NO. 18-1514

United States Court of Appeals

for the First Circuit

COMMONWEALTH OF MASSACHUSETTS,
Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES; U.S. DEPARTMENT OF THE TREASURY; STEVEN T. MNUCHIN, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE TREASURY; U.S. DEPARTMENT OF LABOR; AND R. ALEXANDER ACOSTA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF LABOR,
Defendants-Appellees.

ON APPEAL FROM A FINAL JUDGMENT OF THE DISTRICT COURT

BRIEF OF PLAINTIFF-APPELLANT

MAURA HEALEY
Attorney General of Massachusetts

Julia E. Kobick, No. 1162713
Jon Burke, No. 1184311
Jonathan B. Miller, No. 1143605
Assistant Attorneys General
Elizabeth Carnes Flynn, No. 1184310
Special Assistant Attorney General
One Ashburton Place
Boston, Massachusetts 02108
(617) 963-2559
email: julia.kobick@state.ma.us

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Federal Statutes

Massachusetts Statutes

Federal Rules and Regulations

Massachusetts Rules and Regulations

Miscellaneous

INTRODUCTION

Through this action, the Commonwealth of Massachusetts seeks to protect itself and Massachusetts women from the harms that will result from the Defendants' attempt to nullify the provisions of the Patient Protection and Affordable Care Act ("ACA") that guarantee women equal access to preventive medical care—specifically contraceptive care and services. On October 13, 2017, the Defendants, the Secretaries of the U.S. Departments of Health and Human Services ("HHS"), Labor, and the Treasury, as well as their respective Departments (hereinafter "Departments"), issued two Interim Final Rules ("IFRs") authorizing employers with religious or moral objections to contraception to block their employees, and their employees' dependents, from receiving health insurance coverage for contraceptive care and services. *See* 82 Fed. Reg. 47792; 82 Fed. Reg. 47838 (Joint Appendix ("JA") 836-905).

The Commonwealth sued to enjoin the IFRs, explaining that the Departments' action will injure the Commonwealth's fisc and its quasi-sovereign interests in the health and wellbeing of its residents. The Commonwealth provided extensive evidence that Massachusetts women will lose contraceptive coverage because of the IFRs, and that the Commonwealth will be responsible for providing replacement contraceptive or prenatal care for some of those women through state-funded programs. In addition, the Commonwealth explained, the IFRs have already inflicted

procedural injury on Massachusetts, which was deprived of its right under the Administrative Procedure Act ("APA") to be notified of and to provide comment on the rules before they went into effect. Through this appeal, the Commonwealth seeks reversal of the District Court's ruling that the Commonwealth failed to demonstrate injury-in-fact sufficient to satisfy Article III of the Constitution, and requests that this Court remand this case to the District Court for consideration of the merits of the Commonwealth's claims.

JURISDICTIONAL STATEMENT

The District Court had jurisdiction over this case under 28 U.S.C. § 1331, because the claims asserted by the Commonwealth arise under the Constitution and the laws of the United States. On April 4, 2018, the District Court issued a final judgment that disposed of the Commonwealth's claims. This Court has jurisdiction under 28 U.S.C. § 1291 because, through this appeal, the Commonwealth seeks review of the final decision of the District Court. The Commonwealth's appeal, noticed on May 29, 2018, is timely pursuant to Fed. R. App. P. 4(a)(1)(B)(ii)-(iii).

STATEMENT OF THE ISSUES

Whether the Commonwealth has demonstrated an injury-in-fact sufficient for Article III standing to challenge the IFRs, where the IFRs threaten the Commonwealth with an imminent fiscal injury; the Departments' failure to conduct notice-and-comment rulemaking before issuing the IFRs inflicted a procedural

injury on the Commonwealth; and the IFRs will harm the Commonwealth's quasi-sovereign interests in promoting the health and wellbeing of its residents.

STATEMENT OF THE CASE

The Affordable Care Act and Implementation of the Contraceptive Mandate.

1. Preventive Services Requirement and the Women's Health Amendment.

Congress enacted the ACA, 124 Stat. 119, to ensure that all Americans have access to affordable, quality health care. Among other reforms, the ACA requires employer-sponsored health plans to provide coverage for a broad range of preventive medical services on a no-cost basis—meaning that plan participants cannot be charged cost-sharing payments like copays or deductibles. *See* 42 U.S.C. § 300gg-13.[1] This requirement recognizes that most Americans receive health care coverage through their employers, JA 112, and that preventive care is a fundamental part of "basic health care" that leads to healthier populations and lower health care costs. *See* 78 Fed. Reg. 39870, 39872 (July 2, 2013). Through a provision called the Women's Health Amendment, the preventive services requirement mandates no-cost coverage for, "with respect to women, such additional preventive care and screenings … as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." 42 U.S.C. § 300gg-13(a)(4).

[1] Employers providing "grandfathered health plans"—that is, health plans that existed prior to March 23, 2010 and that have not made certain changes after that date—are not subject to this requirement. *See* 42 U.S.C. §§ 18011(a), (e).

The Women's Health Amendment did not mandate coverage for specific preventive care services. *Id.* Instead, Congress delegated authority to the Health Resources and Services Administration ("HRSA"), an agency within HHS, to determine which services must be covered. *Id.* HRSA, in turn, enlisted the Institute of Medicine ("IOM") to convene a committee of experts to assess what preventive care services were necessary to protect women's health and wellbeing. *See* IOM, Clinical Preventive Services for Women: Closing the Gaps (2011) (JA 126-372).

Access to contraception, the IOM found, reduces unintended pregnancies, adverse pregnancy outcomes, and other negative health consequences for women and children, as well as the number of women seeking abortions. JA 243. Women experiencing unintended pregnancies are more likely than women with planned pregnancies to receive late or no prenatal care, to smoke or consume alcohol during pregnancy, and to be depressed during pregnancy. JA 241. Children born as the result of unintended pregnancy have significantly increased odds of preterm birth and low birth weight compared with children born of planned pregnancies, and are less likely to be breastfed. *Id.* The IOM recognized that there are many methods of Food and Drug Administration ("FDA")-approved contraception, and that access to contraception—particularly more effective, long-lasting methods like intrauterine devices—can be significantly improved when cost-sharing requirements are eliminated. JA 242-47. In light of its review of medical research, the IOM

recommended that the HRSA Guidelines on preventive care for women include all FDA-approved contraceptive methods. JA 247-48.

In accordance with the IOM's recommendation, HRSA's Women's Preventive Services Guidelines required employers to provide "coverage, without cost sharing," for "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity" (hereinafter "the contraceptive mandate"). JA 1344. These Guidelines, including the contraceptive mandate, went into effect in August 2012. As a result of the ACA and the Guidelines, more than 45 million women now receive comprehensive, no-cost coverage for contraceptive care and services through an employer-sponsored plan. *See* 82 Fed. Reg. 47792, 47821 (Oct. 13, 2017). Out-of-pocket expenditures for contraception have fallen by more than 70%. *Id*. at 47805. And in Massachusetts, the ACA has led to a significant decrease in the number of women without contraceptive coverage seeking care through state-funded programs, and to a significant increase in the number of women using more effective forms of contraception. *See* JA 49 (¶ 13); 51 (¶¶ 24-25).

2. The Exemption for Churches and the Accommodation for Nonprofit and Closely-Held For-Profit Employers with Religious Objections to Contraception.

When Congress enacted the preventive services requirement in the ACA, it did not include a conscience amendment that would have permitted employer-

sponsored health plans to deny coverage based upon religious beliefs or moral convictions. *See* 42 U.S.C. § 300gg-13; 158 Cong. Rec. S1115-S1116 (Feb. 29, 2012) (Sen. Blunt). Recognizing that some Americans have religious objections to contraception, the Departments took a series of regulatory actions that sought to strike a balance between employees' statutory right to coverage for contraception, on the one hand, and employers' religious objections to contraception, on the other, to the extent required by the Religious Freedom Restoration Act ("RFRA"). *See* 75 Fed. Reg. 41726 (July 19, 2010); 76 Fed. Reg. 46621 (Aug. 3, 2011); 77 Fed. Reg. 8725 (Feb. 15, 2012); 78 Fed. Reg. 39870 (July 2, 2013); 79 Fed. Reg. 51092 (Aug. 27, 2014); 80 Fed. Reg. 41318 (July 14, 2015).

First, the Departments issued regulations that exempted churches and their integrated auxiliaries from the contraceptive mandate, as required by RFRA. *See* 76 Fed. Reg. 46623; 77 Fed. Reg. 8729; 80 Fed. Reg. 41325. Second, recognizing that certain non-exempt nonprofit organizations also had religious objections to covering contraception, the Departments pledged to develop an alternative process to provide contraceptive coverage to employees of those employers. *See* 77 Fed. Reg. 8728. In 2013, the Departments issued regulations creating that process, called the "Accommodation." *See* 78 Fed. Reg. 39870. Under the Accommodation, a nonprofit organization or institution of higher education that objects to providing contraceptive coverage on religious grounds can self-certify that it qualifies as an "eligible

organization" by submitting a two-page form to its health insurance issuer or third-party administrator. 78 Fed. Reg. 39874-77.[2] Upon receiving the form, the insurer or third-party administrator becomes responsible for removing contraceptive coverage from the employer's plan and making all payments for contraception used by plan participants. *Id.* Through this process, objecting employers and universities are relieved of the requirement to provide contraceptive coverage, while employees and students continue to receive seamless coverage for contraceptive care, as required by the ACA. In response to *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), the Departments later expanded the Accommodation to cover closely-held, for-profit corporations with religious objections to contraception. *See* 80 Fed. Reg. 41318.

Some religious nonprofit organizations, however, were dissatisfied with the Accommodation and demanded that the Departments provide them with an exemption, like the exemption for churches, that would not permit their employees to retain separate coverage for contraception. These employers contended that the Accommodation made them complicit in the provision of contraception to their employees, in violation of their rights under RFRA. Eight out of nine Courts of

[2] In response to the Supreme Court's order in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014), the Departments issued a separate set of regulations that permitted employers claiming the Accommodation to notify HHS, rather than the health insurance issuer or third-party administrator, of their status as an eligible organization. *See* 79 Fed. Reg. 51092.

Appeals rejected the claim, concluding that the Accommodation is consistent with RFRA. *See Eternal Word Television Network, Inc. v. Sec'y of HHS*, 818 F.3d 1122, 1141-42, 1148 (11th Cir. 2016) (collecting cases). The Supreme Court consolidated several of these cases for review in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016). In a *per curiam* decision, the Court remanded the cases for further consideration, with instructions to the parties to continue working toward a mutually acceptable approach that "accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." *Id.* at 1560 (quotation marks omitted). The Court "expresse[d] no view on the merits" of the RFRA claim. *Id.*

In July 2016, the Departments sought public comment on whether the regulations could be modified to "resolve the objections asserted by the plaintiffs in [*Zubik*], while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage." JA 430. After review of the comments, the Departments announced that they were unable to identify a feasible, less burdensome alternative that would satisfy employers' religious objections while still ensuring that "women receive full and equal health coverage, including contraceptive coverage." *Id.*

3. The Interim Final Rules.

On October 13, 2017, the Departments issued two interim final rules—hereinafter the "Religious IFR" and the "Moral IFR"—that abandoned their prior effort to balance the religious liberty of employers with the right of women to seamless, no-cost contraception coverage. *See* 82 Fed. Reg. 47792; 82 Fed. Reg. 47838. The Defendants issued the IFRs, which became effective immediately, without first undertaking the APA's notice-and-comment rulemaking process. *See* 82 Fed. Reg. 47813-15; 82 Fed. Reg. 47854-56.

The IFRs create new "expanded exemptions" from the contraceptive mandate. 82 Fed. Reg. 47794; 82 Fed. Reg. 47840. In addition to the houses of worship already exempted, the Religious IFR exempts any objecting nonprofit organization, closely-held for-profit entity, for-profit entity that is not closely held, other non-governmental employer, institution of higher education, and health insurance issuer offering group or individual insurance coverage. 82 Fed. Reg. 47809-12. The Moral IFR exempts any objecting nonprofit organization, for-profit entity that has no publicly traded ownership interest, institution of higher education, and health insurance issuer offering group or individual insurance coverage. 82 Fed. Reg. 47850-53. These entities are no longer required to include contraceptive coverage in their health plans "to the extent that" they object "based on [their] sincerely held religious beliefs" or their "sincerely held moral convictions." 82 Fed. Reg. 47812;

82 Fed. Reg. 47853. The term "moral convictions" is not defined. Under the IFRs, an objecting entity has two choices: (1) it can use an expanded exemption, which leaves its employees or students without contraceptive coverage, or (2) it can participate in the Accommodation, which still ensures that employees and students retain independent coverage for contraception. 82 Fed. Reg. 47812-13; 82 Fed. Reg. 47854.

The IFRs include a regulatory impact analysis, which provides the Departments' official, legally-required explanation of the IFRs' anticipated effects. *See* 82 Fed. Reg. 47815-24; 82 Fed. Reg. 47856-58. The Departments expect that hundreds of thousands of employees and their dependents nationwide will lose their employer-based contraceptive coverage as a result of the IFRs. *See* 82 Fed. Reg. 47820-22; 82 Fed. Reg. 47856-57. They conservatively estimate that this population includes between 31,715 and 120,000 women of childbearing age who will use a method of contraception covered by the ACA within a month of losing their employer-based coverage. *See* 82 Fed. Reg. 47819-23; 82 Fed. Reg. 47858.[3] They

[3] The number of women affected will certainly be higher over time. These figures are based on the Departments' calculation that "approximately 44.3% of women of childbearing age use women's contraceptive methods covered by the [ACA]." 82 Fed. Reg. 41819. The source cited for this claim is a Fact Sheet published by the Guttmacher Institute, titled "Contraceptive Use in the United States," available at https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states. *See* 82 Fed. Reg. 41819 n. 75. That Fact Sheet, however, indicates only that 44.3% of women of childbearing age have used a contraceptive method

(footnote continued)

also estimate that the out-of-pocket cost of providing replacement contraceptive care for those who lose coverage will be $584 per woman per year, or between $18.5 and $63.8 million annually nationwide. *See* 82 Fed. Reg. 47821, 47823-24; 82 Fed. Reg. 47858. Many of these women who lose coverage, the Departments explain, will be forced to seek contraceptive care from sources other than their usual health care providers. *See* 82 Fed. Reg. 47803. Others will forgo contraception, leading to an increase in unintended pregnancies and negative health consequences for women and children. *See* 82 Fed. Reg. 47828 n. 113; *supra*, at 4.

Massachusetts' Commitment to Ensuring Access to Contraception.

Massachusetts has long recognized the critical role that access to contraceptive care plays in the health and wellbeing of women, children, and families. The Commonwealth supports access to contraceptive care through an interrelated system composed of: (a) contraceptive coverage laws that require health plans to cover no-cost contraception and family planning services; (b) direct coverage of family planning services for individuals eligible for the Commonwealth's Medicaid program, MassHealth; and (c) a network of family

---

covered by the ACA "in the past month." *Id.* Of course, over any period of time longer than a month, a higher, cumulative percentage of women will use these methods of contraception. *See id*. (while only approximately 15% of women have used birth control pills "in the past month," approximately 80% have used them ever).

planning program providers that receive reimbursement from the Department of Public Health's ("DPH") Sexual and Reproductive Health Program ("SRHP").

Contraceptive Equity Law and ACCESS Act. In 2002, the Legislature expanded coverage for contraceptive services, drugs, and devices in "An Act Providing Equitable Coverage of Services Under Health Plans" (hereinafter "Contraceptive Equity Law"). *See* Mass. St. 2002, c. 49, §§ 1-4. The Contraceptive Equity Law required employer-sponsored health plans that cover outpatient services, prescriptions, or devices to provide the same level of coverage for all FDA-approved contraceptive services, prescriptions, and devices. *See* G.L. c. 175, § 47W; G.L. c. 176A, § 8W; G.L. c. 176B, § 4W; G.L. c. 176G, § 4O. Unlike the ACA, however, the law did not mandate no-cost contraceptive coverage. Women covered by the law were still responsible for cost-sharing payments, like deductibles and copays. To remedy that gap, the Legislature passed an "Act Relative to Advancing Contraceptive Coverage and Economic Security in our State," or the "ACCESS Act," in November 2017. The ACCESS Act prohibits employer-sponsored health plans from imposing cost-sharing fees, like deductibles and copays, in connection with the provision of contraception. *See* Mass. St. 2017, c. 120, §§ 3(e)(1), 4(e)(1), 5(e)(1), 6(e)(1).

The Contraceptive Equity Law and ACCESS Act do not apply to self-insured employer plans, which are governed solely by the federal Employee Retirement

Income Security Act ("ERISA"). *See* 29 U.S.C. §§ 1144(a), (b)(2)(A); *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 740-47 (1985). Approximately 56% of Massachusetts residents who have private commercial health insurance receive coverage through a self-insured plan. JA 454. Women covered by these plans who lose contraceptive coverage because of the IFRs will not be protected by Massachusetts' contraceptive coverage laws.

MassHealth Program. MassHealth provides access to integrated health care services for almost two million Massachusetts residents. *See* JA 39 (¶ 4). As part of its mission, and in accordance with federal law, MassHealth guarantees its members access to all FDA-approved contraceptives. *See id.*; 130 Code Mass. Regs. ("C.M.R.") 450.105; 42 U.S.C. § 1396d(a)(4)(C). Eligibility for MassHealth is determined by a combination of income, household composition, age, and medical status. *See* 130 C.M.R. 505.000 *et seq*. In general, residents with incomes of up to 133% of the federal poverty level qualify for MassHealth, but some residents with incomes of up to 300% of the federal poverty level qualify as well. JA 440.

When a Massachusetts resident with employer-sponsored insurance or student health insurance also satisfies MassHealth's eligibility criteria, "MassHealth will 'wrap around' that coverage as a secondary payer to cover a MassHealth level of services and cost sharing not covered by the primary insurance." JA 441; *see also* 130 C.M.R. 450.316-321, 503.007 (MassHealth third-party liability regulations); JA

39 (¶ 4). Currently, MassHealth provides coverage for approximately 150,000 residents who have commercial coverage, including employer-sponsored insurance and student health insurance. *See* JA 39 (¶ 4). Should these residents, or any other residents who meet eligibility requirements, lose contraceptive coverage from their employer-sponsored plans or student health plans because of the IFRs, they will be entitled to receive replacement coverage through MassHealth. *Id.* Under Medicaid rules, Massachusetts is responsible for paying 10% of all family planning services covered by MassHealth. *See* 42 U.S.C. § 1396b(a)(5).

DPH-Funded Clinics. Women may also access contraceptive care through DPH-funded family planning programs. The SRHP funds, among other things, contraceptive care and related services provided by a statewide network of family planning program providers. *See* 101 C.M.R. 312.000; JA 42 (¶ 5); 49 (¶ 11). Funded services include diagnosis and treatment of sexually transmitted diseases, emergency contraception, counseling, and birth control, including all FDA-approved contraceptives. JA 42 (¶ 5). These services are available to a broad range of Massachusetts residents, including (a) Massachusetts residents who make less than 300% of the federal poverty level and are either uninsured or have a health plan that does not cover all contraception methods and services, and (b) Massachusetts residents of any insurance status who need confidential care. JA 42 (¶ 6).

Procedural History.

To seek redress from the fiscal, procedural, and quasi-sovereign injuries inflicted by the IFRs, the Commonwealth filed suit to enjoin the IFRs in October 2017. JA 14-37. The Commonwealth asserted that the IFRs violated the APA's notice-and-comment requirement; are inconsistent with the ACA's requirement that employer-sponsored health plans provide women with coverage for preventive care services, including contraception; amount to an endorsement of religion, in violation of the Establishment Clause of the First Amendment; and discriminate against women, in violation of the Equal Protection guarantee implicit in the Fifth Amendment. JA 31-35. The Departments filed an administrative record as their answer. JA 512-35, 699-727.

