce their laws. HHS states: "if a state has not made the relevant reproductive health care unlawful, *it lacks a legitimate interest* in conducting a criminal, civil, or administrative investigation or proceeding into such health care where the investigation is centered on the mere fact that reproductive health care was or is being provided" (emphasis added).[41] This justification is without merit. States have a legitimate interest in investigating conduct that they have probable cause to believe may be unlawful. States that prohibit abortion except in limited circumstances, or only after the attainment of a certain gestational age or developmental milestone like a detectable heartbeat, must be allowed to investigate to determine whether or not a given abortion was lawful in the first place.

   Under the Proposed Rule, however, States would be forced to cede their powers to investigate criminal abortion-related activity to a health care provider (who may even be the subject of the investigation) and HHS' determination and understanding of State law. But in many cases, a violation of State law can only be determined through an investigation. HHS explains that a State investigation or proceeding regarding abortion could only obtain PHI "[w]here *the regulated entity determines* that the reproductive health care was provided under circumstances where it was unlawful"[42]

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[36] 88 FR 23531.
[37] Section 106 of the Veterans Health Care Act of 1992 (38 USC 1710 note).
[38] 18 U.S.C. § 13.
[39] 88 FR 23531.
[40] 42 U.S.C. §§ 1395w-22(d)(B)(i), 1395dd(c)(1)(A)(ii), (c)(2)(A), (e)(1)(A)(i),(B)(ii).
[41] 88 FR 23531.
[42] Ibid.

(emphasis added). This makes the Proposed Rule completely unworkable and wrongfully assigns health care providers and HHS bureaucrats power to self-enforce and oversee, respectively, State abortion laws in manner unlike how any legitimate health care service is treated under the Privacy Rule. The Proposed Rule also creates confusion for health care providers, who could be subjected to crippling fines imposed by HHS for cooperating with legitimate State law enforcement activities and Court orders.

By tying its requirements to circumstances where the abortion is "permitted by the law of that state,"[43] the Proposed Rule unlawfully thwarts enforcement of Federal criminal laws on abortion, such as those mentioned below. Specifically, this prong would prohibit disclosures for purposes of enforcing Federal abortion laws in States where statutes permit the Federally-prohibited abortion or abortion-related activities at issue, such as partial-birth abortions.

The Proposed Rule Arbitrarily Permits Abortionists to Disclose PHI to Defend Themselves

The Proposed Rule arbitrarily and capriciously permits abortionists and others who facilitate abortion to disclosure abortion-related PHI "to defend any person in a criminal, civil, or administrative proceeding where liability could be imposed on that person for providing such health care,"[44] while simultaneously inhibiting the ability of the state to obtain that same information as part of an investigation or proceeding. The aim of the Proposed Rule is not, therefore, about protecting "an individual's highly sensitive PHI," as HHS asserts in numerous places;[45] rather, it is about insulating the abortion industry from accountability.

The Proposed Rule is Unlawful and Infringes on Congressional Power

The Proposed Rule is plainly unlawful, and, if finalized, would far exceed HHS' authorized power. HIPAA does not provide "clear authorization required by [the Supreme Court's] precedents" to promulgate regulations setting national policy on an issue of major political significance, which abortion surely is.[46] Moreover, the rule comes as Congress "conspicuously and repeatedly declined to enact" legislation similar in nature to the Proposed Rule.[47] The mere fact that HIPAA authorizes the preemption of contrary State laws does not change the fact Congress never authorized HHS to promulgate special protections for abortion, particularly, not to hinder valid criminal and civil investigations under State law.

Far from promoting abortion as the Proposed Rule would, Congress has on numerous occasions acted to limit abortion nationally and rejected attempts to use Federal law to expand or protect abortion. To the contrary, the Proposed Rule's attempt to create special protections for abortion unlawfully interferes with several Federal criminal laws that protect life and prohibit coercive family planning practices. These include: the Federal ban on partial birth abortions,[48] the Federal ban on the mailing and interstate shipment of abortion drugs,[49] the Assimilative Crimes Act (as explained above),[50] the Federal ban on trafficking in human fetal tissue,[51] the Federal ban on coercive abortion and sterilization in Federal

[43] Proposed 45 CFR § 164.502(a)(5)(iii)(C)(3).
[44] 88 FR 23532.
[45] 88 FR 23508.
[46] West Virginia v. EPA, 142 S. Ct. 2587, 2614 (2022).
[47] Ibid., *See* S.1656, H.R. 3420, 118th Congress.
[48] 18 U.S.C. § 1531.
[49] 18 U.S.C. §§ 1461-1462.
[50] 18 U.S.C. § 13.
[51] 42 U.S.C. § 289g-2.

programs,[52] and the Federal ban on Female genital mutilation.[53] Congress' enactment of laws that limit abortion demonstrates Congressional intent that it never intended HIPAA to be used to promote or create special protections for abortion.

IV. Conclusion

This Proposed Rule far exceeds the power HHS was given by Congress to implement HIPAA. It massively expands the power of the federal bureaucracy to illegally override pro-life state laws and to undermine the decision of the Supreme Court in *Dobbs*. If finalized, the Proposed Rule will suppress compliance with Court orders and hamper necessary and legitimate investigations by law enforcement while protecting sex abusers and traffickers and individuals flooding the mail with deadly abortion drugs. We urge HHS to immediately withdraw this dangerous and irresponsible regulation.

Sincerely,

Cindy Hyde-Smith
United States Senator

Christopher H. Smith
Member of Congress

Roger Marshall
United States Senator

David Rouzer
Member of Congress

Mike Braun
United States Senator

Michelle Fischbach
Member of Congress

J.D. Vance
United States Senator

Andy Harris, M.D.
Member of Congress

James Lankford
United States Senator

Diana Harshbarger
Member of Congress

[52] 42 U.S.C. § 300a-8.
[53] 18 U.S.C. § 116.

Mike Lee
United States Senator

Jeff Duncan
Member of Congress

James E. Risch
United States Senator

Jim Banks
Member of Congress

Ted Cruz
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John H. Rutherford
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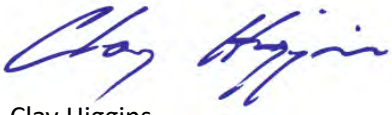

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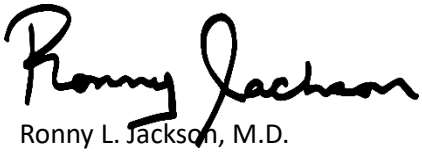

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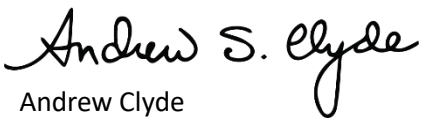

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- **OCR should withdraw its Health Insurance Portability and Accountability Act (HIPAA)[86] guidance on abortion.** OCR should withdraw its June 2022 guidance[87] that purports to address patient privacy concerns following the *Dobbs* decision but is actually a politicized statement in favor of abortion and against *Dobbs*. HIPAA covers patients in the womb, but this guidance treats them as nonpersons contrary to law. The guidance is unnecessary and contributes to ideologically motivated fearmongering about abortion after *Dobbs*.

AUTHOR'S NOTE: The preparation of this chapter was a collective enterprise of selfless individuals involved in the 2025 Presidential Transition Project. All contributors to this chapter are listed at the front of this volume and include former officials in the U.S. Department of Health and Human Services and other agencies, as well as academics, attorneys, and experts in the health care and insurance fields.

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How Trump nominees could make Project 2025 a reality

GOV & POLITICS | Jan 02, 2025 | 2:23 pm ET | By Amanda Becker/The 19th

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Donald Trump, at the time president of the United States, listens to then-Office of Management and Budget Acting Director Russ Vought deliver remarks prior to Trump signing executive orders on Oct. 9, 2019, in the Roosevelt Room of the White House. Official White House Photo by Shealah Craighead

Republican President-elect Donald Trump spent the closing months of his campaign trying to distance himself from a blueprint for his second term known as Project 2025.

Then, in the days after his victory, Trump picked major architects of the Heritage Foundation's vision for key posts in his next administration, setting the stage for them to implement a conservative Christian agenda that has the potential to reshape the federal government and redefine rights long held by all Americans, though likely to disproportionately impact women, LGBTQ+ people and vulnerable populations like the elderly and disabled.