The parties filed cross-motions for summary judgment. JA 7-8. Attached to the Commonwealth's motion were eight declarations from state officials, medical professionals, and investigators that, together with the administrative record, provided extensive evidence on how the Commonwealth would be harmed by the IFRs. JA 36-511, 536-698. Declarations from two physicians explained that women in Massachusetts are likely to lose contraceptive coverage because of the IFRs and seek replacement contraceptive care at SRHP-funded clinics or through MassHealth—care for which the Commonwealth itself would bear costs. JA 50-51 (¶¶ 18-23); 697-98 (¶¶ 27-30). That evidence was further supported by the IFRs'

calculations of the number of women likely to lose contraceptive coverage and by evidence in the administrative record identifying specific Massachusetts employers with self-insured plans that the Departments expect will use the IFRs' expanded exemptions. *See infra*, at 26-32. In addition, the declarations described several of the Commonwealth's state-funded programs that provide contraceptive care and that are available to women in the Commonwealth who lose coverage from their employers. *See* JA 39 (¶ 4); 41-42 (¶¶ 4-7); 45 (¶¶ 5-9); 48-49 (¶¶ 7, 14). Another declaration explained that approximately 25% of women of childbearing age who have employer-sponsored health insurance in Massachusetts have incomes at or below 300% of the federal poverty level, and therefore would qualify for state-funded contraceptive care if they lose coverage because of the IFRs. JA 54-57 (¶¶ 2-8). Elaborating on the Commonwealth's quasi-sovereign interests at issue here, the declarations also explained how access to contraception is essential for women's health and enables women to participate fully and equally in society. *See* JA 50-52 (¶¶ 20-26); 695-96 (¶¶ 12-19).

Before the District Court ruled on the parties' motions, two other district courts granted preliminary injunctions forbidding the Departments to enforce the IFRs anywhere in the United States. *See California v. Health & Human Servs.*, 281 F. Supp. 3d 806 (N.D. Cal. 2017), *appeal pending*, Nos. 18-15144, 18-15166, 18-15255 (9th Cir.); *Pennsylvania v. Trump*, 281 F. Supp. 3d 553 (E.D. Pa. 2017),

appeal pending, Nos. 17-3752, 18-1253 (3d Cir.). Both district courts held that other plaintiff States had standing under Article III to advance their claims. *See California*, 281 F. Supp. 3d at 820-22; *Pennsylvania*, 281 F. Supp. 3d at 564-69. Both district courts also concluded that the plaintiff States were likely to succeed on the merits of their claim that the IFRs were issued in violation of the APA's notice-and-comment rulemaking requirement, and the Pennsylvania court separately held that the IFRs are inconsistent with the ACA's contraceptive mandate. *See California*, 281 F. Supp. 3d at 824-29; *Pennsylvania*, 281 F. Supp. 3d at 570-81.

After holding a hearing on the parties' motions, the District Court in this case granted judgment to the Departments, holding that the Commonwealth did not have standing under Article III to advance its claims. JA 1382-1422. The court concluded that that Commonwealth did not make "the requisite demonstration of specific facts" necessary to show that it would suffer fiscal injury because of the IFRs. JA 1403. It ruled that the Commonwealth failed to "identify any employers that are likely to avail themselves of the expanded exemptions" in the IFRs, and that the Commonwealth therefore did not show that any Massachusetts women would lose coverage and seek replacement state-funded contraceptive care because of the IFRs. JA 1403-18. The court further concluded that, because the Commonwealth did not identify employers likely to use the expanded exemptions, it could not establish that

its procedural or quasi-sovereign interests had been injured. JA 1418-22. The Commonwealth filed a timely notice of appeal. JA 1424-25.

STANDARD OF REVIEW

Whether the Commonwealth established Article III standing is a question of law subject to *de novo* review. *See Maine People's Alliance v. Mallinckrodt, Inc.*, 471 F.3d 277, 283 (1st Cir. 2006). In demonstrating standing on summary judgment, the plaintiff "must 'set forth' by affidavit or other evidence 'specific facts,' … which for purposes of the summary judgment motion will be taken to be true." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992) (quoting Fed. R. Civ. P. 56(e)).

SUMMARY OF THE ARGUMENT

The Commonwealth has standing under Article III to challenge the IFRs because they will inflict an imminent financial injury on Massachusetts. Uncontested record evidence demonstrates a substantial risk that Massachusetts women will lose their employer-based insurance coverage for contraceptive care because of the IFRs. Specifically, the Departments calculated that between 31,715 and 120,000 women of childbearing age currently using contraception will lose contraceptive coverage because of the IFRs. Even after reducing those figures to account for Massachusetts' percentage of the national population and to exclude women protected by Massachusetts' contraceptive coverage laws, the Commonwealth faces a substantial risk that hundreds of Massachusetts women will lose coverage. Multiple Massachusetts employers with self-insured health plans have already expressed

opposition to the contraceptive mandate either through litigation or by using the Accommodation, and the Departments counted at least two of those employers among the employers expected to use the IFRs' expanded exemptions. In addition, uncontested record evidence demonstrates a substantial risk that a significant percentage of the Massachusetts women who will lose contraceptive coverage because of the IFRs will obtain replacement contraceptive care from programs funded by the Commonwealth. Other Massachusetts women will be unable to access effective replacement care, leading to an increase in unintended pregnancies that will impose additional costs on the Commonwealth. This record, supported by concrete evidence and specific facts, establishes that the fiscal injury to the Commonwealth is imminent. *See infra*, at 20-44.

The Commonwealth also has independent standing to challenge the IFRs because it suffered a procedural injury when the Departments failed to provide notice of and accept written comments on the IFRs before they went into effect, as required by the APA. A litigant has standing to challenge an agency's failure to follow mandated procedures if the resulting regulatory action could impair its concrete interests. The Commonwealth easily met this standard. It set forth far more than a reasonable claim that the IFRs will cause it economic harm and threaten its quasi-sovereign interests. *See infra*, at 44-50.

Finally, the threat the IFRs pose to the Commonwealth's quasi-sovereign interests in the health and wellbeing of its residents provides a third basis for standing under Article III. Access to affordable contraception is of critical importance to Massachusetts women, children, and families. For this reason, the Commonwealth has enacted contraceptive coverage laws that, like the ACA, guarantee no-cost, seamless access to contraceptive care. Because of preemption by ERISA, however, Massachusetts' laws cannot protect the majority of Massachusetts' residents. The Commonwealth's inability to use its sovereign lawmaking powers to fully protect the health and wellbeing of its residents underscores the injury to its quasi-sovereign interests and entitles the Commonwealth to special solicitude in the standing analysis. Moreover, because the Commonwealth brings this suit against federal agencies that have violated rights guaranteed its residents by Congress, it may assert *parens patriae* standing based upon its quasi-sovereign injury. *See infra*, at 50-54.

ARGUMENT

I. Massachusetts Has Standing to Challenge the IFRs Because They Threaten to Inflict a Fiscal Injury on the Commonwealth.

Massachusetts has standing under Article III to advance its claims because the IFRs, if implemented, will inflict financial harm on the Commonwealth, which will bear the costs of replacement contraceptive or prenatal care for some of the Massachusetts women who will lose contraceptive coverage.

To establish Article III standing, a plaintiff must show an injury that is "concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 149 (2010); *see also Lujan*, 504 U.S. at 560-61. There can be no question, and the District Court did not express any doubt, that the fiscal injury identified by the Commonwealth is concrete and particularized, that the injury will be fairly traceable to the IFRs, and that a ruling in favor of the Commonwealth would redress that injury. JA 1397-1422.[4] There likewise *should* be no question that the fiscal injury is also "actual or imminent." The record in this case—including declarations submitted by the Commonwealth and documents in the administrative record—demonstrates that the injury is imminent because there is a substantial risk that the Commonwealth will be financially responsible for replacement medical care for some of the women who will lose contraceptive coverage because of the IFRs.

A. To Demonstrate Standing, the Commonwealth Was Required to Demonstrate a "Substantial Risk" that the IFRs Would Inflict Fiscal Harm.

The "imminence concept, while … far reaching, is bounded by its Article III purpose: 'to ensure that the alleged injury is not too speculative.'" *Berner v.*

[4] The Departments raised no argument that the Commonwealth failed to satisfy the "zone-of-interests" test to assert claims under the APA. The argument is therefore waived. *See Lexmark Int'l Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128-31 & n. 3-4 (2014) (zone-of-interests test is not a standing requirement and does not implicate the jurisdiction of the courts).

Delahanty, 129 F.3d 20, 24 (1st Cir. 1997) (quoting *Lujan*, 504 U.S. at 564 n. 2). In line with that purpose, "[a]n allegation of future injury" under the imminence test "suffice[s] if the threatened injury is 'certainly impending' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014) ("*SBA List*") (quoting *Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 409, 414 n. 5 (2013)). This Court follows the "disjunctive framing of the test" made plain in *SBA List* and *Clapper*: "injury is imminent if it is certainly impending *or* if there is a substantial risk that harm will occur." *Reddy v. Foster*, 845 F.3d 493, 500 (1st Cir. 2017) (emphasis in original); *accord Attias v. Carefirst, Inc.*, 865 F.3d 620, 626-27 (D.C. Cir. 2017).

Decisions from this Court have long applied formulations of the substantial risk test, across diverse contexts, when determining whether allegations of future injury satisfy Article III. In environmental cases, for example, this Court has held that "[t]o establish an injury in fact based on a probabilistic harm, a plaintiff must show that there is a substantial probability that harm will occur." *Maine People's Alliance*, 471 F.3d at 283-85 (recognizing standing when plaintiffs demonstrated that the defendant's discharge of mercury into a river "may well present an imminent and substantial danger to the environment"). And in cases seeking pre-enforcement review of statutes, regulations, and policies based on substantial risk of injury, a plaintiff must only show "a credible threat of enforcement." *SBA List*, 134 S. Ct. at

2342-43. In *Berner v. Delahanty*, for example, this Court held that a lawyer had standing to challenge a judge's policy prohibiting the wearing of political buttons in his courtroom, even though the lawyer had no cases pending before the judge, because the facts established a "realistic risk of future exposure to the challenged policy." 129 F.3d at 24-25. "The law of averages," this Court ruled, "strongly suggests that vocational demands will bring [the plaintiff] before each and all of [the state court judges] in the months and years to come," and that the plaintiff would therefore be confronted with the judge's button ban in the future. *Id.*; *see also Dudley v. Hannaford Bros. Co.*, 333 F.3d 299, 306 (1st Cir. 2003) (plaintiff showed a "real and immediate threat" of future harm because "the offending policy remain[ed] firmly in place").

This Court also has applied the substantial risk test when plaintiffs allege a "sequence of economic events" that would likely result in monetary harm. *Adams v. Watson*, 10 F.3d 915, 922 (1st Cir. 1993). In *Adams*, out-of-state milk producers challenged a Massachusetts milk pricing order. *Id.* at 916-17. Their complaint alleged a series of economic events, based on "elemental laws of cause and effect predicated on actual market experience and probable market behavior," that would likely result in "reduced out-of-state milk sales to Massachusetts dealers at lower prices." *Id.* at 923-24. Finding that the complaint alleged a "sufficient likelihood of harm" and a "realistic danger of sustaining a direct injury," this Court held that the

plaintiffs had standing. *Id.* at 922-23.

Similarly, the Supreme Court found standing in *Monsanto Co. v. Geertson Seed Farms*, a case that also involved a chain of events that gave rise to a "substantial risk" that the plaintiffs, conventional alfalfa farmers, would be harmed by a federal agency's decision to deregulate a variety of genetically engineered alfalfa. 561 U.S. at 153-55. The injury—the "'significant risk of gene flow to non-genetically engineered varieties of alfalfa'"—was premised on evidence that "genetically engineered alfalfa 'seed fields [we]re currently being planted in all the major alfalfa seed production areas'; the bees that pollinate alfalfa 'have a range of at least two to ten miles'; and the alfalfa seed farms were concentrated in an area well within the bees' pollination range." *Clapper*, 568 U.S. at 420 (quoting *Monsanto*, 561 U.S. at 153-55 & n. 3). This chain of events, involving the likelihood that bees would infect conventional alfalfa plants with the deregulated, genetically engineered gene, satisfied the imminence requirement of Article III. *Monsanto*, 561 U.S. at 155; *accord Clapper*, 568 U.S.at 420.

When applying the substantial risk test to a fiscal injury, this Court has emphasized that plaintiffs need not show a substantial risk of a large economic loss. Rather, "[i]t is a bedrock proposition that 'a relatively small economic loss—even an 'identifiable trifle'—is enough to confer standing.'" *Katz v. Pershing, LLC*, 672 F.3d 64, 76 (1st Cir. 2012) (quoting *Adams*, 10 F.3d at 924); *see also Gianfrecesco*

v. Town of Wrentham, 712 F.3d 634, 638 (1st Cir. 2013) ("economic harm is a 'paradigmatic' injury-in-fact for standing purposes" (citing *Danvers Motor Co. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005))). Any economic loss "affords a constitutionally cognizable stake sufficient to ensure [the] vigorous prosecution of the litigation." *Adams*, 10 F.3d at 924. For that reason, the Supreme Court has "allowed important interests to be vindicated by plaintiffs with no more at stake in the outcome of an action than … a $5 fine and costs … [or] a $1.50 poll tax." *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 689 n. 14 (1973). In addition, a plaintiff "'does not have to await the consummation of the threatened injury to obtain preventive relief.'" *Blum v. Yaretsky*, 457 U.S. 991, 1000 (1982) (quoting *Pennsylvania v. West Virginia*, 262 U.S. 553, 593 (1923)). "[I]t could hardly be thought that [governmental] action likely to cause harm cannot be challenged until it is too late." *Adams*, 10 F.3d at 924 (quotation marks omitted).

Applied to this case, this precedent on standing required the Commonwealth to establish a substantial risk that the IFRs will cause it to expend some money providing replacement care to women who lose contraceptive coverage because of the IFRs. The Commonwealth was not required to demonstrate that it would incur large economic costs; instead, a substantial risk that the Commonwealth would bear *any* additional costs is sufficient to confer standing. Nor was the Commonwealth obliged to wait until after women lose coverage and are forced to obtain state-funded

replacement contraceptive care. Rather, it was entitled to challenge the IFRs as soon as it became clear that Massachusetts faces a substantial risk of such economic harm.

B. The Commonwealth Established a "Substantial Risk" That the IFRs Will Cause Women in Massachusetts to Lose Contraceptive Coverage and, Consequently, Seek State-Funded Contraceptive Care.

Analyzed under the correct legal standard, the record before the District Court was more than sufficient to show a "substantial risk" that women in Massachusetts will lose contraceptive coverage because of the IFRs, and that the Commonwealth will bear the cost of replacement contraceptive or prenatal care for some of those women. *Reddy*, 845 F.3d at 500.

1. The Commonwealth Established a Substantial Risk that the IFRs Will Cause Women in Massachusetts to Lose Contraceptive Coverage.

The Departments' own analysis of the IFRs' regulatory impact, together with supporting evidence in the administrative record and the Commonwealth's uncontested declarations, establishes a substantial risk that Massachusetts women will lose coverage if the IFRs go into effect. The regulatory impact analysis calculates that between 31,715 and 120,000 women of childbearing age who are currently using an affected method of contraception will lose coverage as a result of the IFRs and be immediately harmed. *See* 82 Fed. Reg. 47815-24; 82 Fed. Reg. 47856-58; *supra*, at 10. Based upon Massachusetts' share of the national population

(2.1%)[5], between 666 and 2,520 Massachusetts women of childbearing age who are currently using contraception will likely lose their employer-based coverage because of the IFRs. Adjusting these figures to exclude women in fully-insured plans covered by Massachusetts' contraceptive coverage laws,[6] between 373 and 1,413 Massachusetts women in self-insured plans will lose coverage because of the IFRs.[7]

The details of the Departments' regulatory impact analysis confirm that Massachusetts employers, like employers in other States, are likely to use the IFRs' expanded exemptions, causing Massachusetts women to lose contraceptive coverage. To calculate the lower and upper bounds of their estimated range of women affected by the IFRs, the Departments used two different methods, either of which demonstrates a substantial risk of harm to Massachusetts. The Departments base the upper bound estimate—120,000 women—on nationwide survey data concerning the number of employers that excluded contraceptive coverage from

---

[5] *See* U.S. Census Bureau, *Quick Facts: Massachusetts*, https://www.census.gov/quickfacts/MA; U.S. Census Bureau, *U.S. and World Population Clock*, https://www.census.gov/popclock/.

[6] The Departments' data, like Massachusetts' data, indicates that approximately 56% of persons with employer-sponsored health care are in a self-insured plan, while 44% are in a fully-insured plan. *See* 82 Fed. Reg. 47820 (56.1%); JA 454 (56%).

[7] The Departments' analysis indicates that fully-insured and self-insured employers are equally likely to have objections to providing contraceptive care and will claim exemptions at similar rates. *See* 82 Fed. Reg. 47820-21 (assuming that the distribution of self-insured and fully-insured plans among employees covered by the Accommodation conforms to the national average).

their insurance plans in 2010, before the ACA went into effect. *See* 82 Fed. Reg. 47821-24. The Departments use this data to produce a statistical estimate of the number of employers that will use the expanded moral and religious exemptions. There is nothing in the survey data, or the Departments' use of it, to suggest that Massachusetts will be peculiarly unaffected by the IFRs. Like Massachusetts, 28 other States had already enacted contraceptive equity laws at the time the survey was taken, and thus non-ERISA plans in those States *could not* exempt contraception coverage even if they wished to do so. JA 189.

The Departments base the lower bound estimate—31,715 women—primarily on the number of (non-exempt) employers that have asserted religious objections to providing contraceptive coverage under the ACA, either through litigation ("litigating employers") or by using the existing Accommodation ("accommodated employers"). *See* 82 Fed. Reg. 47815-21.[8] After analyzing the available information

[8] Of the 31,715 women included in the lower bound estimate, only 15 are attributable to the new moral exemption. *See* 82 Fed. Reg. 47856-58. For the purposes of the lower bound estimate, the Departments further assume that employers that have not previously objected to the contraceptive mandate generally will not make use of the expanded exemptions. *See, e.g.*, 82 Fed. Reg. 47818. The upper bound, in contrast, accounts for the strong likelihood that employers other than litigating and accommodated employers will make use of the expanded exemptions. *See* 82 Fed. Reg. 47821-24, 47856-58 (acknowledging "uncertainty" in the lower bound estimate for Moral IFR as basis for including the upper bound).

(footnote continued)

about these employers, the Departments conclude that most litigating employers,[9] and slightly more than half of accommodated employers (109 of 209)[10], will make use of the expanded exemptions created by the IFRs. *See* 82 Fed. Reg. 47815-21.

The Departments calculate that approximately 8,700 women of childbearing age who are currently using affected methods of contraception will lose coverage as a result of *litigating* employers' use of the expanded exemptions—including Massachusetts employers. 82 Fed. Reg. 47820. The spreadsheet the Departments used to make these calculations is included in the record. *See* JA 1348-54. In the spreadsheet, the Departments identify two Massachusetts employers, Autocam Medical Devices, LLC ("Autocam Medical") and Hobby Lobby Stores, Inc. ("Hobby Lobby"), that they expect will use the expanded exemptions, and which have self-insured plans[11] exempt from regulation under Massachusetts'

---

[9] The group of litigating employers includes churches, affiliated organizations, and other entities using church plans that are already effectively exempt from the contraceptive mandate. 82 Fed. Reg. 47819-20. The Departments do not include these entities among the employers it expects to use the expanded exemptions, but estimate that effectively all other litigating employers will do so. *Id.*

[10] The Departments' estimate of 209 accommodated employers was originally made by HHS in 2014. *See* 82 Fed. Reg. 47817-18. HHS characterized the figure as "likely … [an] underestimate." 80 Fed. Reg. 41332.

[11] Autocam Medical and Hobby Lobby disclosed that they sponsored self-insured plans during the course of litigation with the Departments. *See Autocam Corp. v. Sebelius*, 730 F.3d 618, 621 (6th Cir. 2013), *vacated and remanded*, 134 S. Ct. 2901 (2014); *Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 1124 (10th Cir. 2013).

(footnote continued)

contraceptive coverage laws.[12] Autocam Medical is a Michigan-based company with a manufacturing facility in Plymouth.[13] JA 1348, 1352. Hobby Lobby is an Oklahoma-based company with four retail stores in Massachusetts, located in Holyoke, Athol, Braintree, and Seekonk.[14] Although the record does not identify the number of Massachusetts employees and dependents covered by these companies' plans, the record does disclose that the companies employ 183 and 13,240 employees, respectively. JA 1348, 1352. The Departments further estimate that "for each employee policyholder, there is approximately one dependent." 82 Fed. Reg. 47819.

In addition to women employed by these litigating employers, the Departments conclude that 23,000 women of childbearing age who are currently

[12] The spreadsheet also identifies Little Sisters of the Poor, which operates a senior care facility in Somerville. JA 1352. Because the Little Sisters may be utilizing a self-insured church health plan that is effectively exempt from regulation under ERISA, they are not included in the Departments' estimate of the number of litigating employers likely to make use of the expanded exemptions.

[13] Autocam Medical's registration with the Secretary of the Commonwealth, kept as part of the records of a government agency whose accuracy cannot reasonably be questioned, *see* Fed. R. Evid. 201(b)(2), is available at http://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSummary.aspx?FEIN=270597574&SEARCH_TYPE=1.