One of these architects is Russell Vought, whom Trump has again tapped to lead his Office of Management and Budget, or OMB, an under-the-radar entity to most Americans that wields immense influence over the federal government by crafting the president's budget. If confirmed by the Senate, a very likely outcome, Vought will

This article was originally published by The 19th,

be optimally positioned to inject Project 2025's priorities – many of which reflect his career-long push to dismantle programs for low-income Americans and expand the president's authority – across the federal agencies and departments that OMB oversees.

Ben Olinsky, who advised Democratic former President Barack Obama on labor and workforce policy before joining the liberal-leaning Center for American Progress, where he works on issues related to the economy and governance, said that Vought's vision for OMB as presented in Project 2025 is "to basically change the plumbing so they can do whatever they want without any meaningful checks and balances" during Trump's second term.

a nonprofit newsroom covering gender, politics, and policy. The Arizona Mirror is a founding member of The 19th News Network.

"I think that it's important to really make sure [Americans] understand what the plans are for changing the plumbing," Olinsky said.

Vought has firsthand knowledge of the OMB's wide-ranging scope. During Trump's first term, he was OMB's deputy director, acting director and, finally, confirmed director. In those roles, he helped then-President Trump craft a plan to jettison job protections for thousands of federal workers and assisted with a legally ambiguous effort to redirect congressionally appropriated foreign aid for Ukraine.

In the years since, as Trump staved off legal threats and convictions to build a winning bid to return to the White House, Vought has refined his thinking and strategies about how to best force agencies to "come to heel and do what the president has been telling them to do," as he put it in a recent interview.

Vought has used two pro-Trump groups he founded – the nonprofit Center for Renewing America and its advocacy arm, America Restoration Action – to discredit structural racism as a driver for inequality and attempt to stymie diversity, equity and inclusion (DEI) efforts. In August, he told a pair of British journalists posing as potential donors that the Center for Renewing America is "an organization I helped turn into the Death Star," the fictional Star Wars space station that can destroy planets, and it "is accomplishing all of the debates you are reading about."

The chapter that Vought wrote for Project 2025 details how the Office of Management and Budget could be a vehicle to advance the Christian nationalist agenda he favors – and he has not hesitated to talk about it.

"I think you have to rehabilitate Christian nationalism," Vought told the British journalists at the Centre for Climate Reporting, which released video of the conversation that was recorded using hidden cameras.

In an interview with conservative activist Tucker Carlson shortly after Trump's reelection, Vought likened OMB to the "nerve center" through which a president can ensure their policy directives trickle down to the multitude of federal agencies and a civilian workforce of more than two million people.

"Properly understood, [OMB] is a President's air-traffic control system with the ability and charge to ensure that all policy initiatives are flying in sync and with the authority to let planes take off and, at times, ground planes that are flying off course," Vought wrote in Project 2025.

He sees two primary ways to ground wayward planes: by eliminating potential dissent within agencies and withholding money appropriated by Congress for projects and programs the president does not support.

Both would clear the way for Trump's next administration to implement many of the priorities detailed in Project 2025, which could essentially redefine rights, systems and cultural norms for all Americans.

Some of Project 2025's recommendations include restricting abortion access and supporting a "biblically based" definition of family, because the "male-female dyad is essential to human nature," by replacing policies related to LGBTQ+ equity with those that "support the formation of stable, married, nuclear families."

It also suggests transforming the FBI into a politically motivated entity to settle scores and barring U.S. citizens from receiving federal housing assistance if they live with anyone who is not a citizen or permanent legal resident, which would serve Trump's campaign promise to take extraordinary measures to crack down on illegal immigration. During remarks in September titled "Theology of America's Statecraft: The Case for Immigration Restriction," Vought justified the separation of families and condemned so-called sanctuary cities, or those that pass laws that limit their cooperation with federal immigration authorities. "Failing to secure the border is a complete abdication of [the government's] God-given responsibility," he said.

Olinsky explained that while many of the policies in Project 2025 have been floating around Republican circles in Washington for years without gaining much traction, the document is a detailed roadmap that shows how its authors believe they can finally deliver on key pieces of their conservative Christian agenda.

"One, it says all of the quiet parts out loud about the full scope of the agenda. And then the second thing, which I think is something folks should really pay attention to, is it says how they're going to accomplish it, practically, by using executive action," Olinsky said.

In many ways, Vought's approach to bending the federal government to a president's will began taking shape during Trump's first administration. In late 2020, as Trump's first term drew to a close, Vought helped him craft an executive order known as "Schedule F," which reclassified thousands of civil servants and, with that, stripped them of their job protections; Vought recommended that close to 90 percent of OMB's workforce be reclassified.