[14] Hobby Lobby's registration with the Secretary of the Commonwealth is available at http://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSummary.aspx?FEIN=001017460&SEARCH_TYPE=1.

(footnote continued)

using contraception will lose coverage as a result of *accommodated* employers' use of the IFRs' expanded exemptions—and, again, including Massachusetts employers. *See* 82 Fed. Reg. 47820-21. The Departments expect that 56.1% of those who lose coverage, or 12,903 women, will be enrolled in self-insured plans that are exempt from regulation under state contraceptive coverage laws. *Id*. at 47820.[15] While the Departments do not know the identity of many employers that are using the Accommodation, *see* 82 Fed. Reg. 47815-21,[16] the administrative record does include a list of some employers that have notified the Departments of their "religious objections to providing contraceptive coverage." *See* JA 1355-80. The list identifies at least one accommodated employer located in Massachusetts that has a self-insured plan exempt from Massachusetts' contraceptive coverage laws: Cummins-Allison Corporation, an Illinois-based company with an office located in Framingham. *See* JA 1355.[17]

---

[15] The Departments can make this distinction because they have access to information concerning user-fee reductions provided to third-party administrators in order to compensate them for making contraceptive coverage available to employees enrolled in self-insured plans as part of the Accommodation. *See* 82 Fed. Reg. 47820.

[16] Employers are not required to provide notice to the Departments in order to use the Accommodation, and many have not done so. *See* 82 Fed. Reg. at 47817-18.

[17] Cummins-Allison Corporation's registration with the Secretary of the Commonwealth is available at http://corp.sec.state.ma.us/CorpWeb/CorpSearch/CorpSummary.aspx?FEIN=350145140&SEARCH_TYPE=1.

The Departments' analysis thus indicates that Massachusetts women face a substantial risk of losing contraceptive coverage as a result of the IFRs, even after accounting for Massachusetts' contraceptive coverage laws. Although those laws provide important protections for Massachusetts residents with fully-insured plans, *see supra*, at 12-13, the majority of women who lose coverage as a result of the IFRs will be covered by self-insured plans that are not subject to state regulation because of ERISA preemption. *See* 82 Fed. Reg. 47820-21. In other words, state laws may mitigate, but will not eliminate, loss of coverage in Massachusetts.

2. The Commonwealth Established a Substantial Risk that Some of the Women Who Will Lose Contraceptive Coverage in Massachusetts Will Obtain State-Funded Contraceptive Care or Prenatal Care for Unintended Pregnancies.

In addition to establishing a substantial risk that women in Massachusetts will lose contraceptive coverage because of the IFRs, the record also establishes that, in turn, the Commonwealth will incur costs as a result. Some of the women who lose their employer-sponsored contraceptive coverage will acquire "free or subsidized contraception" through a program funded by the Commonwealth. *See* 82 Fed. Reg. 47803, 47807, 47820. Others will be unable to acquire replacement contraception, leading to an increase in the number of unintended pregnancies. *See* 82 Fed. Reg. 47828 n. 113 (the "noteworthy potential impacts" of the IFRs include "increased expenditures on pregnancy-related medical services"). Either way, the

Commonwealth will bear financial responsibility for some of this replacement medical care.

First, the Commonwealth will incur significant costs in providing replacement contraceptive care to women who lose contraceptive coverage. The Commonwealth funds multiple programs that provide free or subsidized contraceptive services to residents, including clinics funded through the SRHP program, MassHealth, and the UMass healthcare system. *See* JA 39 (¶ 4); 41-42 (¶¶ 4-7); 45 (¶¶ 5-9); 48-49 (¶¶ 7, 14). Some of these programs extend eligibility to women with incomes up to 300% of the federal poverty line, *see* JA 41-42 (¶¶ 4-7), meaning that even women with household incomes of $75,000 per year and above may be eligible. *See* 83 Fed. Reg. 2642, 2643 (Jan. 18, 2018) (federal poverty line is set at $25,100 for a family of four). Uncontested record evidence demonstrates that approximately 25% of the women who lose coverage because of the IFRs will be eligible to receive contraception through a program funded by the Commonwealth. *See* JA 56-58 (¶¶ 6-8). This means that of the estimated 373 to 1,413 Massachusetts women of childbearing age using contraception who are likely to lose coverage as a result of the IFRs, *see supra*, at 27, between 93 and 354 will qualify for state-funded programs. At an annual cost of $584 per woman, *see* 82 Fed. Reg. 47821, the total cost of providing replacement contraception for this population would be between

$54,312 and $206,736.[18]

Second, the Commonwealth will incur costs providing pre- and post-natal care to some of the women who lose contraceptive coverage and consequently experience an unintended pregnancy. As the Departments have acknowledged, there is no effective substitute for the seamless, no-cost coverage guaranteed by the ACA. *See, e.g.*, 78 Fed. Reg. 39888. The medical research underpinning the contraceptive mandate shows that even "minor obstacles"—like having to find, access, or pay for alternative sources of care, distinct from a woman's regular doctor—significantly deter use of contraception, and that, in turn, reduced access to contraception leads to an increase in the rate of unintended pregnancies. JA 698 (¶ 30); *accord Priests for Life v. U.S. Dept. of Health & Human Servs.*, 772 F.3d 229, 235 (D.C. Cir. 2014), *vacated and remanded*, 136 S. Ct. 1557 (2016). While women who lose contraceptive coverage as a result of the IFRs will not lose employer-sponsored coverage for pregnancy-related care, some costs associated with unintended pregnancies will nonetheless be passed on to the Commonwealth through programs that provide wraparound coverage for copays, deductibles, co-insurance, emergency room and hospital costs, and other amounts not covered by residents' primary insurance. *See* 130 C.M.R. 450.317 (MassHealth's wrap-around insurance

[18] In certain cases, most notably with MassHealth, the Commonwealth will share the cost of services with the federal government. *See supra*, at 14. However, even a fraction of this cost would be more than sufficient to confer standing.

regulations). Indeed, the average employer-sponsored plan has an annual deductible of $1,505 for individuals and $4,527 for families. JA 1009, 1018. And most plans impose additional cost-sharing fees on members for emergency room and hospital care. *See* JA 1006, 1022-23. The Commonwealth already spends approximately $138 million annually as a result of unintended pregnancies. *See* JA 508 (tbl. 4).

These costs greatly exceed what the Commonwealth needs to show in order to establish standing. To confer standing, an economic injury need not be significant, "it need only exist." *Rental Housing Ass'n of Greater Lynn, Inc. v. Hills*, 548 F.2d 388, 390 (1st Cir. 1977). Moreover, basic rules of "cause and effect based on … probable market behavior" indicate that women who lose their employer-sponsored coverage will seek out state-funded programs. *Adams*, 10 F.3d at 923. Put simply, a decrease in employer-sponsored coverage for contraception will lead to an increase in demand for alternative sources of coverage and care. And for many women, the most readily available and affordable alternative will be a state-funded program. *See* JA 695 (¶ 10) (providers will refer patients that lose coverage to state-funded programs). In fact, the Departments repeatedly acknowledge that women who lose coverage as a result of the IFRs will receive contraception from state-funded programs, *see* 82 Fed. Reg. at 47803, 47807, 47820; and the declarations submitted by the Commonwealth concur that the IFRs will likely result "in an increase in the number of Massachusetts residents eligible for and receiving services funded [by the

Commonwealth]," JA 43 (¶ 8).

Massachusetts' "actual market experience" confirms that residents who lose employer-sponsored coverage will seek out and receive state-funded services. *Adams*, 10 F.3d 923. When Massachusetts residents need to supplement their private insurance coverage, they seek care at state-funded clinics and coverage through MassHealth. *See* JA 39 (¶ 4); 49 (¶¶ 12-14). MassHealth, for example, already provides wraparound coverage to more than 150,000 residents who have inadequate commercial insurance. *See* JA 39 (¶ 4). This number is attributable in significant part to the fact Massachusetts providers routinely screen patients for eligibility for state-funded programs and refer those that qualify to clinics or enroll them in MassHealth. *See* JA 49 (¶ 14); *See* JA 695 (¶¶ 10-11).

Taken together, this "combination of facts reflected by the record" readily establishes a substantial risk that the IFRs will impose financial costs on Massachusetts. *Berner*, 129 F.3d at 24. That is all that is required for Article III.

C. The District Court Overlooked Record Evidence and Made Errors of Law When It Concluded That the Commonwealth Did Not Establish Fiscal Injury.

In determining that the Commonwealth did not establish imminent fiscal injury, the District Court overlooked evidence in the record, failed to "tak[e] [as] true" the uncontested facts in the Commonwealth's declarations, and made several additional errors of law. *Lujan*, 504 U.S. at 561. Specifically, the court disregarded

the evidence of Massachusetts employers that, according to the Departments, will likely use the expanded exemptions in the IFRs. And even if the Commonwealth had not identified these employers, it was entitled to rely on the evidence in the IFRs themselves, along with its declarations and evidence in the administrative record, all of which was more than sufficient to show a substantial risk of injury to Massachusetts' fisc.

1. The District Court Overlooked Record Evidence When It Ruled that the Commonwealth Did Not Identify Massachusetts Employers Likely to Use the IFRs' Expanded Exemptions.

The District Court principally faulted the Commonwealth for "fail[ing] to set forth specific facts establishing that it will likely suffer future injury from the defendants' conduct." JA 1383. The court wrote that the Commonwealth was required to identify some "employers that are likely to avail themselves of the expanded exemptions" in order to show a likelihood "that *some funds* will be expended and *some women* will lose [contraceptive] coverage" because of the IFRs. JA 1413-14 (emphasis in original). Had the "Commonwealth identified a number of 'litigating entities' that employed residents of Massachusetts or identified entities currently using the accommodation that are likely to use the expanded exemption[s]," the court wrote, the Commonwealth would have made a sufficient showing of imminent future injury. JA 1414. The District Court concluded, however, that "the Commonwealth [did] not identify any employers that are likely to avail

themselves of the expanded exemptions." JA 1413-14.

Even if the Commonwealth was required to identify specific Massachusetts employers to establish a substantial risk of fiscal harm—a proposition that the Commonwealth disputes, *see infra*, at 41-44—the Commonwealth in fact met that very standard. As the court elsewhere acknowledged, the Commonwealth identified two "litigating entities"—Hobby Lobby and Little Sisters of the Poor—that employ Massachusetts residents. *See* JA 1430-31 (identifying the employers); JA 1410 (acknowledging as much); *supra*, at 29-30. In addition, the administrative record includes at least two more Massachusetts employers, Cummins-Allison and Autocam Medical, that either participated in litigation challenging the contraceptive mandate or notified the Departments that they object to the mandate. *See supra*, at 29-31. Hobby Lobby, Cummins-Allison, and Autocam Medical all sponsor self-insured health plans and therefore are not subject to Massachusetts' contraceptive coverage laws. *See supra*, at 29-31. And the Departments counted Hobby Lobby and Autocam Medical among employers that *would* use the expanded exemptions when they calculated the number of women likely to be harmed by the IFRs. *See supra*, at 29-30. In addition to this evidence, the Commonwealth provided declarations explaining that Massachusetts employers are likely to use the IFRs' exemptions. One physician's declaration stated that she "anticipate[s] that some women in Massachusetts will lose coverage for contraceptive services as a result of their

employer's exercise of one of the IFRs' exemptions." JA 697 (¶ 27). Another stated that she "anticipate[s] that additional women who lose coverage for contraceptive services because of the IFRs, either as the primary insured or the dependent, will seek care at" state-funded health centers. JA 50 (¶ 18).

The District Court erred in disregarding this evidence and in refusing to take as true the testimony in the Commonwealth's declarations. *See Lujan*, 504 U.S. at 561. It then compounded its error by further faulting the Commonwealth on the ground that Massachusetts employers likely to use the IFRs' expanded exemptions did not declare their intention to use those exemptions by moving to intervene in the Commonwealth's lawsuit. JA 1410-11. Conditioning standing on an employer's voluntary intervention in litigation to which it is not a party in order to affirm that it will use an expanded exemption is tantamount to requiring the Commonwealth to show—through extraordinary means—that the fiscal injury is "certainly impending." But as this Court explained last year, "injury is imminent if it is certainly impending *or* if there is a substantial risk that harm will occur." *Reddy*, 845 F.3d at 500 (emphasis in original).

An employer's public affirmation, or, for that matter, intervention in a lawsuit, plainly is not necessary to establish a substantial risk that the IFRs will harm the Commonwealth's fisc. In a comparable case, Texas was not required to identify the noncitizens who would apply for state-subsidized driver's licenses in order to

establish fiscal injury likely to be caused by a federal policy that enabled those noncitizens to get licenses. *See Texas v. United States*, 809 F.3d 134, 155-56 (5th Cir. 2015), *aff'd by an equally divided Court*, 136 S. Ct. 2271 (2016) (per curiam). And in *Massachusetts v. EPA*, the Commonwealth was not required to identify the parcels of state land that would be lost to sea level rise in order to establish injury likely to be caused by the federal government's refusal to regulate carbon dioxide. *See* 549 U.S. 497, 523 n. 21 (2007). Similarly, in this case, the Commonwealth was not required to identify particular employers that have already declared their intention to drop contraceptive coverage, or women who have already lost coverage, in order to establish that its fiscal injury is "actual or imminent." Rather, it was more than sufficient to identify Massachusetts employers that are likely to drop coverage because of the IFRs, employers that the Departments themselves expect to use the IFRs' expanded exemptions.[19]

[19] The District Court made yet another error by suggesting that Pennsylvania and California had standing to sue because Little Sisters chapters intervened in their lawsuits, while Massachusetts does not have standing because the local Little Sisters chapter did not intervene in this lawsuit. JA 1410-11. Little Sisters chapters nationwide all "adhere to the same religious beliefs" and are all "operated under the control of the larger congregation," even though each chapter is separately incorporated as a nonprofit. *Pennsylvania v. President of the United States of Am.*, 888 F.3d 52, 54 (3d Cir. 2018) (quotation marks omitted). If the Little Sisters chapters in Pennsylvania and California expected to use the expanded exemptions, the Massachusetts chapter would as well, because each chapter is controlled by the central Little Sisters congregation.

2. The District Court Erred When It Ruled that the IFRs' Estimates of Women Likely to Be Harmed, Together with the IFRs' Conclusion that States Will Provide Those Women Replacement Care, Were Insufficient to Confer Standing on Massachusetts.

Even if the Commonwealth had not identified specific Massachusetts employers likely to use the expanded exemptions, the IFRs themselves provide the "specific facts" necessary to establish that the Commonwealth faces a substantial risk of fiscal injury. In holding otherwise, the District Court made several errors of law rooted in its misunderstanding of the ACCESS Act and of how the Departments estimated the likely impact of their IFRs.

As discussed, the Departments estimated, based on the public record and additional facts available to them, that nationwide, between 31,715 and 120,000 women of childbearing age who are currently using contraception will lose contraceptive coverage because of the IFRs. 82 Fed. Reg. 47819-23; 82 Fed. Reg. 47858; *supra*, at 26. After reducing those numbers by the Commonwealth's proportion of the nationwide population and further reducing that number to include only persons covered by self-insured plans, Massachusetts has between 373 and 1,413 women of childbearing age actively using contraception in plans not subject to Massachusetts' contraceptive coverage laws who will lose coverage. *Supra*, at 27. The Commonwealth's evidence demonstrated that a quarter of these women will have incomes that qualify them for state-funded contraceptive services, *supra*, at 33,

and the IFRs admitted that States like Massachusetts will provide replacement care for these women. *Supra*, at 11; 82 Fed. Reg. 47803 ("The availability" of "State[] and local programs that provide free or subsidized contraceptives for low-income women" "diminishes the Government's interest in applying the Mandate to objecting employers.").

That likely "chain of … events" is not speculative; it is supported at every step by specific evidence, and it accords with "elemental laws of cause and effect" and "rational economic assumptions." *Adams*, 10 F.3d at 919, 923. As the Supreme Court recognized in *Clapper* and *Monsanto*, a substantial risk of future injury can be premised on a chain of causal events, so long as the chain is supported by "concrete evidence." *Clapper*, 568 U.S. at 420; *accord Monsanto*, 561 U.S. at 153-55 & n. 3. Relying on the Departments' own evidence and its supplemental declarations, as it was entitled to do, the Commonwealth easily met that standard here. This case is not, as the District Court suggested, akin to *Summers v. Earth Island Institute*, which rejected a theory of organizational standing based on a "statistical probability that some of [the organization's] members [we]re threatened with concrete injury." 555 U.S. 488, 497-98 (2009); *see* JA 1405 n. 2. The statistical probability referenced in *Summers* was unsupported by concrete evidence that an individual member of the organization would be injured. *See* 555 U.S. at 497-98. In contrast, the Commonwealth provided extensive concrete evidence that women in Massachusetts

will lose coverage because of the IFRs and *will* obtain state-funded contraceptive care.

In failing to recognize the Commonwealth's imminent fiscal injury, the District Court made other basic errors. First, it claimed that "the Commonwealth does not address the 'ACCESS Act,' which was enacted after the filing of this lawsuit." JA 1406. In fact, the Commonwealth addressed that law repeatedly, as the court later acknowledged. *See* JA 1407-08; JA 1433-34; Pltfs.' Memorandum in support of Summ. J., at 11-12, No. 17-cv-11930-NMG (D. Mass.), ECF No. 26. As discussed, Massachusetts has had a contraceptive mandate applicable to fully-insured plans since the Contraceptive Equity Law was enacted in 2002. *See* Mass. St. 2002, c. 49, §§ 1-4. The ACCESS Act simply required those fully insured plans to also cover copays, deductibles, and similar costs. *See supra*, at 12. The ACCESS Act did not change the number of employers required to provide contraceptive coverage under state law, as the District Court suggested, because those employers had been subject to the Contraceptive Equity Law since 2002. And neither of Massachusetts' contraceptive coverage laws applies to self-insured health plans, which cover 56% of employees and dependents with employer-sponsored insurance in Massachusetts. 82 Fed. Reg. 47820; JA 454.

The District Court further claimed that it cannot know whether this 56% "of the Massachusetts workforce" unprotected by state contraceptive coverage laws

"overlaps with the 31% of employees in the private sector employed by publicly traded companies who the Departments estimate will not be affected." JA 1407-08. This analysis reveals confusion about how the Departments reached their estimates. Both the lower and upper bound figures are already adjusted to exclude employees of publicly traded companies; the group of litigating and accommodated employers did not include any publicly traded companies, and the upper bound estimate includes only "private, non-publicly traded employers." 82 Fed. Reg. 47817, 47822-23; JA 1348-80 (spreadsheets).

Fundamentally, the District Court failed to recognize the "specific facts" marshaled by the Commonwealth to demonstrate that it faces a substantial risk of fiscal injury. *Lujan*, 504 U.S. at 561. The Commonwealth's claim of standing is not novel or speculative; indeed, the two other courts that addressed State challenges to the IFRs easily concluded, without referencing specific employers, that those States "will incur economic obligations, either to cover contraceptive services necessary to fill in the gaps left by the 2017 IFRs or for expenses associated with unintended pregnancies." *California*, 281 F. Supp. 3d at 822 (quotation marks omitted); *see also Pennsylvania*, 281 F. Supp. 3d at 567. As in those cases, Massachusetts faces imminent fiscal injury from the IFRs.

II. The Commonwealth Has Suffered a Procedural Injury That Provides an Alternative Basis for Its Standing to Challenge the IFRs.

The Departments' failure to engage in notice-and-comment rulemaking in

violation of the APA inflicted a procedural injury on the Commonwealth that provides an alternative basis for its standing to challenge the IFRs. The APA grants the Commonwealth a procedural right to participate in notice-and-comment rulemaking and to challenge regulatory action that adversely affects its interests. *See, e.g.*, *Texas*, 809 F.3d at 162-63. A litigant vested with a procedural right has standing to challenge regulatory action if (1) the action threatens a concrete interest, *see Save Our Heritage, Inc. v. FAA*, 269 F.3d 49, 55 (1st Cir. 2001); and (2), there is "some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant," *Massachusetts*, 549 U.S. at 518. The Commonwealth more than met this standard.

A. The Departments' Failure to Follow Notice-and-Comment Rulemaking Imposed a Procedural Injury on the Commonwealth.

The APA requires federal agencies to follow a three-step procedure before promulgating a rule. *See Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 752 (D.C. Cir. 2001). The agency must first publish a "[g]eneral notice of proposed rule making," then "give interested persons an opportunity to participate in the rulemaking," and finally provide "a concise and general statement of [the rule's] basis and purpose" upon announcing the final rule. 5 U.S.C. §§ 553(b), (c). Rather than comply with these procedures, the Departments issued interim final rules that became effective upon their release. *See* 82 Fed. Reg. 47813-15; 82 Fed. Reg. 47854-56. The Departments offered two justifications for their failure to provide notice and

accept comments. First, they contended that provisions of the Internal Revenue Code, ERISA, and the Public Health Service Act authorize them to promulgate the rules as interim final regulations. *See id*. Under the three cited provisions, the Secretaries "may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this part" and "may promulgate any interim final rules as the Secretary determines are appropriate to carry out this part." 29 U.S.C. § 1191c; 26 U.S.C. § 9833 (replacing "part" with "chapter"); 42 U.S.C. § 300gg-92 (replacing "part" with "subchapter"). Second, they invoked the good cause exception to the APA's rulemaking requirements. *See* 82 Fed. Reg. 47813-15; 82 Fed. Reg. 47854-56. Neither justification suffices.

The Departments' claim that they have statutory authorization to dispense with notice-and-comment rulemaking has been repeatedly considered, analyzed, and rejected by the courts. *See California*, 281 F. Supp. 3d at 825-27; *Pennsylvania*, 281 F. Supp. 3d at 571-72; *Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402, 444 (W.D. Pa. 2013); *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 17-19 (D.D.C. 2010). Under 5 U.S.C. § 559, an agency may bypass the notice-and-comment process only "when a subsequent statute 'plainly expresses a congressional intent to depart from normal APA procedures.'" *Lake Carriers' Ass'n v. EPA*, 652 F.3d 1, 6 (D.C. Cir. 2011) (quoting *Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998)). Statutes that satisfy this standard use mandatory language ("shall" rather

than "may") and expressly direct agencies to follow "procedures [and timelines] so clearly different from those required by the APA that [Congress] must have intended to displace the norm." *Asiana Airlines*, 134 F.3d at 397-98; *see also Methodist Hospital of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994). The provisions the Departments cite are general grants of rulemaking authority commonly included in statutes; they use permissive rather than mandatory language and do not supply the plain statement necessary to supersede the APA's notice and comment provisions. *See California*, 281 F. Supp. 3d at 825-27; *Pennsylvania*, 281 F. Supp. 3d at 571-72; *Geneva Coll.*, 929 F. Supp. 2d at 444; *Coalition for Parity*, 709 F. Supp. 2d at 18-19.

The Department's "good cause" argument fares no better. The APA permits agencies to dispense with notice-and-comment rulemaking only for good cause—when doing so would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). This Court has interpreted the exception narrowly and restricts its use to emergency situations. *See Levesque v. Block*, 723 F.2d 175, 184-85 (1st Cir. 1983) (providing standards); *Kollett v. Harris*, 619 F.2d 134, 145 (1st Cir. 1980) (good cause exception is "narrowly construed").

The Departments incorrectly contend that the "public interest" and "impracticable" prongs of the exception justify their failure to follow notice-and-comment procedures. *See* 82 Fed. Reg. 47814-15; 82 Fed. Reg. 47855. This Court

has made clear that "any time one can expect real interest from the public in the content of the proposed regulation, notice-and-comment rulemaking will not be contrary to the public interest" unless it would "prevent an agency from operating." *Levesque*, 723 F.2d at 184. Here, the Departments cannot plausibly argue a lack of interest in the substance of the IFRs; on the contrary, they highlight the volume of comments on prior versions of the rules. *See* 82 Fed. Reg. 47814. And they do not even attempt to establish that following notice and comment rulemaking would "prevent [them] from operating." *Levesque*, 723 F.2d at 184.

An agency may only invoke impracticability when "the agency [can]not both follow [notice-and-comment rulemaking] and execute its statutory duties." *Id.* Again, the Departments do not even attempt to meet this standard. They contend only that notice-and-comment rulemaking would have been complicated by ongoing litigation. 82 Fed. Reg. 47814, 47855. But nothing about that ongoing litigation "unavoidably prevented" the agencies from complying with the APA. *Kollett*, 619 F.2d at 145.

B. The Commonwealth Has Standing to Seek Redress for This Procedural Injury Because The IFRs Threaten Its Concrete Interests.

There is no real dispute that there is "some possibility" that enjoining the IFRs would cause the Departments to reconsider their actions. Nor are there legitimate

grounds to question that the IFRs threaten the Commonwealth's concrete interests. The District Court erred as a matter of law in holding otherwise.

As discussed, the Commonwealth has made a "reasonable claim" that the IFRs will have at least a "minimal" impact on the State fisc. *Town of Winthrop v. FAA*, 535 F.3d 1, 7 (1st Cir. 2008) (quoting *Save Our Heritage*, 269 F.3d at 56); *see also Nulankeyutmonen Nkihtaqmikon v. Impson*, 503 F.3d 18, 28 (1st Cir. 2007) (parties suffering a procedural injury must show "a demonstrable risk to their interests"). And as discussed below, the IFRs also threaten the Commonwealth's quasi-sovereign interests in protecting the health and wellbeing of its residents. *See Alfred L. Snapp & Sons, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982). Nothing more is required. *See Save Our Heritage*, 269 F.3d at 55 (party alleging procedural injury has standing if it is "threatened by injury in fact to a cognizable interest").

The District Court ruled that the Commonwealth did not have standing to challenge the IFRs based upon its procedural injury because it "failed … to demonstrate that an actual injury to its economic or quasi-sovereign interests is likely to occur." JA 1421-22. The court based this ruling entirely upon its determination that the Commonwealth had not shown that women in Massachusetts were likely to lose contraceptive coverage as a result of the IFRs, which, for the reasons explained, is itself incorrect. Furthermore, in ruling that the Commonwealth was required to establish a separate "actual injury" to its fiscal and quasi-sovereign interests, the

Court misapprehended the nature of procedural standing. *See Nulankeyutmonen*, 503 F.3d at 28. "Violations of procedural rights … receive special treatment when it comes to standing." *Dubois v. U.S. Dept. of Agriculture*, 102 F.3d 1273, 1281 n. 10 (1st Cir. 1996) (internal quotations omitted). To "enforce a procedural requirement," a party must demonstrate only that a violation of that requirement "*could impair* a separate concrete interest of theirs." *Lujan*, 504 U.S. at 568 (emphasis added); *see also id.* at 565 n. 2, 572 n. 7 (a party that has suffered a procedural injury need not meet the normal standards for "immediacy," which is a component of imminence); *Nulankeyutmonen*, 503 F.3d at 28 (recognizing standing in a procedural injury case based upon a "potential harm … not certain [to occur]"). Thus, while a "procedural injury *in vacuo*" is insufficient to confer Article III standing, *see Summers*, 555 U.S. 488, 496, a procedural injury together with a "reasonable claim of minimal impact [to concrete interests] is enough." *Save Our Heritage*, 269 F.3d at 56. Even if the Commonwealth had not established that the IFRs will imminently injure its fiscal and quasi-sovereign interests, it clearly met this lesser standard.

III. The Commonwealth Has Standing Because of Injuries to Its Quasi-Sovereign Interests in the Health and Wellbeing of Its Residents.

While the record of economic and procedural harm in this case would be sufficient to confer standing on any litigant, "[i]t is of considerable relevance that the party seeking review here is a sovereign State and not … a private individual." *Massachusetts*, 549 U.S. at 518. When a State invokes federal jurisdiction to protect

its "quasi-sovereign interest in the health and well-being … of its residents," *Alfred L. Snapp*, 458 U.S. at 607, it must be given "special solicitude" in the standing analysis. *Massachusetts*, 549 U.S. at 518-21.[20] And a State's standing to challenge federal regulatory action is at its strongest where, as here, that action threatens its interrelated proprietary, quasi-sovereign, and sovereign interests. *Id.* at 521; *see also Texas*, 809 F.3d at 152-53; *Wyoming ex rel. Crank v. United States*, 539 F.3d 1236, 1241-42 (10th Cir. 2008).[21]

The IFRs threaten the Commonwealth's quasi-sovereign interests in protecting the health and wellbeing of its residents and in "securing [them] from the harmful effects of discrimination." *Alfred L. Snapp*, 458 U.S. at 592, 609. The IFRs selectively attack women's right to seamless contraceptive coverage guaranteed by

[20] In *Massachusetts*, the Court additionally indicated that the fact Commonwealth had been given a procedural right to challenge regulatory action (or inaction) under the Clean Air Act weighed in favor of according the State special solicitude. 549 U.S. at 520. Here, the Commonwealth enjoys an equivalent procedural right to challenge regulatory action under the APA. *See* 5 U.S.C. § 706; *see also Texas*, 809 F.3d at 152 (the APA is "easily adequate to justify 'special solicitude'").

[21] Proprietary, quasi-sovereign, and sovereign harms frequently overlap. *See, e.g.*, *Texas*, 809 F.3d at 152-53 (federal DAPA program threatened Texas with a financial injury, affected its quasi-sovereign interests by placing pressure on it to change its laws in order to avoid the financial injury, and thereby also implicated its sovereign interest in enforcing its laws); *see also Massachusetts*, 549 U.S. at 519-20 (noting the connection between Massachusetts' inability to use its sovereign powers to combat climate change and its quasi-sovereign interest in protecting its territory from harm caused by climate change).

the ACA. *See Zubik*, 136 S. Ct. at 1561 (Sotomayor, J. concurring). The medical evidence underpinning the contraceptive mandate establishes that access to affordable contraception advances educational opportunity, workplace equality, and financial empowerment for women; improves the health of women and children; and reduces healthcare related costs for individuals and families (and the State). *See* JA 50-52 (¶¶ 20-26); 695-96 (¶¶ 12-19).

That the Commonwealth's quasi-sovereign interest in its residents' health and wellbeing encompasses an interest in safeguarding residents' access to contraception is confirmed by a simple fact: Massachusetts has used its "sovereign lawmaking powers" to provide residents the same right to comprehensive, no-cost contraceptive coverage that the IFRs will undermine. *See Alfred L. Snapp*, 458 U.S. at 607 ("One helpful indication in determining whether an alleged injury to the health and welfare of its citizens [implicates a State's quasi-sovereign interests] … is whether the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers."). The Commonwealth was compelled to file this action only because federal law—ERISA—preempts application of its Contraceptive Equity Law and ACCESS Act to the type of self-insured plans that cover the majority of its residents. *See supra*, at 12-13.

This action, then, is a "suit by a State for an injury to it in its capacity of quasi-sovereign," *Massachusetts*, 549 U.S. at 518 (quoting *Georgia v. Tennessee Copper*

Co., 206 U.S. 230, 237 (1907)), that also "implicate[s] [broader] sovereignty concerns." *Texas*, 809 F.3d at 153-54; *see also Wyoming*, 539 F.3d at 1241-42 ("The States have a legally protected sovereign interest in 'the exercise of sovereign power over individuals and entities within the relevant jurisdiction, which involves the power to create and enforce a legal code.'" (quoting *Alfred L. Snapp*, 458 U.S. at 601)). The fact that the Commonwealth has been prevented by federal law from using its "sovereign lawmaking powers" to control the behavior of employers located within its borders, and has been forced to resort to invoking the jurisdiction of the federal courts to protect the critical interests of its residents, certainly entitles it to "special solicitude" in the standing analysis. *Massachusetts*, 549 U.S. at 520-21. But the injury to the Commonwealth's legally protected quasi-sovereign interests also provides an alternative basis for the Commonwealth to assert standing in this proceeding. *See Alfred L. Snapp*, 458 U.S. at 607 (States have standing to proceed as *parens patriae* to assert injuries to their quasi-sovereign interests).[22]

* * *

Each of the injuries asserted by the Commonwealth independently establishes injury-in-fact sufficient to invoke federal court jurisdiction. But the combination of

[22] While a State may not proceed as *parens patriae* against the federal government in order to avoid the application of federal law to its residents, it may proceed against federal agencies to vindicate the rights Congress has afforded to those residents. *See Massachusetts*, 549 U.S. at 520 n. 17. That is exactly what the Commonwealth is doing in this case.

the injuries, together with the fact that it is a sovereign State that seeks redress in federal court for those injuries, resolves any doubt over the existence of a cognizable case and controversy under Article III. This case plainly has the "concrete adverseness [needed to] sharpe[n] the presentation of the issues," *City of Los Angeles v. Lyons*, 461 U.S. 95, 101 (1983), and these important issues—involving the deprivation of Massachusetts women's right to contraceptive coverage guaranteed by the ACA—should be addressed on the merits.

CONCLUSION

For the foregoing reasons, this Court should reverse the District Court's judgment and remand this case for further proceedings on the merits.

Respectfully submitted,

COMMONWEALTH OF
MASSACHUSETTS,

By its attorney,

MAURA HEALEY
ATTORNEY GENERAL

/s/ Julia E. Kobick

Julia E. Kobick, No. 1162713
Jon Burke, No. 1184311
Jonathan B. Miller, No. 1143605
Assistant Attorneys General
Elizabeth Carnes Flynn, No. 1184310
Special Assistant Attorney General
Office of the Attorney General
One Ashburton Place
Boston, Massachusetts 02108
(617) 963-2559
julia.kobick@state.ma.us

Dated: September 17, 2018

Certificate of Compliance with Rule 32

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 12,754 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 14-point Times New Roman font.

/s/ Julia E. Kobick
Counsel for the Commonwealth of Massachusetts

Dated: 9/17/2018

Certificate of Service

I hereby certify that on September 17, 2018 I electronically filed the foregoing document with the United States Court of Appeals for the First Circuit by using the CM/ECF system. I certify that the following parties or their counsel of record are registered as ECF Filers and that they will be served by the CM/ECF system:

Karen Schoen, Esq.
U.S. Department of Justice
950 Pennsylvania Ave. NW, Rm. 7533
Washington, DC 20530

Matthew M. Collette, Esq.
U.S. Department of Justice
950 Pennsylvania Ave. NW, Rm. 7527
Washington, DC 20530

Lowell V. Sturgill Jr., Esq.
U.S. Department of Justice
950 Pennsylvania Ave. NW, Rm. 7241
Washington, DC 20530

Counsel for Defendants-Appellees

/s/ Julia E. Kobick
Julia E. Kobick, No. 1162713
Assistant Attorney General
Government Bureau
Office of the Attorney General
One Ashburton Place
Boston, Massachusetts 02108
(617) 963-2559
julia.kobick@state.ma.us

Counsel for the Commonwealth of Massachusetts

Dated: 9/17/2018

ADDENDUM

United States District Court
District of Massachusetts

Commonwealth of Massachusetts, **Plaintiff,** **v.** **United States Department of Health and Human Services; Alex M. Azar II, in his official capacity as Secretary of Health and Human Services; United States Department of the Treasury; Steven T. Mnuchin, in his official capacity as Secretary of the Treasury; United States Department of Labor; and R. Alexander Acosta, in his official capacity as Secretary of Labor,** **Defendants.**	**Civil Action No. 17-11930-NMG**

MEMORANDUM & ORDER

GORTON, J.

This case involves a dispute about the validity of two Interim Final Rules (“IFRs”) issued by the United States Department of Health and Human Services, the United States Department of the Treasury and the United States Department of Labor (collectively “defendants” or “the Departments”) on October 6, 2017. The IFRs expand the religious exemption to the

contraceptive mandate of the Affordable Care Act ("ACA") and create a new moral exemption to that mandate.

The Commonwealth of Massachusetts ("plaintiff" or "the Commonwealth") alleges that 1) the Departments did not engage in notice and comment rulemaking before issuing the IFRs in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, 2) the IFRs are not in accordance with law and exceed the defendants authority in violation of the APA, 5 U.S.C. § 706, 3) the IFRs violate the Establishment Clause of the First Amendment of the United States Constitution and 4) the IFRs violate the equal protection guarantee of the Due Process Clause of the Fifth Amendment of the United States Constitution. The Commonwealth requests that this Court declare the IFRs unlawful and permanently enjoin their implementation on a nationwide, universal basis.

Pending before the Court are plaintiff's motion for summary judgment and defendants' cross-motion to dismiss or for summary judgment. Because the Commonwealth has failed to set forth specific facts establishing that it will likely suffer future injury from the defendants' conduct, it lacks standing to prosecute this action and defendants' motion for summary judgment will therefore be allowed and plaintiff's motion for summary judgment will be denied.

I. Background

A. The contraceptive mandate

The Patient Protection and Affordable Care Act generally requires that employer-sponsored healthcare plans include a range of preventive care services on a no-cost basis ("the preventive services requirement"). See 42 U.S.C. §§ 18022 & 300gg-13. That requirement mandates no-cost coverage

> with respect to women, . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration ["HRSA"].

S. Amdt. 2791, 111th Congress (2009-2010).

Thus, instead of including specific preventive care services, Congress delegated authority to HRSA, an agency within the Department of Health and Human Services ("HHS"). HRSA and HHS enlisted the Institute of Medicine ("IOM"), which convened a committee to assess what preventive services should be included. The IOM recommended that the services include

> the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

IOM Report at 104.

Accordingly, when the HRSA promulgated its Women's Preventive Services Guidelines in August 2011, non-exempt employers were required to provide

> coverage, without cost sharing, [for] [a]ll Food and Drug Administration-approved contraceptive methods,

sterilization procedures, and patient education and counseling

("the contraceptive mandate"). Those guidelines went into effect in August, 2012. The HRSA updated the Women's Preventive Services Guidelines in December 2016, reaffirming that the Guidelines should continue to require full coverage for contraceptive care and services.

B. Accommodations for religious objections to the contraceptive mandate

In 2011 and 2012, the Departments issued regulations automatically exempting churches and their integrated auxiliaries, conventions and associations of churches and the exclusively religious activities of religious orders from the contraceptive mandate. This "Church Exemption" corresponds to a category of employers defined in the Internal Revenue Code. See 77 Fed. Reg. 8725, 8726 (citing 26 U.S.C. §§ 6033(a)(3)(A)(i) and (iii)). The Departments recognized that "certain non-exempted, non-profit organizations" also had religious objections to covering contraceptive services but determined that exempting such employers was not required by RFRA and was inconsistent with the ACA. 77 Fed. Reg. 8725, 8728. Internal church decisions, the Departments explained in later regulations, are afforded a "particular sphere of autonomy" that does not extend to other religious employers. 80 Fed. Reg. 41,318, 41,325.

In 2013, the Departments issued regulations providing an accommodation for objecting religious, non-profit organizations and institutions of higher education. The accommodation created a system whereby insurers and third parties paid the full cost of contraceptive care and employees received seamless coverage ("the accommodation process"). That process was expanded to cover closely held, for-profit companies in response to Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014), in which the Supreme Court held that the contraceptive mandate violated the Religious Freedom Restoration Act ("RFRA") for certain closely-held, for-profit employers. The Court held that the "HHS contraceptive mandate substantially burden[ed] the exercise of religion." Id. at 2775 (internal quotation omitted) (citing 42 U.S.C. § 2000bb–1(a)). The accommodation process, the Court explained, was a "less restrictive means" of furthering the government interest and thus RFRA required that the accommodation be expanded to include certain closely held corporations. Id. at 2780-82.

In a separate series of cases, religious organizations such as universities and healthcare providers that did not perform "exclusively religious activities" challenged the legality of the accommodation process itself. See Zubik v. Burwell, 136 S. Ct. 1557 (2016). In May, 2016, those cases were remanded to their respective circuit courts for further consideration of

whether the accommodation process could be altered to address the religious employers' concerns while still providing seamless contraceptive coverage. In January, 2017, after reviewing more than 50,000 comments, the Departments announced that the answer was "No". No alternative, the Departments explained, would pose a lesser burden on religious exercise while ensuring contraceptive coverage.

C. The Interim Final Rules

On May 4, 2017, the President issued an "Executive Order Promoting Free Speech and Religious Liberty." Exec. Order No. 13,798, 92 Fed. Reg. 21,674 (May 4, 2017). That order instructed agencies

> [to] consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4).

Id.

The Departments of the Treasury, Labor and HHS issued the two Interim Final Rules ("IFRs") at issue in this case on October 6, 2017. See 82 Fed. Reg. 47,799 ("Religious Exemption Rule"); 82 Fed. Reg. 47,838 ("Moral Exemption Rule").

The IFRs create an expanded religious exemption. The HRSA exempts objecting entities "from any guidelines' requirements that relate to the provision of contraceptive services." 45 C.F.R. § 147.132(a). The Religious Exemption Rule expands

objecting entities to include any non-governmental plan sponsor that objects to

> establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

45 C.F.R. § 147.132(a)(2).

The religious exemption also applies to institutions of higher education in their arrangement of student health insurance coverage to the extent of that institution's sincerely held religious beliefs. 45 C.F.R. § 147.132(a)(ii). It exempts all employers with a religious objection, as opposed to the prior Church Exemption covering churches, associations of churches and the exclusively religious activities of religious orders. It also affects religious non-profit organizations in that objecting organizations formerly subject to the accommodation process may now seek the exemption.