President Joe Biden rescinded the executive order on his third day in office. Project 2025 recommends reinstating it.

Former Trump officials, campaign advisers and others in his orbit have already identified as many as 50,000 federal employees who could be fired, according to published reports. And just last month, Senate Republicans blocked a Democratic effort to codify protections for these workers ahead of Trump's — and likely Vought's — return.

Sen. Tim Kaine of Virginia, a Democrat who sponsored the legislation to protect federal employees, warned of a "loyalty-based system that would impede the work of the federal government, expose people to intimidation and bring people into jobs that are not qualified to do them, thus risking the American public's safety and quality of life."

Vought is among the Trump loyalists who have been open about their desire to slash the federal workforce — as a route to purge critics, improve efficiency or both.

In the interview with Carlson, Vought said, "There certainly is going to be mass layoffs and firings, particularly at some of the agencies that we don't even think should exist." His language appeared to communicate an effort to ensure obedience and compliance. With the firings and layoffs, Vought said he wants to avoid having "really awesome Cabinet secretaries sitting on top of massive bureaucracies that largely don't do what they tell them to do."

Trump's transition team did not respond to requests to discuss Vought's selection for OMB or the chapter he wrote for Project 2025 about the agency. The 19th reached out to Vought through his Center for Renewing America, which likewise did not respond to a request for comment.

Power of the Purse

During Trump's first term, OMB helped find money to begin building a small section of wall along the U.S.-Mexico border — a key campaign promise Trump made in 2016 — "because Congress wouldn't give him the ordinary money," Vought told Carlson.

Trump also enlisted OMB to withhold $400 million in military aid that Congress approved for Ukraine, as Trump and his associates tried to pressure the country to investigate Biden and his family. The move prompted the abuse-of-power case House Democrats made against Trump during his first impeachment, when Vought defied a subpoena to testify. The Government Accountability Office, a nonpartisan watchdog, concluded that the scheme violated the 1974 Impoundment Control Act. Days later, the Republican-led Senate acquitted Trump. (Trump had eventually released the aid.)

When Trump subsequently nominated Vought to lead OMB in 2020, Democrats opposed him because of his approach to impoundment authority. He was nonetheless confirmed.

Vought's path to confirmation is all but certain this time around: Republicans control the Senate, the congressional chamber charged with approving presidential nominations. Very likely to feature in his confirmation hearings is Vought's belief that the OMB can help Trump overcome opposition and implement policy priorities, possibly including those contained in Project 2025, by redirecting or refusing to spend funds appropriated by Congress, which under the Constitution holds the power of the purse.

"Making Impoundment Great Again!" Vought wrote in June on X, riffing on the "Make America Great Again" slogan that has come to define Trump's movement.

Trump spent his campaign insisting that he had not read Project 2025 and did not know its authors. "I have no idea who is behind it. I disagree with some of the things they're saying and some of the things they're saying are absolutely ridiculous and abysmal," he wrote in a July post on his Truth Social platform.

But of the more than 350 people who contributed to Project 2025, at least 60 percent are linked to the incoming president, according to a list of contributors and their ties reviewed by The 19th. They range from appointees and nominees from Trump's first administration, like Vought, to members of his previous transition team and those who served on commissions and as unofficial advisers.

Democrats, including Vice President Kamala Harris, seized on Project 2025 during their campaigns to highlight the dangers they believe are posed by a second Trump presidency. At 920 pages, it offers a vision of government that is far more detailed and specific than the policy proposals put forward by Trump directly. The "Agenda 47" on Trump's campaign website was a list of 20 bullet points that included vague policies like "end the weaponization of government against the American people" and "unite our country by bringing it to new and record levels of success."

When Trump announced Vought as his OMB pick, he said Vought "knows exactly how to dismantle the Deep State and end Weaponized Government." His other selections for OMB leadership posts include anti-abortion activist Ed Martin and Vought's colleague at the Center for Renewing America, Mark Paoletta, whom the president-elect praised as a "conservative warrior."

One question as Trump takes office on January 20 and Vought, if confirmed, helps him control the government's workforce and purse strings, is which version of the country they will promote and whose rights are – and aren't – protected.

PUBLISHED ON

Arizona Mirror

Phoenix, AZ

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