Under the preceding Administration, no moral exemption to the contraceptive mandate existed in any form. The Moral Exemption Rule provides an exemption for nonprofit organizations and for-profit entities with no publicly traded ownership interests that object to

> establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

45 C.F.R. § 147.133(a)(2).

D. Estimated Impact of the IFRs

The Departments provided two estimates for the number of women who will likely be affected by the IFRs nationwide. The first, lower, estimate is derived largely from the Departments' experience litigating the contraceptive mandate, the Church Exemption and the accommodation.

The Departments begin their estimate by excluding certain categories of employers as unlikely to avail themselves of the expanded exemptions. The Religious IFR estimates that, for certain categories of employers, no women of child bearing age that use contraception and had access to no-cost contraceptive care through their employer before the Religious IFR was put into effect would lose coverage because of the employer's availment of the Religious IFR. Although these employers would be transitioning from the accommodation to the exemption, the Departments estimated that the Religious IFR would have no effect on those employers' employees. That is because

> the Departments continue to assume that such plans are similar to other objecting entities using self-insured church plans with respect to their third party administrators being unlikely to provide contraceptive coverage to plan participants and beneficiaries under the previous rule.

82 Fed. Reg. 47792, 47816.

The Departments excluded certain categories of employers from their estimates because the Departments deemed those employers unlikely to avail themselves of the exemption. For instance, the Departments state that

> although publicly traded entities could make use of exempt status under these interim final rules, the Departments do not expect that very many will do so.

82 Fed. Reg. 47792, 47816; see also 82 Fed. Reg. 47792, 47816 ("No publicly traded for-profit entities have filed lawsuits challenging the mandate.").

The Departments estimate that 209 entities will make use of the expanded religious exemption nationwide. This number was originally put forth in August 2014 and July 2015 as HHS's estimate of how many entities would avail themselves of the accommodation process. See 82 Fed. Reg. 47792, 47817. The figure was based on

> 122 eligible entities that had filed litigation challenging the accommodation process, and 87 closely held for-profit entities that had filed suit challenging the Mandate in general.

Id. (citing 79 Fed. Reg. 51096; 80 Fed. Reg. 41336).

Overall, the Departments estimate that of the 209 previously accommodated litigating entities, 109 "will make use of their exempt status, and 100 will continue using the accommodation." See id. In addition, the Departments assume

that nine entities newly eligible for the accommodation "will use the voluntary accommodation moving forward." See id.

Assuming that some of the previously accommodated litigating entities will continue using the accommodation while others will use the exemption, the Departments estimate that

> 109 entities will use the voluntary accommodation moving forward, 100 of which were already using the previous accommodation, and that 109 entities that have been using the previous accommodation will use the expanded exemption instead.

See id.

The Departments "expect approximately 23,000 women that use contraception covered by the guidelines to be affected" by those previously accommodated entities switching to the expanded religious exemption. Id.

The Departments estimate that those 209 litigating entities that were neither exempt nor likely using self-insured church plans "employed approximately 65,000 persons, male and female." See 82 Fed. Reg. 47792, 47819. The Departments estimate that the 65,000 figure includes

> approximately 7,221 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that have filed lawsuits challenging the Mandate, where those plans are neither exempt under the prior rule nor are self-insured church plans.

See id.

In addition, the agencies estimate that an additional 1,462 women who obtained student plans from "educational institutions objecting to the mandate as applied to student coverage" would be affected by the IFRs nationwide.

Putting the figures together, the Departments estimate that approximately 31,700 women throughout the country who are of child-bearing age and use FDA-approved contraception will be affected. Of those, 1,462 come from objecting educational institutions, 7,221 come from entities that challenged the mandate and were not exempt under the prior rule and 23,000 come from formerly accommodated entities that now will use the exemption. The estimate was produced by relying on these different groups of employers, although the Departments conceded that there may be overlap between groups.

Finally, the Departments estimate that the only non-profit entities that will use the expanded Moral Exemption will be entities "whose employees also oppose the coverage". Similarly, the Departments estimate that "no entities with non-religious moral objections to the mandate will be institutions of higher education" that provide student coverage. The Departments estimate 15 women employed by for-profit entities that are not publicly traded and have non-religious moral objections to the contraception mandate will lose coverage because of the expanded moral exemption. Id.

E. Upper Bound Estimated Impact

The Departments' "upper bound" estimate extrapolates from the number of women of child bearing age using FDA-approved contraception who were covered by plans that omitted contraception before the ACA's contraception mandate came into effect.[1] The Departments conclude that approximately 574,000 women of childbearing age who use contraceptives covered by the guidelines were covered by plans that omitted contraceptive coverage prior to the ACA. 82 Fed. Reg. 47792, 47822 (citation omitted).

That number was then reduced to account for publicly traded employers and houses of worship, integrated auxiliaries and self-insured church plans which would not provide contraception before the new interim rules and would continue not to do so thereafter. See id.

The Departments conclude that 362,100 women of childbearing age who use contraceptives covered by the guidelines were employed by private, non-publicly traded companies that denied contraceptive coverage in 2010. Id. Hence, the Departments

[1] Both parties note that the Departments excluded the 31% of employer respondents which did not know whether they offered such coverage. The Commonwealth asserts that this drastically underestimates the correct number but Defendants respond that the employers most likely to hold a religious or moral objection to contraception would also be likely to know whether they provided contraception.

estimate that 362,100 affected women is the "upper bound" nationwide impact of the IFRs.

F. Massachusetts state legislation

The Commonwealth of Massachusetts has addressed the issue of contraceptive access through state legislation. In 2002, the Commonwealth enacted the Contraceptive Equity Law. See Mass. St. 2002, ch. 49, §§ 1-4. That statute requires employer-sponsored health plans that cover outpatient services, prescriptions or devices to provide the same level of coverage for all FDA-approved contraceptive services, prescriptions and devices. See M.G.L. c. 175, § 47W; M.G.L. c. 176A, § 8W; M.G.L. c. 176B, § 4W; M.G.L. c. 176G, § 4O. The law does not mandate that those benefits be provided at no cost. Instead, covered citizens are still responsible for deductibles, copays and other cost-sharing payments.

In November, 2017, Massachusetts enacted "an Act Relative to Advancing Contraceptive Coverage and Economic Security in Our State," otherwise known as the "ACCESS Act". See Mass. St. 2017, ch. 120. The bill was reported out of the House Committee on Financial Services on November 6, 2017, enacted on November 14, 2017, and signed into law on November 20, 2017. The statute has been described as "codifying the Affordable Care Act's guarantee of no copay birth control coverage into state law." See "With Governor's Signature, Massachusetts protects birth control

access", Planned Parenthood Action Fund, Nov. 20, 2017, available online at https://perma.cc/44NZ-9RMC.

The statute prohibits certain employer-sponsored health plans from imposing cost-sharing fees (such as co-pays and deductibles) in connection with the provision of contraceptives. See, e.g., Mass. St. 2017, ch. 120, § 4 (providing that insurance contracts between a subscriber and corporations that provide benefits for outpatient services shall offer "at least 1 drug, device or other product . . . [for all] FDA approved contraceptive drugs, devices and other products [excluding male condoms and certain oral contraceptives] . . . without cost-sharing").

The ACCESS Act includes no moral exemption. Churches and "qualified church-controlled organization[s]" are exempted from certain provisions of the Act, provided that they

> provide written notice to prospective enrollees prior to enrollment with the plan and such notice shall list the contraceptive health care methods and services for which the employer will not provide coverage for religious reasons.

See, e.g., Mass. St. 2017, ch. 120, § 3. The exemption does not extend farther than those organizations and mirrors the Departments' previous Church Exemption. As such, some employers that are able to invoke an exemption from the ACA mandate under

the expanded exemptions of the IFRs are unable to invoke an exemption under the ACCESS Act mandate.

Neither the ACCESS Act nor the Contraceptive Equity Law apply to self-insured employer plans. Rather, such plans are governed by the Employee Retirement Income Security Act ("ERISA"). 29 U.S.C. §§ 1144(a), (b)(2)(A).

G. Massachusetts' system of contraceptive care

The Commonwealth of Massachusetts "supports access to contraceptive care and services through an interrelated system" that includes direct coverage and reimbursements. In Massachusetts, Medicaid and the Children's Health Insurance Program ("CHIP") are combined into one program called MassHealth. Almost two million Massachusetts residents are enrolled members of the program. Contraceptive services are a federally-mandated Medicaid benefit for eligible enrollees.

In addition, MassHealth serves as a secondary payer for approximately 150,000 residents who have commercial coverage, including employer-sponsored insurance and student health insurance. This means that MassHealth provides "wrap around" coverage for certain services not provided by the resident's commercial insurance, including federally mandated Medicaid benefits such as contraceptive services. Should an employer avail itself of the religious or moral exemption in the IFRs, "wrap around" enrollees will be entitled to receive replacement

coverage through MassHealth. Under federal law, the Commonwealth is responsible for paying 10% of all sums expended on the "offering, arranging, and furnishing . . . of family planning services and supplies." See 42 U.S.C. § 1396b(a)(5).

The Sexual and Reproductive Health Program ("SRHP") of the Massachusetts Department of Public Health ("DPH") reimburses a network of family planning program providers offering contraception in the Commonwealth. Approximately three-quarters of SRHP's funding emanates from state appropriation. The SRHP funds plans that offer low or no-cost contraceptive services to low-income Massachusetts residents, including all FDA-approved contraceptives. Those services are available to 1) uninsured Massachusetts residents whose income is less than 300% of the federal poverty level, 2) Massachusetts residents whose income is less than 300% of the federal poverty level with a health plan that does not cover all contraception methods and services and 3) Massachusetts residents of any insurance status who desire confidential care.

II. Analysis

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that

there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

If the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). Summary judgment is appropriate if, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law.

In the administrative law context, the summary judgment rubric has a "special twist". Assoc'd Fisheries of Me., Inc. v. Daley, 127 F.3d 104, 109 (1st Cir. 1997). In this context, a court reviews "an agency action not to determine whether a dispute of fact remains but, rather, to determine" whether the

agency acted lawfully. Boston Redevelopment Auth. v. Nat'l Park Serv., 838 F.3d 42, 47 (1st Cir. 2016) (citing Mass. Dep't of Pub. Welfare v. Sec'y of Agric., 984 F.2d 514, 526 (1st Cir. 1993)). Where the parties treat the matter as a petition for judicial review of agency action, the district court should "follow[] the parties' lead and adjudicate[] the case in that manner." Boston Redevelopment Auth. v. Nat'l Park Serv., 838 F.3d 42, 47 (1st Cir. 2016). Here, the Commonwealth urges this Court to treat its motion for summary judgment as "a vehicle to tee up [the] case for judicial review" and defendants do not dispute that characterization. Accordingly, the Court will "follow the parties' lead". Id.

Standing

While the judicial review standard applies to the merits of the Commonwealth's claims, "[t]he party invoking federal jurisdiction bears the burden of establishing" standing. Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992). Because the elements of standing are

> an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation.

Id.

General and hypothetical allegations of injury cannot succeed at the summary judgment stage, where "plaintiffs must do

more than merely allege legal injury." Penobscot Nation v. Mills, 861 F.3d 324, 337 (1st Cir. 2017). At this stage, plaintiff must set forth by affidavit or other evidence "specific facts" to establish standing. Defs. of Wildlife, 504 U.S. at 551 (quoting Fed. R. Civ. P. 56(e)) (internal quotation marks omitted).

Article III confines the jurisdiction of a federal court to actual "cases" or "controversies". Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc., 454 U.S. 464, 471 (1982). The "irreducible constitutional minimum of standing" requires that a plaintiff 1) suffered an injury in fact, 2) fairly traceable to the actions of the defendant that is 3) likely to be redressed by a favorable judicial decision. Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016). To establish Article III standing, a plaintiff must demonstrate that the injury in fact is "concrete, particularized, and actual or imminent". Blum v. Holder, 744 F.3d 790, 796 (1st Cir. 2014) (citing Monsanto Co. v. Geertson Seed Farms, 561 U.S. 139, 148 (2010)). The Supreme Court has emphasized that concreteness requires that the alleged injury "actually exist" and amount to more than an "abstract" injury. Spokeo, 136 S.Ct. at 1548. Particularity reflects the notion that an injury "must affect the plaintiff in a personal and individual way". Defs. of Wildlife, 504 U.S. at 560 n.1.

The standing inquiry is affected here by the fact that the plaintiff is the Commonwealth of Massachusetts. "States are not normal litigants for the purposes of invoking federal jurisdiction." Massachusetts v. E.P.A., 549 U.S. 497, 518 (2007).

The Supreme Court has articulated a variety of theories by which a state may attempt to invoke federal jurisdiction. It may sue to vindicate its sovereign interests, its quasi-sovereign interests or its non-sovereign interests. See generally Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez, 458 U.S. 592, 600-602 (1982). Sovereign interests and certain non-sovereign interests, such as proprietary interests, reflect a direct injury to the state itself. See id. Under the parens patriae doctrine, in contrast, states "represent the interests of their citizens." Id. at 603 (citing North Dakota v. Minnesota, 263 U.S. 365 (1923)) (additional citations omitted). The injury the state asserts in such a case is "an injury to what has been characterized as a quasi-sovereign interest." Id. at 601 (internal quotation omitted). A quasi-sovereign interest is "a judicial construct that does not lend itself to a simple or exact definition. Id. It is clear, however, that if a state is "only a nominal party without a real interest of its own then it will not have standing under the parens patriae doctrine."

Id. at 600 (citing Pennsylvania v. New Jersey, 426 U.S. 660 (1976)) (additional citations omitted).

Massachusetts proffers three injuries to establish standing: an injury to the state fisc, an injury to the health and well-being of its residents and a procedural injury under the APA. The Court will consider the three theories of the Commonwealth seriatim.

Fiscal Injury

A state may sue to protect an injury to its sovereign interests, such as "the power to create and enforce a legal code" or the demand that other sovereigns recognize its borders. See, e.g., New York v. United States, 505 U.S. 144 (1992) (holding that portions of the Low–Level Radioactive Waste Policy Amendments Act of 1985 unconstitutionally commandeered state legislative policy in violation of the Tenth Amendment). A state may also incur an injury to its proprietary interests. See Snapp, 458 U.S. at 601. For example, a state may "own land or participate in a business venture." Id. When pursuing such a nonsovereign interest, the state "is likely to have the same interests as other similarly situated proprietors." Id. The Commonwealth does not explain whether it considers the injury alleged in this case to implicate a sovereign interest or a non-sovereign interest and the Court takes no position in that regard.

The Commonwealth asserts that in the short and long term, the IFRs will

> inflict significant financial harm on the Commonwealth, which will be legally obligated to assume the costs of contraceptive, prenatal and postnatal care for many women who lose coverage.

Specifically, the Commonwealth explains that

> the IFRs will result in thousands of Massachusetts women losing coverage for contraceptive care and services.

The Departments insist that such a theory fails as a matter of law because "a state cannot establish standing based on a claim of injury from such alleged indirect effects." Contra Texas v. United States, 809 F.3d 134 (5th Cir. 2015), aff'd by an evenly divided Court, 136 S. Ct. 2271 (2016) (per curiam). Assuming, without deciding, that the Commonwealth's theory succeeds as a matter of law, plaintiff has not made the requisite demonstration of specific facts.

Proportional theory

The Court will refer to the Commonwealth's first theory of standing as its "proportional theory". The Commonwealth bases its opinion upon the Departments' estimate and then makes a back-of-the-envelope reckoning.

The Commonwealth alleges that "the Departments likely underestimate" the number of people who will lose coverage because of the IFRs and the percentage of those people who are

women of childbearing age who use contraception. On the other hand, it denies that the estimates render the IFRs "arbitrary and capricious" in violation of the Administrative Procedure Act. Accordingly, although the parties quibble about whether various figures over (or under) estimate the number of affected women, the Court will assume that the Departments' figures comprise an accurate estimation.

The Commonwealth adds the Departments' moral and religious exemption estimates together to reach a total of between 31,715 and 120,015 women of child-bearing age who are currently using contraception who will be affected by the IFRs nationwide. The Commonwealth then multiplies the Departments' nationwide estimate by the appropriate population percentage (2.1%) to conclude that "between 666 and 2,520 Massachusetts women" who are currently using contraception will likely lose comprehensive employer-sponsored contraceptive coverage.

The Departments determined that the average financial transfer effect attributed to a woman's loss of contraception would be approximately $584 per year. Multiplying that $584 figure by the Commonwealth's affected employee estimates yields an increased annual out-of-pocket cost of contraceptives of between $388,944 and $1,471,680. The Commonwealth claims it "will be responsible for a significant share of these costs."

In a motion for summary judgment challenging a plaintiff's standing to sue, the burden is on the plaintiff to demonstrate standing with "specific facts." Defs. of Wildlife, 504 U.S. at 561. Inference and speculation do not suffice. See Rathbun v. Autozone, Inc., 361 F.3d 62, 66 (1st Cir. 2004) (citation omitted)). The Commonwealth's proportional theory is unsupported by facts sufficient to satisfy its burden.[2]

The Commonwealth contends that the proportional theory suffices because

> the Departments have provided no reason to doubt that a proportionate number of [affected] women will reside in Massachusetts.

The Commonwealth, however, misapprehends its burden. See Clapper v. Amnesty Int'l USA, 568 U.S. 398, 412 n. 4 (2013) ("[I]t is [plaintiffs'] burden to prove their standing by pointing to specific facts, not the Government's burden to disprove standing . . . .") (citing Defs. of Wildlife, 504 U.S. at 561). This Court has "an independent obligation to assure that standing exists, regardless of whether it is challenged" by the parties. Id. at 499 (citing Bender v. Williamsport Area School Dist., 475 U.S. 534, 541 (1986)). That requires, "at the

[2] Other courts have expressed doubt about such an approach. Cf. Summers v. Earth Island Inst., 555 U.S. 488, 497 (2009) (rejecting theory of organizational standing whereby an organization may demonstrate injury in fact if "there is a statistical probability that some of those members are threatened with concrete injury").

summary judgment stage, a factual showing of perceptible harm." Defs. of Wildlife, 504 U.S. at 566; cf. Summers, 555 U.S. at 499 ("While it is certainly possible — perhaps even likely — that one individual will meet all of these criteria, that speculation does not suffice.").

The unsupported assumption of the Commonwealth that it will be proportionally affected by the IFRs is also tenuous. Most importantly, the Commonwealth does not address the "ACCESS Act", which was enacted after the filing of this lawsuit. That state statute was reported out of the House Committee on Financial Services exactly one month after the IFRs were promulgated and was signed into law two weeks later. In its amended complaint and motion for summary judgment, the Commonwealth states that the statute was enacted to "remedy [the] gap" of the Contraceptive Equity Law, which, "unlike the ACA . . . does not mandate no-cost contraceptive coverage." At oral argument, counsel for the Commonwealth explained that the statute requires essentially the same coverage as the ACA mandate.

The ACCESS Act does not protect all Massachusetts employees. It does not apply to self-insured employer plans, for instance, which are governed solely by federal law, see 29 U.S.C. §§ 1144(a), (b)(2)(A). Nevertheless, the Act will almost certainly compel some employers that would otherwise avail

themselves of the expanded exemptions to provide their employees no-cost contraceptive coverage.

Unlike the expanded religious exemption and the new moral exemption of the IFRs, the ACCESS Act includes a church exemption that mirrors the Church Exemption found in the Departments' previous regulations. Compare M.G.L. c. 175, § 47W(c) (providing an exemption if the employer is a "church or qualified church-controlled organization") with 77 Fed. Reg. 8725, 8726 (providing an exemption for "churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order"). Thus, certain Massachusetts employers that were ineligible for the exemption under previous federal regulations and became eligible under the new IFRs, are not eligible for an exemption under the ACCESS Act.

At oral argument, plaintiff's counsel emphasized that 60% of the State's workforce will not be covered by the protection afforded by the ACCESS Act. When the Court inquired about what kinds of employers the Commonwealth expects to use the expanded exemptions but not to be covered by the ACCESS Act, however, counsel responded that the relevant inquiry involves statistical probabilities and not individual employers. That approach produces further uncertainty. For instance, it is unclear how 60% of the Massachusetts workface overlaps with the 31% of

employees in the private sector employed by publicly traded companies who the Departments estimate will not be affected.

Without further information about the 60% of employers referred to, the Court cannot determine whether it is likely that the Commonwealth will incur a fiscal injury. It is clear that, given the new ACCESS Act, Massachusetts will be affected differently by the IFRs than other states but it is not at all clear how the coverage of the ACCESS Act will impact employers who may have intended to utilize the expanded exemptions. The Commonwealth, as well as this Court, is left to surmise.

The Commonwealth has not established that it is likely that any Massachusetts employers will avail themselves of the IFRs' expanded exemptions. The enactment of the ACCESS Act renders suspect the Commonwealth's assumption that the IFRs would affect women proportionally throughout the country. To the extent the ACCESS Act affects the "metes and bounds" of the Commonwealth's injury, see Massachusetts v. E.P.A., 549 U.S. 497, 523 n. 21 (2007), its impact is irrelevant. To the extent the Act affects the likelihood that the Commonwealth will be injured, however, plaintiff's failure to address its impact highlights the risk of turning "a live, concrete dispute", see Warth v. Seldin, 422 U.S. 490, 517 (1975), into a "generalized grievance[]". See Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 97 (1998)

(quoting Schlesinger v. Reservists Comm. to Stop the War, 418 U.S. 208, 217 (1974)).

The State protests that the Departments have made it "nearly impossible to identify whether specific employers have claimed (or will claim) an exemption." As a matter of law, to the extent that it is "nearly impossible" to identify employers availing themselves of an exemption, the Commonwealth's burden to demonstrate standing is not abated. Cf. Clapper v. Amnesty Int'l USA, 568 U.S. 398, 420 (2013) (rejecting plaintiffs' suggestion "that they should be held to have standing because otherwise the constitutionality of [the provision] could not be challenged"); see also Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc., 454 U.S. 464, 489 (1982) ("[T]he assumption that if [plaintiffs] have no standing to sue, no one would have standing, is not a reason to find standing.") (quoting Schlesinger v. Reservists Committee to Stop the War, 418 U.S. 208, 227 (1974)).

Relying on the Departments' approximation methodology, however, certain employers are easily identifiable. The Departments rely on the number of employers that litigated the contraception mandate or accommodation. The Departments identified 209 such institutions: 122 that challenged the accommodation process and 87 for-profit employers that challenged the mandate. At oral argument, the Commonwealth

noted that at least two such entities have locations in Massachusetts: Hobby Lobby and the Little Sisters of the Poor but it conceded that it is unaware whether any such entities intend to make use of the expanded exemptions.

In this respect, Massachusetts stands in sharp contrast to Pennsylvania and California, two states that have also challenged the IFRs under the APA and the Constitution. See Pennsylvania v. Trump, No. 2:17-cv-04540-WB (E.D. Pa. filed Oct. 11, 2017); California v. HHS, No. 2:17-cv-04540-WB (N.D. Cal. filed Oct. 11, 2017)[3]. There is no doubt that employers in Pennsylvania and California intend to use the IFR's expanded exemptions, a prerequisite to a state incurring an injury to its state fisc or to the health and well-being of its residents. As to whether any Massachusetts employers intend to use the expanded exemptions, the record is uniquely obscure.

In Pennsylvania, Little Sisters of the Poor Saints Peter and Paul Home filed an emergency motion to intervene. See Emergency Motion to Intervene, Pennsylvania, ECF No. 19. That organization, a religious, nonprofit corporation operated by an order of Roman Catholic nuns, is located in Pittsburgh, Pennsylvania. In its motion, the Little Sisters stated that

[3] Delaware, Virginia, Maryland and New York joined the suit as plaintiffs after the filing thereof. See First Amended Complaint, California v. HHS, No. 2:17-cv-04540-WB (N.D. Cal. Nov. 1, 2017), ECF No. 24.

they intend to use the expanded religious exemption granted by the IFR. See Memorandum in Support of Emergency Motion to Intervene, Pennsylvania, ECF No. 19-1 at 10. Similarly, in the California case, Little Sisters of the Poor Jeanne Jugan Residence, located in San Pedro, California, moved to intervene. See Motion to Intervene, California, ECF No. 38. The California intervenors also expressed their intention to use the expanded religious exemption. See id. at 1. In this case, by contrast, the Little Sisters of the Poor Jeanne Jugan Residence in Somerville is profoundly absent.

The Commonwealth contends that a proportionate number of affected women will reside in Massachusetts. Instead of supporting that assumption, it relies on the fact that "the Departments have provided no reason to doubt that" proportionate figure. Such an approach risks disposing of "that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination." Massachusetts v. E.P.A., 549 U.S. 497, 517 (2007) (quoting Baker v. Carr, 369 U.S. 186, 204 (1962)). To dispense with this requirement would be to allow an Article III court to "serve as a forum for generalized grievances." See Hollingsworth v. Perry, 133 S. Ct. 2652, 2662, 186 L. Ed. 2d 768 (2013) (quoting Lance v. Coffman, 549 U.S. 437, 439 (2007) (per curiam); cf. Massachusetts v. Mellon, 262 U.S. 447, 488 (1923) ("The party who invokes the

power must be able to show . . . that he has sustained or is immediately in danger of sustaining some direct injury . . . and not merely that he suffers in some indefinite way in common with people generally."). As the Court has outlined above, the Massachusetts ACCESS Act provides good reason to believe that Massachusetts women are less likely to be affected.

Metes and bounds

The State maintains that "[t]he Commonwealth need not" identify any Massachusetts employer that is likely to avail itself of the new exemptions. According to the Commonwealth, a plaintiff need not "allege an injury with exactitude, but must only establish the likelihood that an injury will occur." Relying on Massachusetts v. EPA, the Commonwealth correctly submits that it need not lay out "the metes and bounds" of its injury. See Massachusetts v. EPA, 549 U.S. 497, 523 n. 21 (2007). In that decision, the Supreme Court explained that the plaintiffs did not need to "quantify Massachusetts' land loss with the exactitude [the dissent] would prefer." Id. The Court noted that

> the likelihood that Massachusetts' coastline will recede has nothing to do with whether petitioners have determined the precise metes and bounds of their soon-to-be-flooded land.

Id.

Thus, the Court required plaintiffs to demonstrate that some of the land owned by Massachusetts would likely be flooded but did not require the Commonwealth to estimate just how much of its land would be lost. Applying that lesson to this case, Massachusetts need not present a precise estimate of how much money the state will spend or how many women will no longer have access to no-cost contraceptive coverage ("the metes and bounds" of the injury). It must, however, demonstrate that it is likely that some funds will be expended and some women will lose that coverage ("the likelihood").

In the EPA case, the Supreme Court relied on the Commonwealth's affidavit that explained that it "owns, operates and maintains approximately 53 coastal state parks, beaches, reservations, and wildlife sanctuaries" along with other identifiable properties and facilities. See Massachusetts, 549 U.S. at 522 n. 19; see also id. at 522 ("Because the Commonwealth owns a substantial portion of the state's coastal property, it has alleged a particularized injury in its capacity as a landowner.") (internal quotation omitted). Thus, the Commonwealth identified many properties that were likely to be injured but was not asked to specify which property or how many properties would be injured.

In the case at bar, by contrast, the Commonwealth does not identify any employers that are likely to avail themselves of

the expanded exemptions, much less identify employees who will cause the Commonwealth the alleged "significant financial harm". A more accurate analogue to Massachusetts v. EPA would be presented if the Commonwealth identified a number of "litigating entities" that employed residents of Massachusetts or identified entities currently using the accommodation that are likely to use the expanded exemption, and then explained that it is unknown which or how many of those employers would claim the expanded exemptions, thereby eventually causing the Commonwealth financial harm.

The Commonwealth's affidavits

As an alternative to its proportional theory, the Commonwealth relies on affidavits it has filed and made part of the record. For instance, Massachusetts offers the declaration of Caryn Dutton, M.D., M.S., the Medical Director of the Gynecology Practice Brigham & Women's Hospital in Boston, Massachusetts, who testifies, based on her personal knowledge, that

> [i]f the IFRs are permitted to go into effect, I anticipate that some women in Massachusetts will lose coverage for contraceptive services as a result of their employer's exercise of one of the IFRs' exemptions.

The declaration does not provide the methodology that led Dr. Dutton to her supposition. Cf. SMS Sys. Maint. Servs., Inc. v. Digital Equip. Corp., 188 F.3d 11, 25 (1st Cir. 1999)

("Expert testimony that offers only a bare conclusion is insufficient to prove the expert's point.") (citation omitted). Nor does Dr. Dutton state that her belief arises from patients informing her that they will lose contraceptive coverage due to their employers' exemption. Cf. Fed. R. Evid. 803(4) (excluding from the rule against hearsay "statements made for medical diagnosis or treatment"). At the summary judgment stage, the party invoking federal jurisdiction "can no longer rest on mere allegations but must set forth by affidavit or other evidence specific facts." Clapper v. Amnesty Int'l USA, 568 U.S. 398, 412 (2013) (quoting Defenders of Wildlife, 504 U.S. at 561). Specific facts, not "general averments", are required. Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 888 (1990) ("The object of [Rule 56(e)] is not to replace conclusory allegations of the complaint or answer with conclusory allegations of an affidavit."). Dr. Dutton's affidavit does not proffer specific facts.

Similarly, the Commonwealth's declaration from financial investigator Colleen Frost does not demonstrate that the IFRs will cause injury to the Commonwealth. Frost estimates that between 365,000 and 380,000 Massachusetts residents, or roughly 25% of the women residents, are between the ages of 15 and 45 with employer or union provided health insurance and in household insurance units with income less than or equal to 300%

of the Federal Poverty Level. That estimate does not alone demonstrate that the Commonwealth will incur a significant financial burden. The declaration is intended to establish that "a significant percentage of Massachusetts women who lose employer-sponsored coverage will be eligible" to receive care through Massachusetts programs.

To the extent the estimated number of women includes government employees and employees protected by Massachusetts' ACCESS Act who could not be affected by the expanded exemptions, the estimate is meaningless. More importantly, however, because the plaintiff has not demonstrated that any particular women in Massachusetts will likely lose contraceptive coverage because of the expanded exemptions, the estimate does not demonstrate that the Commonwealth will incur an injury to the state fisc. It is the Commonwealth's burden to set forth specific facts sufficient to support standing and it has not satisfied that burden. See United States v. AVX Corp., 962 F.2d 108, 120 (1st Cir. 1992).

Article III standing is a threshold issue in every case. McInnis-Misenor v. Maine Med. Ctr., 319 F.3d 63, 67 (1st Cir. 2003). It "is upon the litigant whose standing is challenged" to demonstrate that the case is properly justiciable. Town of Norwood v. F.E.R.C., 202 F.3d 392, 405 (1st Cir. 2000) (citations omitted). At the summary judgment stage, a party "cannot rest on mere allegations, but must set forth by

affidavit or other evidence specific facts" which the Court will accept as true. Libertad v. Welch, 53 F.3d 428, 436 (1st Cir. 1995) (citing Defs. of Wildlife, 504 U.S. at 561-62). Here, the record is devoid of necessary specific facts.

In Libertad, for instance, the First Circuit held that an association failed to demonstrate standing because the court

> combed through the voluminous record and [was] unable to find any evidence, or even any specific allegation, that the [association] ha[d] sustained any injury to business or property as a result of Appellees' conduct.

See id. at 437; cf. id. at 437 n.4 (explaining that the association "could have standing to sue . . . [but that] [t]he record before us, . . . does not sufficiently establish" the required element of injury).

In contrast to that association, clinics and directors demonstrated standing because the record was

> replete with evidence of the extensive property damage caused by Appellees' blockades at the clinics: broken locks, damages gates, vandalism, strewn litter on the grounds, to give examples.

Id. at 437-38.

The Commonwealth does not need a record "replete with evidence", but it does need specific facts demonstrating that it is "likely to suffer future injury" from the defendants' conduct. See City of Los Angeles v. Lyons, 461 U.S. 95, 105, (1983). Plaintiff, "as the party invoking federal jurisdiction, bears the burden of establishing" standing. Spokeo, Inc. v.

Robins, 136 S. Ct. 1540, 1547 (2016), as revised (May 24, 2016). Where the nonmoving party bears the burden of proof on an issue, it "must point to specific facts to defeat summary judgment." Advanced Flexible Circuits, Inc. v. GE Sensing & Inspection Techs. GmbH, 781 F.3d 510, 518 (1st Cir. 2015) (citing Ahern v. Shinseki, 629 F.3d 49, 54 (1st Cir. 2010)).

Quasi-sovereign interests

The Commonwealth asserts that the IFRs will inflict an injury to its quasi-sovereign interests in the health and well-being of its residents and in securing its residents from the harmful effects of discrimination. Massachusetts has, however, failed to set forth facts demonstrating such a claim.

Quasi-sovereign interests, which are distinct from sovereign, proprietary and sovereign interests, consist of a "set of interests that a state has in the well-being of its populace." Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez, 458 U.S. 592, 602 (1982). Two general categories of quasi-sovereign interests are well accepted:

> First, a State has a quasi-sovereign interest in the health and well-being-both physical and economic-of its residents in general. Second, a State has a quasi-sovereign interest in not being discriminatorily denied its rightful status within the federal system.

Id. at 607.

In such a case, the state does not allege a direct injury or sue on its own behalf. See, e.g., State of Ga. v. Tennessee

Copper Co., 206 U.S. 230, 237 (1907) (finding that Georgia has standing to bring injunctive action against out-of-state corporation because it "has an interest independent of and behind the titles of its citizens, in all the earth and air within its domain"). Rather, a state sues in a representative capacity as parens patriae of its citizens. See Wyoming v. Oklahoma, 502 U.S. 437, 448–449, 451 (1992).

The Commonwealth argues that, as a state asserting a quasi-sovereign interest, it is "entitled to special solicitude in the standing analysis." Although a state may not "protect her citizens from the operation of federal statutes," a state may "assert its rights under federal law." Massachusetts v. EPA, 549 U.S. at 520 n. 10. Accordingly, where a state has a procedural right and a stake in protecting its "quasi-sovereign interests," it is "entitled to special solicitude in [the court's] standing analysis." Massachusetts, 549 U.S. at 520. The Departments dispute whether the Commonwealth can assert an interest that is separate from the personal interest of the affected women, such that it cannot assert an injury to a quasi-sovereign interest.

This Court need not determine whether Massachusetts is entitled to special solicitude in this case because, even if it is, the Commonwealth cannot overcome the lack of specific facts in the record. The Supreme Court held in the Massachusetts opinion that

> Because the Commonwealth owns a substantial portion of the state's coastal property, . . . it has alleged a particularized injury in its capacity as a landowner.

Id. at 522 (internal citation omitted) (footnote omitted). Nothing in the majority's opinion indicates that "but for" the special solicitude accorded the Commonwealth, it would not have satisfied the injury-in-fact element of standing.

Plaintiff's quasi-sovereign interest theory of standing is wanting for the same reason as its financial harm theory: lack of specific facts demonstrating that the Commonwealth will likely be injured. The Commonwealth does not identify any particular woman who is likely to lose contraceptive coverage because of the IFRs. It does not identify any Massachusetts employer that is likely to avail itself of the expanded exemptions. The proportional estimate relies on conjecture and speculation. The Commonwealth's affidavits with respect to whether women in the state will be affected are conclusory and bereft of substance.

To satisfy the injury-in-fact requirement, plaintiffs "need only show that they were directly affected by the conduct complained of, and therefore have a personal stake in the suit." Libertad, 53 F.3d at 439. "[I]t does not suffice for plaintiffs to show merely that they bring a justiciable issue before the court." Becker v. Fed. Election Comm'n, 230 F.3d 381, 385 (1st Cir. 2000). The Commonwealth must demonstrate standing "in the

same way as any other matter on which the plaintiff bears the burden of proof." Hochendoner v. Genzyme Corp., 823 F.3d 724, 730 (1st Cir. 2016) (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992)). Just as plaintiff fails to demonstrate that its fisc will be injured by the expanded exemptions, it has not demonstrated that the health and well-being of its citizens will be adversely affected by the IFRs. Cf. United States v. AVX Corp., 962 F.2d 108, 117 (1st Cir. 1992) ("[S]peculative argumentation . . . cannot pass muster where standing is contested").

Procedural Injury

The Commonwealth contends that defendants' failure to engage in notice and comment rulemaking in violation of the APA creates a procedural injury sufficient to create Article III standing.

To establish injury-in-fact in the procedural injury setting, a plaintiff must show that the government action at issue "will cause a distinct risk to a particularized interest of the plaintiff." Town Of Winthrop v. F.A.A., 535 F.3d 1, 6 (1st Cir. 2008) (citations omitted). The Commonwealth proposes that "the IFRs will directly harm Massachusetts' economic and quasi-sovereign interests." The State has failed, however, to demonstrate that an actual injury to its economic or quasi-

sovereign interests is likely to occur. Accordingly, its procedural injury theory is lacking as well.

Merits

"Standing is a threshold question in every case", Summers v. Fin. Freedom Acquisition LLC, 807 F.3d 351, 355 (1st Cir. 2015) (citing Warth v. Seldin, 422 U.S. 490, 498, (1975)) and this Court finds that plaintiff has failed to set forth specific facts demonstrating that it is likely to incur an injury caused by defendants' conduct. Cf. Defs. of Wildlife, 504 U.S. at 561. Accordingly, the Court declines, at this time, to address the merits of the Commonwealth's statutory or constitutional claims.

ORDER

For the foregoing reasons, plaintiff's motion for summary judgment (Docket No. 21) is **DENIED** and defendants' motion for summary judgment (Docket No. 32) is **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton____
Nathaniel M. Gorton
United States District Judge

Dated March 12, 2018

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 6A. Public Health Service (Refs & Annos)
Subchapter XXV. Requirements Relating to Health Insurance Coverage (Refs & Annos)
Part A. Individual and Group Market Reforms (Refs & Annos)
Subpart II. Improving Coverage (Refs & Annos)

42 U.S.C.A. § 300gg-13

§ 300gg-13. Coverage of preventive health services

Currentness

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for--

(1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and [1]

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph. [2]

(5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) Interval

(1) In general

The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) Minimum

The interval described in paragraph (1) shall not be less than 1 year.

(c) Value-based insurance design

The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

CREDIT(S)

(July 1, 1944, c. 373, Title XXVII, § 2713, as added Pub.L. 111-148, Title I, § 1001(5), Mar. 23, 2010, 124 Stat. 131.)

Footnotes

1 So in original. The word "and" probably should not appear.

2 So in original. The period probably should be a semicolon.

42 U.S.C.A. § 300gg-13, 42 USCA § 300gg-13

Current through P.L. 115-223. Also includes P.L. 115-225 to 115-231 and 115-235, 115-236. Title 26 current through P.L. 115-237.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9827]

RIN 1545–BN92

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9940–IFC]

RIN 0938–AT20

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions. These interim final rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave the ''accommodation'' process in place as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These interim final rules and temporary regulations are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by ''Preventive Services,'' may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9940–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9940–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492–4305 or *marketreform@cms.hhs.gov* for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Congress has consistently sought to protect religious beliefs in the context of health care and human services, including health insurance, even as it has sought to promote access to health services.[1] Against that backdrop,

[1] See, for example, 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their ''religious beliefs or moral convictions''); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–31 (protecting any ''health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan'' in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of ''the provision of

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, ''with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by'' by HRSA (the ''Guidelines''). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, ''the Departments'' [3])—exercised the same discretion to allow exemptions to those requirements. Through rulemaking, including three interim final rules, the Departments allowed exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or the ''Mandate'') as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1. Much of that litigation continues to this day.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as the interests served by the existing Guidelines, regulations, and accommodation process; [4] the extensive litigation; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); protection of the free exercise of religion in the First Amendment and by Congress in the Religious Freedom Restoration Act of 1993; Congress' history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under section 2713(a)(4) of the PHS Act; the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; the regulatory process and comments submitted in various requests for public comments (including in the Departments' 2016 Request for Information).

In light of these factors, the Departments issue these new interim final rules to better balance the Government's interest in ensuring coverage for contraceptive and sterilization services in relation to the Government's interests, including as reflected throughout Federal law, to provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, ''[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.''

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS Act requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

contraceptive coverage by health insurance plans'' in the District of Columbia, ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions.''); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions''); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their ''religious or conscientious commitment to offer only natural family planning''); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on ''religious beliefs or moral objections''); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on ''conscience'' as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on ''moral or religious grounds''); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on ''religious beliefs or moral convictions''); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); also, see 8 U.S.C. 1182(g) (protecting vaccination objections by ''aliens'' due to ''religious beliefs or moral convictions''); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on ''moral or religious convictions''); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their ''religious or moral objection'').

[2] This document's references to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

[3] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[4] In this document, we generally use ''accommodation'' and ''accommodation process'' interchangeably.

The Departments have consistently interpreted section 2714(a)(4) PHS Act's grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act's reference to ''comprehensive guidelines supported by HRSA for purposes of this paragraph'' to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines ''supported by HRSA for purposes of this paragraph,'' the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from ''the other guidelines referenced in section 2713(a) of the PHS Act, which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients.'' Id. Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4) of the PHS Act, the Departments have previously promulgated regulations defining the scope of permissible exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92)

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 of the PHS Act for grandfathered plans. In contrast, this exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include: Section 2704 of the PHS Act, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708 of the PHS Act, which prohibits excessive waiting periods (as of January 1, 2014); section 2711 of the PHS Act, which relates to lifetime limits; section 2712 of the PHS Act, which prohibits rescission of health insurance coverage; section 2714 of the PHS Act, which extends dependent coverage until age 26; and section 2718 of the PHS Act, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that ''longstanding Federal laws to protect conscience * * * remain intact,'' including laws that protect religious beliefs (and moral convictions) from certain requirements in the health care context. While the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect religious beliefs regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in accordance with the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, ''Clinical Preventive Services for Women, Closing the Gaps'' (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[6]

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of ''contraceptives'' certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,[7] the IOM's recommendation included several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason

[5] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[6] Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings ''with respect to women,'' the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[7] FDA's guide ''Birth Control: Medicines To Help You,'' specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and ''may also work * * * by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

distinct from whether they also oppose contraception or sterilization.

One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He argued that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by the United States Preventive Services Task Force (USPSTF), HRSA's Bright Futures Project, and the Advisory Committee on Immunization Practices (ACIP) leads to lower rates of disability or disease and increased rates of well-being. He further argued that ''the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered,'' and that ''the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy.'' Dr. LoSasso also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] (IOM 2011 at 231–32). In its response to Dr. LoSasso, the other 15 committee members stated, in part, that ''At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions.''

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM *https://www.hrsa.gov/womensguidelines/*. The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specify that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.[9] The 2011 interim final rules defined an exempt ''religious employer'' narrowly as one that: (1) Had the inculcation of religious values as its purpose; (2) primarily employed persons who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a nonprofit organization, as described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Those relevant sections of the Code include only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of a religious order. The practical effect of the rules' definition of ''religious employer'' was to create potential uncertainty about whether employers, including many of those houses of worship or their integrated auxiliaries, would fail to qualify for the exemption if they engaged in outreach activities toward persons who did not share their religious tenets.[10] As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some ''States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services.'' (76 FR 46623). That same day, HRSA exercised the discretion described in the 2011 interim final rules to provide the exemption.

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of ''religious employer'' in the 2011 interim final rules without modification (2012 final regulations).[11] (77 FR 8725). The exemption did not require religious employers to file any certification form or comply with any other information collection process.

Contemporaneous with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).[12] The guidance provided that the temporary safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. The temporary safe harbor did not apply to for-profit entities. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve ''two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services.'' (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of ''religious employer'' for purposes of the religious employer

[8] The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

[9] The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011 (76 FR 46621).

[10] See, for example, Comments of the United States Conference of Catholic Bishops on Interim Final Rules on Preventive Services, File Code CMS–9992–IFC2 (Aug. 31, 2011).

[11] The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

[12] Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: *http://www.lb7.uscourts.gov/documents/12cv3932.pdf*. The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled ''Student Health Insurance Coverage'' published March 21, 2012 (77 FR 16457).

exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer (1) have the inculcation of religious values as its purpose, (2) primarily employ persons who share its religious tenets, and (3) primarily serve persons who share its religious tenets.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible religious nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations ''may be less likely than'' employees of exempt houses of worship and integrated auxiliaries to share their employer's faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization's plan—and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries.

On August 15, 2012, the Departments also extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

[13] The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations ''does not undermine the governmental interests furthered by the contraceptive coverage requirement.'' (78 FR 39874). But, like the 2013 NPRM, the July 2013 regulations assumed that ''[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection'' to contraceptives (*Id.*).

The July 2013 regulations also finalized an accommodation for eligible organizations. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization's plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect.[14] With respect to fully insured group health plans, the issuer was expected to bear the cost of such payments,[15] and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations.

With respect to self-insured group health plans, the July 2013 final regulations specified that the self-certification was an instrument under which the plan was operated and that it obligated the third party administrator to provide or arrange for contraceptive coverage by operation of section 3(16) of ERISA. The regulations stated that, by submitting the self-certification form, the eligible organization ''complies'' with the contraceptive coverage requirement and does not have to contract, arrange, pay, or refer for contraceptive coverage. See, for example, Id. at 39874, 39896. Consistent with these statements, the Departments, through the Department of Labor, issued a self-certification form, EBSA Form 700. The form stated, in indented text labeled as a ''Notice to Third Party Administrators of Self-Insured Health Plans,'' that ''[t]he obligations of the third party administrator are set forth in 26 CFR 54.9815–2713A, 29 CFR 2510.3–16, and 29 CFR 2590.715–2713A'' and concluded, in unindented text, that ''[t]his form is an instrument under which the plan is operated.''

The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. The guidance extending the safe harbor included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary safe harbor if no prior form had been submitted.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others. Religious plaintiffs principally argued that the Mandate violated the Religious Freedom Restoration Act of 1993 (RFRA) by forcing them to provide coverage or payments for sterilization and contraceptive services, including what they viewed as early abortifacient items, contrary to their religious beliefs. Based on this claim, in July 2012 a

[14] See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.

[15] ''[P]roviding payments for contraceptive services is cost neutral for issuers.'' (78 FR 39877).

Federal district court issued a preliminary injunction barring the Departments from enforcing the Mandate against a family-owned business. *Newland* v. *Sebelius,* 881 F. Supp. 2d. 1287 (D. Colo. 2012). Multiple other courts proceeded to issue similar injunctions against the Mandate, although a minority of courts ruled in the Departments' favor. *Compare Tyndale House Publishers, Inc.* v. *Sebelius,* 904 F. Supp. 2d 106 (D.D.C. 2012), and *The Seneca Hardwood Lumber Company, Inc.* v. *Sebelius* (sub nom *Geneva Coll.* v. *Sebelius),* 941 F. Supp. 2d 672 (W.D. Pa. 2013), with *O'Brien* v. *U.S. Dep't of Health & Human Servs.,* 894 F. Supp. 2d 1149 (E.D. Mo. 2012).

A circuit split swiftly developed in cases filed by religiously motivated for-profit businesses, to which neither the religious employer exemption nor the eligible organization accommodation (as then promulgated) applied. Several for-profit businesses won rulings against the Mandate before the Unites States Court of Appeals for the Tenth Circuit, sitting en banc, while similar rulings against the Departments were issued by the Seventh and District of Columbia (DC) Circuits. *Hobby Lobby Stores, Inc.* v. *Sebelius,* 723 F.3d 1114 (10th Cir. 2013); *Korte* v. *Sebelius,* 735 F.3d 654 (7th Cir. 2013); *Gilardi* v. *U.S. Dep't of Health & Human Servs.,* 733 F.3d 1208 (D.C. Cir. 2013). The Third and Sixth Circuits disagreed with similar plaintiffs, and in November 2013 the U.S. Supreme Court granted certiorari in *Hobby Lobby* and *Conestoga Wood Specialties Corp.* v. *Secretary of U.S. Department of Health & Human Services,* 724 F.3d 377 (3d Cir. 2013), to resolve the circuit split.

On June 30, 2014, the Supreme Court ruled against the Departments and held that, under RFRA, the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[16] *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Court held that the ''contraceptive mandate 'substantially burdens' the exercise of religion'' as applied to employers that object to providing contraceptive coverage on religious grounds, and that the plaintiffs were therefore entitled to an exemption unless the Mandate was the least restrictive means of furthering a compelling governmental interest. *Id.* at 2775. The Court observed that, under the compelling interest test of RFRA, the Departments could not rely on interests ''couched in very broad terms, such as promoting 'public health' and 'gender equality,' but rather, had to demonstrate that a compelling interest was served by refusing an exemption to the ''particular claimant[s]'' seeking an exemption. *Id.* at 2779. Assuming without deciding that a compelling interest existed, the Court held that the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner. The Court observed that ''[t]he most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections.'' *Id.* at 2780. The Court also observed that the Departments had ''not provided any estimate of the average cost per employee of providing access to these contraceptives,'' nor ''any statistics regarding the number of employees who might be affected because they work for corporations like Hobby Lobby, Conestoga, and Mardel''. *Id.* at 2780–81. But the Court ultimately concluded that it ''need not rely on the option of a new, government-funded program in order to conclude that the HHS regulations fail the least-restrictive means test'' because ''HHS itself ha[d] demonstrated that it ha[d] at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs.'' *Id.* at 2781–82. The Court explained that the ''already established'' accommodation process available to nonprofit organizations was a less-restrictive alternative that ''serve[d] HHS's stated interests equally well,'' although the Court emphasized that its ruling did not decide whether the accommodation process ''complie[d] with RFRA for purposes of all religious claims''. *Id.* at 2788–82.

Meanwhile, another plaintiff obtained temporary relief from the Supreme Court in a case challenging the accommodation under RFRA. Wheaton College, a Christian liberal arts college in Illinois, objected that the accommodation was a compliance process that rendered it complicit in delivering payments for abortifacient contraceptive services to its employees. Wheaton College refused to execute the EBSA Form 700 required under the July 2013 final regulations. It was denied a preliminary injunction in the Federal district and appellate courts, and sought an emergency injunction pending appeal from the Unites States Supreme Court on June 30, 2014. On July 3, 2014, the Supreme Court issued an interim order in favor of the College, stating that, ''[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing [the Mandate] against the [plaintiff] . . . pending final disposition of appellate review.'' *Wheaton College* v. *Burwell.* 134 S. Ct. 2806, 2807 (2014). The order stated that Wheaton College did not need to use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for injunctive relief. *Id.*

In response to this litigation, on August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of the Department of Health and Human Services that an eligible organization had religious objections to coverage of all or a subset of contraceptive services. (79 FR 51092). In response to *Hobby Lobby,* the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations. (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption, and neither added a certification requirement for exempt entities.

In October 2014, based on an interpretation of the Supreme Court's interim order, HHS deemed Wheaton College as having submitted a sufficient notice to HHS. HHS conveyed that interpretation to the DOL, so as to trigger the accommodation process.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The preamble to the July 2015 final regulations stated that, through the accommodation, payments

[16] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

for contraceptives and sterilization would be provided in a way that is ''seamless'' with the coverage that eligible employers provide to their plan participants and beneficiaries. *Id.* at 41328. The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

When an eligible organization maintains an insured group health plan or student health plan and provides the alternative notice, the July 2015 final regulations provide that HHS will inform the health insurance issuer of its obligations to cover contraceptive services to which the eligible organization objects. Where an eligible organization maintains a self-insured plan under ERISA and provides the alternative notice, the regulations provide that DOL will work with HHS to send a separate notification to the self-insured plan's third party administrator(s). The regulations further provide that such notification is an instrument under which the plan is operated for the purposes of section 3(16) of ERISA, and the instrument would designate the third party administrator as the entity obligated to provide or arrange for payments for contraceptives to which the eligible organization objects. The July 2015 final regulations continue to apply the amended notice requirement to eligible organizations that sponsor church plans exempt from ERISA pursuant to section 4(b)(2) of ERISA, but acknowledge that, with respect to the operation of the accommodation process, section 3(16) of ERISA does not provide a mechanism to impose an obligation to provide contraceptive coverage as a plan administrator on those eligible organizations' third party administrators. (80 FR 41323).

Meanwhile, a second split among Federal appeals courts had developed involving challenges to the Mandate's accommodation. Many religious nonprofit organizations argued that the accommodation impermissibly burdened their religious beliefs because it utilized the plans the organizations themselves sponsored to provide services to which they objected on religious grounds. They objected to the self-certification requirement on the same basis. Federal district courts split in the cases, granting preliminary injunction motions to religious groups in the majority of cases, but denying them to others. In most appellate cases, religious nonprofit organizations lost their challenges, where the courts often concluded that the accommodation imposed no substantial burden on their religious exercise under RFRA. For example, *Priests for Life* v. *U.S. Dep't of Health and Human Servs.,* 772 F. 3d 229 (D.C. Cir. 2014); *Little Sisters of the Poor Home for the Aged* v. *Burwell,* 794 F.3d 1151 (10th Cir. 2015); *Geneva Coll.* v. *Sec'y U.S. Dep't of Health & Human Servs.,* 778 F.3d 422 (3d Cir. 2015). But the Eighth Circuit disagreed and ruled in favor of religious nonprofit employers. *Dordt College* v. *Burwell,* 801 F.3d 946, 949–50 (8th Cir. 2015) (relying on *Sharpe Holdings, Inc.* v. *U.S. Dep't of Health & Human Servs.,* 801 F.3d 927 (8th Cir. 2015)).

On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik* v. *Burwell.* The Court held oral argument on March 23, 2016, and, after the argument, asked the parties to submit supplemental briefs addressing ''whether and how contraceptive coverage may be obtained by petitioners' employees through petitioners' insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees''. In a brief filed with the Supreme Court on April 12, 2016, the Government stated on behalf of the Departments that the accommodation process for eligible organizations with insured plans could operate without any self-certification or written notice being submitted by eligible organizations.

On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik,* vacating the judgments of the Courts of Appeals and remanding the cases ''in light of the substantial clarification and refinement in the positions of the parties'' in their supplemental briefs. (136 S. Ct. 1557, 1560 (2016).) The Court stated that it anticipated that, on remand, the Courts of Appeals would ''allow the parties sufficient time to resolve any outstanding issues between them.'' *Id.* The Court also specified that ''the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice'' while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, some meetings were held between attorneys for the Government and for the plaintiffs in those cases. Separately, at various times after the Supreme Court's remand order, HHS and DOL sent letters to the issuers and third party administrators of certain plaintiffs in *Zubik* and other pending cases, directing the issuers and third party administrators to provide contraceptive coverage for participants in those plaintiffs' group health plans under the accommodation. The Departments also issued a Request for Information (RFI) on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016.

On December 20, 2016, HRSA updated the Guidelines via its Web site, *https://www.hrsa.gov/womensguidelines2016/index.html.* HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the contraceptive method). They also specified that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process.

On January 9, 2017, the Departments issued a document entitled, ''FAQs About Affordable Care Act Implementation Part 36'' (FAQ).[17] The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. Thus, the

[17] Available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

litigation on remand from the Supreme Court remains unresolved.

A separate category of unresolved litigation involved religious employees as plaintiffs. For example, in two cases, the plaintiff-employees work for a nonprofit organization that agrees with the employees (on moral grounds) in opposing coverage of certain contraceptives they believe to be abortifacient, and that is willing to offer them insurance coverage that omits such services. See *March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015); *Real Alternatives,* 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). In another case, the plaintiff-employees work for a State government entity that the employees claim is willing, under State law, to provide a plan omitting contraception consistent with the employees' religious beliefs. See *Wieland* v. *HHS,* 196 F. Supp. 3d 1010 (E.D. Mo. 2016). Those and similar employee-plaintiffs generally contend that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from their willing employer or in the individual market, because the Departments offer no exemptions encompassing either circumstance. Such challenges have seen mixed success. Compare, for example, *Wieland,* 196 F. Supp. 3d at 1020 (concluding that the Mandate violates the employee plaintiffs' rights under RFRA and permanently enjoining the Departments) and *March for Life,* 128 F. Supp. 3d at 133–34 (same), with *Real Alternatives,* 2017 WL 3324690 at *18 (affirming dismissal of employee plaintiffs' RFRA claim).

On May 4, 2017, the President issued an ''Executive Order Promoting Free Speech and Religious Liberty.'' Regarding ''Conscience Protections with Respect to Preventive-Care Mandate,'' that order instructs ''[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services [to] consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code.''

II. RFRA and Government Interests Underlying the Mandate

RFRA provides that the Government ''shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability'' unless the Government ''demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.'' 42 U.S.C. 2000bb–1(a) and (b). In *Hobby Lobby,* the Supreme Court had ''little trouble concluding'' that, in the absence of an accommodation or exemption, ''the HHS contraceptive mandate 'substantially burden[s]' the exercise of religion. 42 U.S.C. 2000bb–1(a).'' 134 S. Ct. at 2775. And although the Supreme Court did not resolve the RFRA claims presented in *Zubik* on their merits, it instructed the parties to consider alternative accommodations for the objecting plaintiffs, after the Government suggested that such alternatives might be possible.

Despite multiple rounds of rulemaking, however, the Departments have not assuaged the sincere religious objections to contraceptive coverage of numerous organizations, nor have we resolved the pending litigation. To the contrary, the Departments have been litigating RFRA challenges to the Mandate and related regulations for more than 5 years, and dozens of those challenges remain pending today. That litigation, and the related modifications to the accommodation, have consumed substantial governmental resources while creating uncertainty for objecting organizations, issuers, third party administrators, employees, and beneficiaries. Consistent with the President's Executive Order and the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.

These interim final rules (and the companion interim final rules published elsewhere in this **Federal Register**) are the result of that reexamination. The Departments acknowledge that coverage of contraception is an important and highly sensitive issue, implicating many different views, as reflected in the comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. After reconsidering the interests served by the Mandate in this particular context, the objections raised, and the applicable Federal law, the Departments have determined that an expanded exemption, rather than the existing accommodation, is the most appropriate administrative response to the religious objections raised by certain entities and organizations concerning the Mandate. The Departments have accordingly decided to revise the regulations channeling HRSA authority under section 2713(a)(4) of the PHS to provide an exemption from the Mandate to a broader range of entities and individuals that object to contraceptive coverage on religious grounds, while continuing to offer the existing accommodation as an optional alternative. The Departments have also decided to create a process by which a willing employer and issuer may allow an objecting individual employee to obtain health coverage without contraceptive coverage. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

In addition to relying on the text of section 2713(a)(4) of the PHS Act and the Departments' discretion to promulgate rules to carry out the provisions of the PHS Act, the Departments also draw on Congress' decision in the Affordable Care Act neither to specify that contraception must be covered nor to require inflexible across-the-board application of section 2713 of the PHS Act. The Departments further consider Congress' extensive history of protecting religious objections when certain matters in health care are specifically regulated—often specifically with respect to contraception, sterilization, abortion, and activities connected to abortion.

Notable among the many statutes (listed in footnote 1 in Section I-Background) that include protections for religious beliefs are, not only the Church Amendments, but also protections for health plans or health care organizations in Medicaid or Medicare Advantage to object ''on moral or religious grounds'' to providing coverage of certain counseling or referral services. (42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1396u–2(b)(3)). In addition, Congress has protected individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31 (May 5, 2017). Congress likewise provided that, if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans,'' ''it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for

religious beliefs and moral convictions''. *Id.* at Division C, Title VIII, Sec. 808. In light of the fact that Congress did not require HRSA to include contraception in Guidelines issued under section 2713 of the PHS Act, we consider it significant, in support of the implementation of those Guidelines by the expanded exemption in these interim final rules, that Congress' most recent statement on the prospect of Government mandated contraceptive coverage was to express the specific intent that a conscience clause be provided and that it should protect religious beliefs.

The Departments' authority to guide HRSA's discretion in determining the scope of any contraceptive coverage requirement under section 2713(a)(4) of the PHS Act includes the authority to provide exemptions and independently justifies this rulemaking. The Departments have also determined that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance violates their rights under RFRA.

A. Elements of RFRA

1. Substantial Burden

The Departments believe that agencies charged with administering a statute or associated regulations or guidance that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining how to avoid the imposition of such burden. The Departments have previously contended that the Mandate does not impose a substantial burden on entities and individuals. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with religious objections, our argument was rejected in *Hobby Lobby,* which held that the Mandate imposes a substantial burden. (134 S. Ct. at 2775–79.) With respect to whether the Mandate imposes a substantial burden on entities that may choose the accommodation, but must choose between the accommodation, the Mandate, or penalties for noncompliance, a majority of Federal appeals courts have held that the accommodation does not impose a substantial burden on such entities (mostly religious nonprofit entities).

The Departments have reevaluated our position on this question, however, in light of all the arguments made in various cases, public comments that have been submitted, and the concerns discussed throughout these rules. We have concluded that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA. We believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing a substantial burden, to the burdens that an entity faces when it religiously opposes participating in the accommodation process or the straightforward Mandate, and is subject to penalties or disadvantages that apply in this context if it chooses neither. As the Eighth Circuit stated in *Sharpe Holdings,* ''[i]n light of [nonprofit religious organizations'] sincerely held religious beliefs, we conclude that compelling their participation in the accommodation process by threat of severe monetary penalty is a substantial burden on their exercise of religion. . . . That they themselves do not have to arrange or pay for objectionable contraceptive coverage is not determinative of whether the required or forbidden act is or is not religiously offensive''. (801 F.3d at 942.)

Our reconsideration of these issues has also led us to conclude, consistent with the rulings in favor of religious employee plaintiffs in *Wieland* and *March for Life* cited above, that the Mandate imposes a substantial burden on the religious beliefs of individual employees who oppose contraceptive coverage and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because of the Mandate's prohibition on that employer and/or issuer providing them with such a plan.

Consistent with our conclusion earlier this year after the remand of cases in *Zubik* and our reviewing of comments submitted in response to the 2016 RFI, the Departments believe there is not a way to satisfy all religious objections by amending the accommodation. Accordingly, the Departments have decided it is necessary and appropriate to provide the expanded exemptions set forth herein.

2. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Under such circumstances, the Departments are required by law to alleviate the substantial burden created by the Mandate. Here, informed by the Departments' reassessment of the relevant interests, as well as by our desire to bring to a close the more than 5 years of litigation over RFRA challenges to the Mandate, the Departments have determined that the appropriate administrative response is to create a broader exemption, rather than simply adjusting the accommodation process.

RFRA requires the Government to respect religious beliefs under ''the most demanding test known to constitutional law'': Where the Government imposes a substantial burden on religious exercise, it must demonstrate a compelling governmental interest and show that the law or requirement is the least restrictive means of furthering that interest. *City of Boerne* v. *Flores,* 521 U.S. 507, 534 (1997). For an interest to be compelling, its rank must be of the ''highest order''. *Church of the Lukumi Babalu Aye, Inc.* v. *City of Hialeah,* 508 U.S. 520, 546 (1993); see also *Sherbert* v. *Verner,* 374 U.S. 398, 406–09 (1963); *Wisconsin* v. *Yoder,* 406 U.S. 205, 221–29 (1972). In applying RFRA, the Supreme Court has ''looked beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants.'' *Gonzales* v. *O Centro Espirita Beneficente Uniao do Vegetal,* 546 U.S. 418, 431 (2006). To justify a substantial burden on religious exercise under RFRA, the Government must show it has a compelling interest in applying the requirement to the ''particular claimant[s] whose sincere exercise of religion is being substantially burdened.'' *Id.* at 430–31. Moreover, the Government must meet the ''exceptionally demanding'' least-restrictive-means standard. *Hobby Lobby,* 134 S. Ct. at 2780. Under that standard, the Government must establish that ''it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting parties.'' *Id.*

Upon further examination of the relevant provisions of the Affordable Care Act and the administrative record on which the Mandate was based, the Departments have concluded that the application of the Mandate to entities with sincerely held religious objections to it does not serve a compelling governmental interest. The Departments have reached that conclusion for multiple reasons, no one of which is dispositive.

First, Congress did not mandate that contraception be covered at all under the Affordable Care Act. Instead, Congress merely provided for coverage

of ''such additional preventive care and screenings'' for women ''provided for in comprehensive guidelines supported by [HRSA].'' Congress, thus, left the identification of any additional required preventive services for women to administrative discretion. The fact that Congress granted the Departments the authority to promulgate all rules appropriate and necessary for the administration of the relevant provisions of the Code, ERISA, and the PHS Act, including by channeling the discretion Congress afforded to HRSA to decide whether to require contraceptive coverage, indicates that the Departments' judgment should carry particular weight in considering the relative importance of the Government's interest in applying the Mandate to the narrow population of entities exempted in these rules.

Second, while Congress specified that many health insurance requirements added by the Affordable Care Act—including provisions adjacent to section 2713 of the PHS Act—were so important that they needed to be applied to all health plans immediately, the preventive services requirement in section 2713 of the PHS Act was not made applicable to ''grandfathered plans.'' That feature of the Affordable Care Act is significant: As cited above, seven years after the Affordable Care Act's enactment, approximately 25.5 million people are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act. We do not suggest that a requirement that is inapplicable to grandfathered plans or otherwise subject to exceptions could never qualify as a serving a compelling interest under RFRA. For example, ''[e]ven a compelling interest may be outweighed in some circumstances by another even weightier consideration.'' *Hobby Lobby,* 134 S. Ct. at 2780. But Congress' decision not to apply section 2713 of the PHS Act to grandfathered plans, while deeming other requirements closely associated in the same statute as sufficiently important to impose immediately, is relevant to our assessment of the importance of the Government interests served by the Mandate. As the Departments observed in 2010, those immediately applicable requirements were ''particularly significant.'' (75 FR 34540). Congress' decision to leave section 2713 out of that category informs the Departments' assessment of the weight of the Government's interest in applying the Guidelines issued pursuant to section 2713 of the PHS Act to religious objectors.

Third, various entities that brought legal challenges to the Mandate (including some of the largest employers) have been willing to provide coverage of some, though not all, contraceptives. For example, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of 14 of 18 FDA-approved women's contraceptive and sterilization methods. (134 S. Ct. at 2766.) With respect to organizations and entities holding those beliefs, the fact that they are willing to provide coverage for various contraceptive methods significantly detracts from the government interest in requiring that they provide coverage for other contraceptive methods to which they object.

Fourth, the case for a compelling interest is undermined by the existing accommodation process, and how it applies to certain similarly situated entities based on whether or not they participate in certain self-insured group health plans, known as church plans, under applicable law. The Departments previously exempted eligible organizations from the contraceptive coverage requirement, and created an accommodation under which those organizations bore no obligation to provide for such coverage after submitting a self-certification or notice. Where a non-exempt religious organization uses an insured group health plan instead of a self-insured church plan, the health insurance issuer would be obliged to provide contraceptive coverage or payments to the plan's participants under the accommodation. Even in a self-insured church plan context, the preventive services requirement in section 2713(a)(4) of the PHS Act applies to the plan, and through the Code, to the religious organization that sponsors the plan. But under the accommodation, once a self-insured church plan files a self-certification or notice, the accommodation relieves it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would normally transfer the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but not as they pertain to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs to become administrators of those plans to provide such coverage, has led to significant incongruity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

More specifically, issuers and third party administrators for some, but not all, religious nonprofit organizations are subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they participate in a self-insured church plan. Notably, many of those nonprofit organizations are not houses of worship or integrated auxiliaries. Under section 3(33)(C)(iv) of ERISA, many organizations in self-insured church plans need not be churches, but can merely ''share[] common religious bonds and convictions with [a] church or convention or association of churches''. The effect is that many similar religious organizations are being treated very differently with respect to their employees receiving contraceptive coverage—depending on whether the organization is part of a church plan—even though the Departments claimed a compelling interest to deny exemptions to all such organizations. In this context, the fact that the Mandate and the Departments' application thereof ''leaves appreciable damage to [their] supposedly vital interest unprohibited'' is strong evidence that the Mandate ''cannot be regarded as protecting an interest 'of the highest order.' '' *Lukumi,* 508 U.S. at 520 (citation and quotation marks omitted).

Fifth, the Departments' previous assertion that the exemption for houses of worship was offered to respect a certain sphere of church autonomy (80 FR 41325) does not adequately explain some of the disparate results of the existing rules. And the desire to respect church autonomy is not grounds to prevent the Departments from expanding the exemption to other religious entities. The Departments previously treated religious organizations that operate in a similar fashion very differently for the purposes of the Mandate. For example, the Departments exempted houses of worship and integrated auxiliaries that may conduct activities, such as the

operating of schools, that are also conducted by non-exempt religious nonprofit organizations. Likewise, among religious nonprofit groups that were not exempt as houses of worship or integrated auxiliaries, many operate their religious activities similarly even if they differ in whether they participate in self-insured church plans. As another example, two religious colleges might have the same level of religiosity and commitment to defined ideals, but one might identify with a specific large denomination and choose to be in a self-insured church plan offered by that denomination, while another might not be so associated or might not have as ready access to a church plan and so might offer its employees a fully insured health plan. Under the accommodation, employees of the college using a fully insured plan (or a self-insured plan that is not a church plan) would receive coverage of contraceptive services without cost sharing, while employees of the college participating in the self-insured church plan would not receive the coverage where that plan required its third party administrator to not offer the coverage.

As the Supreme Court recently confirmed, a self-insured church plan exempt from ERISA through ERISA 3(33) can include a plan that is not actually established or maintained by a church or by a convention or association of churches, but is maintained by ''an organization . . . the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches'' (a so-called ''principal-purpose organization''). See *Advocate Health Care Network* v. *Stapleton,* 137 S. Ct. 1652, 1656–57 (U.S. June 5, 2017); ERISA 3(33)(C). While the Departments take no view on the status of these particular plans, the Departments acknowledge that the church plan exemption not only includes some non-houses-of-worship as organizations whose employees can be covered by the plan, but also, in certain circumstances, may include plans that are not themselves established and maintained by houses of worship. Yet, such entities and plans—if they file a self-certification or notice through the existing accommodation—are relieved of obligations under the contraceptive Mandate and their third party administrators are not subject to a requirement that they provide contraceptive coverage to their plan participants and beneficiaries.

After considering the differential treatment of various religious nonprofit organizations under the previous accommodation, the Departments conclude that it is appropriate to expand the exemption to other religious nonprofit organizations with sincerely held religious beliefs opposed to contraceptive coverage. We also conclude that it is not appropriate to limit the scope of a religious exemption by relying upon a small minority of State laws that contain narrow exemptions that focus on houses of worship and integrated auxiliaries. (76 FR 46623.)

Sixth, the Government's interest in ensuring contraceptive coverage for employees of particular objecting employers is undermined by the characteristics of many of those employers, especially nonprofit employers. The plaintiffs challenging the existing accommodation include, among other organizations, religious colleges and universities, and religious orders that provide health care or other charitable services. Based in part on our experience litigating against such organizations, the Departments now disagree with our previous assertion that ''[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection.'' [18] (78 FR 39874.) Although empirical data was not required to reach our previous conclusion, we note that the conclusion was not supported by any specific data or other source, but instead was intended to be a reasonable assumption. Nevertheless, in the litigation and in numerous public comments submitted throughout the regulatory processes described above, many religious nonprofit organizations have indicated that they possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Some of the religious nonprofit groups challenging the accommodation claim that their employees are required to adhere to a statement of faith which includes the entities' views on certain contraceptive items.[19] The Departments recognize, of course, that not all of the plaintiffs challenging the accommodation require all of their employees (or covered students) to share their religious objections to contraceptives. At the same time, it has become apparent from public comments and from court filings in dozens of cases—encompassing hundreds of organizations—that many religious nonprofit organizations express their beliefs publicly and hold themselves out as organizations for whom their religious beliefs are vitally important. Employees of such organizations, even if not required to sign a statement of faith, often have access to, and knowledge of, the views of their employers on contraceptive coverage, whether through the organization's published mission statement or statement of beliefs, through employee benefits disclosures and other communications with employees and prospective employees, or through publicly filed lawsuits objecting to providing such coverage and attendant media coverage. In many cases, the employees of religious organizations will have chosen to work for those organizations with an understanding—explicit or implicit—that they were being employed to advance the organization's goals and to be respectful of the organization's beliefs even if they do not share all of those beliefs. Religious nonprofit organizations that engage in expressive activity generally have a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[20]

Given the sincerely held religious beliefs of many religious organizations, imposing the contraceptive-coverage requirement on those that object based on such beliefs might undermine the Government's broader interests in ensuring health coverage by causing the entities to stop providing health coverage. For example, because the Affordable Care Act does not require

[18] In changing its position, an agency ''need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates.'' *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009).

[19] See, for example, *Geneva College* v. *Sebelius*, 929 F. Supp. 2d 402, 411 (W.D. Pa. 2013); *Grace Schools* v. *Sebelius*, 988 F. Supp. 2d 935, 943 (N.D. Ind. 2013); Comments of the Council for Christian Colleges & Universities, re: CMS–9968–P (filed Apr. 8, 2013) (''On behalf of [] 172 higher education institutions . . . a requirement for membership in the CCCU is that full-time administrators and faculty at our institutions share the Christian faith of the institution.'').

[20] Notably, ''the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.'' *Boy Scouts of America* v. *Dale,* 530 U.S. 640, 655 (2000).

institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or be subject to the accommodation with respect to such populations.[21]

Seventh, we now believe the administrative record on which the Mandate rests is insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. To begin, in support of the IOM's recommendations, which HRSA adopted, the IOM identified several studies showing a preventive services gap because women require more preventive care than men. (IOM 2011 at 19–21). Those studies did not identify contraceptives or sterilization as composing a specific portion of that gap, and the IOM did not consider or establish in the report whether any cost associated with that gap remains after all other women's preventive services are covered without cost-sharing. *Id.* Even without knowing what the empirical data would show about that gap, the coverage of the other women's preventive services required under both the HRSA Guidelines and throughout section 2713(a) of the PHS Act—including annual well-woman visits and a variety of tests, screenings, and counseling services—serves at a minimum to diminish the cost gap identified by IOM for women whose employers decline to cover some or all contraceptives on religious grounds.[22]

Moreover, there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families. According to the Guttmacher Institute, government-subsidized family planning services are provided at 8,409 health centers overall.[23] The Title X program, for example, administered by the HHS Office of Population Affairs (OPA), provides a wide variety of voluntary family planning information and services for clients based on their ability to pay, through a network that includes nearly 4,000 family planning centers. *http://www.hhs.gov/opa/title-x-family-planning/* Individuals with family incomes at or below the HHS poverty guideline (for 2017, $24,600 for a family of four in the 48 contiguous States and the District of Columbia) receive services at no charge unless a third party (governmental or private) is authorized or obligated to pay for these services. Individuals with incomes in excess of 100 percent up to 250 percent of the poverty guideline are charged for services using a sliding fee scale based on family size and income. Unemancipated minors seeking confidential services are assessed fees based on their own income level rather than their family's income. The availability of such programs to serve the most at-risk women (as defined in the IOM report) diminishes the Government's interest in applying the Mandate to objecting employers. Many forms of contraception are available for around $50 per month, including long-acting methods such as the birth control shot and intrauterine devices (IUDs).[24] Other, more permanent forms of contraception like implantables bear a higher one-time cost, but when calculated over the duration of use, cost a similar amount.[25] Various State programs supplement the Federal programs referenced above, and 28 States have their own mandates of contraceptive coverage as a matter of State law. This existing inter-governmental structure for obtaining contraceptives significantly diminishes the Government's interest in applying the Mandate to employers over their sincerely held religious objections.

The record also does not reflect that the Mandate is tailored to the women most likely to experience unintended pregnancy, identified by the 2011 IOM report as ''women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority''. (IOM 2011 at 102). For example, with respect to religiously objecting organizations, the Mandate applies in employer-based group health plans and student insurance at private colleges and universities. It is not clear that applying the Mandate among those objecting entities is a narrowly tailored way to benefit the most at-risk population. The entities appear to encompass some such women, but also appear to omit many of them and to include a significantly larger cross-section of women as employees or plan participants. At the same time, the Mandate as applied to objecting employers appears to encompass a relatively small percentage of the number of women impacted by the Mandate overall, since most employers do not appear to have conscientious objections to the Mandate.[26] The Guttmacher Institute, on which the IOM relied, further reported that 89 percent of women who are at risk of unintended pregnancy and are living at 0 through 149 percent of the poverty line are already using contraceptives, as are 92 percent of those with incomes of 300 percent or more of the Federal poverty level.[27]

The rates of—and reasons for—unintended pregnancy are notoriously difficult to measure.[28] In particular, association and causality can be hard to disentangle, and the studies referred to by the 2011 IOM Report speak more to association than causality. For example, IOM 2011 references Boonstra, et al.

[21] See, for example, Manya Brachear Pashman, ''Wheaton College ends coverage amid fight against birth control mandate,'' Chicago Tribune (July 29, 2015); Laura Bassett, ''Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate,'' HuffPost (May 15, 2012).

[22] The Departments are not aware of any objectors to the contraceptive Mandate that are unwilling to cover any of the other preventive services without cost sharing as required by PHS Act section 2713.

[23] ''Facts on Publicly Funded Contraceptive Services in the United States,'' March 2016.

[24] See, for example, Caroline Cunningham, ''How Much Will Your Birth Control Cost Once the Affordable Care Act Is Repealed?'' *Washingtonian* (Jan. 17, 2017), available at *https://www.washingtonian.com/2017/01/17/how-much-will-your-birth-control-cost-once-the-affordable-care-act-is-repealed/*; also, see *https://www.plannedparenthood.org/learn/birth-control.*

[25] *Id.*

[26] Prior to the implementation of the Affordable Care Act approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2010 Annual Survey'' at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf.* It is not clear whether the minority of employers who did not cover contraception refrained from doing so for conscientious reasons or for other reasons. Estimates of the number of women who might be impacted by the exemptions offered in these rules, as compared to the total number of women who will likely continue to receive contraceptive coverage, is discussed in more detail below.

[27] ''Contraceptive Use in the United States,'' September 2016.

[28] The IOM 2011 Report reflected this when it cited the IOM's own 1995 report on unintended pregnancy, ''The Best Intentions'' (IOM 1995). IOM 1995 identifies various methodological difficulties in demonstrating the interest in reducing unintended pregnancies by means of a coverage mandate in employer plans. These include: The ambiguity of intent as an evidence-based measure (does it refer to mistimed pregnancy or unwanted pregnancy, and do studies make that distinction?); ''the problem of determining parental attitudes at conception'' and inaccurate methods often used for that assessment, such as ''to use the request for an abortion as a marker''; and the overarching problem of ''association versus causality,'' that is, whether intent causes certain negative outcomes or is merely correlated with them. IOM 1995 at 64–66. See also IOM 1995 at 222 (''the largest public sector funding efforts, Title X and Medicaid, have not been well evaluated in terms of their net effectiveness, including their precise impact on unintended pregnancy'').

(2006), as finding that, ''as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined,'' [29] and Santelli and Melnikas as finding that ''increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use''. IOM 2011 at 105.[30] In this respect, the report does not show that access to contraception causes decreased incidents of unintended pregnancy, because both of the assertions rely on association rather than causation, and they associate reduction in unintended pregnancy with increased use of contraception, not merely with increased access to such contraceptives.

Similarly, in a study involving over 8,000 women between 2012 and 2015, conducted to determine whether contraceptive coverage under the Mandate changed contraceptive use patterns, the Guttmacher Institute concluded that ''[w]e observed no changes in contraceptive use patterns among sexually active women.'' [31] With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship).[32] Another study, which proposed an economic model for the decision to engage in sexual activity, stated that ''[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.'' [33] Regarding emergency contraception in particular, ''[i]ncreased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates.''[34] In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent,[35] unintended pregnancy rates in the Unites States rose from 35.4 percent[36] to 49 percent.''[37] The Departments note these and other studies[38] to observe the complexity and uncertainty in the relationship between contraceptive access, contraceptive use, and unintended pregnancy.

Contraception's association with positive health effects might also be partially offset by an association with negative health effects. In 2013 the National Institutes of Health indicated, in funding opportunity announcement for the development of new clinically useful female contraceptive products, that ''hormonal contraceptives have the disadvantage of having many undesirable side effects[,] are associated with adverse events, and obese women are at higher risk for serious complications such as deep venous thrombosis.'' [39] In addition, IOM 2011 stated that ''[l]ong-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011).'' (IOM 2011 at 107). However, after IOM 2011 made this statement, AHRQ (a component of HHS) completed its systematic evidence review.[40] Based on its review, AHRQ stated that: ''[o]varian cancer incidence was significantly reduced in OC [oral contraceptive] users''; ''[b]reast cancer incidence was slightly but significantly increased in OC users''; ''[t]he risk of cervical cancer was significantly increased in women with persistent human papillomavirus infection who used OCs, but heterogeneity prevented a formal meta-analysis''; ''[i]ncidences of both colorectal cancer [] and endometrial cancer [] were significantly reduced by OC use''; ''[t]he risk of vascular events was increased in current OC users compared with nonusers, although the increase in myocardial infarction was not statistically significant''; ''[t]he overall strength of evidence for ovarian cancer prevention was moderate to low''; and ''[t]he simulation model predicted that the combined increase in risk of breast and cervical cancers and vascular events was likely to be equivalent to or greater than the decreased risk in ovarian cancer.''[41] Based on these findings, AHRQ concluded that ''[t]here is insufficient evidence to recommend for or against the use of OCs solely for the primary prevention of ovarian cancer . . . . the harm/benefit ratio for ovarian cancer prevention alone is uncertain, particularly when the

[29] H. Boonstra, et al., ''Abortion in Women's Lives'' at 18, *Guttmacher Inst.* (2006).

[30] Citing John S. Santelli & Andrea J. Melnikas, ''Teen Fertility in Transition: Recent and Historic Trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371 (2010).

[31] Bearak, J.M. and Jones, R.K., ''Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis,'' 27 *Women's Health Issues* 316 (Guttmacher Inst. May–June 2017), available at *http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.*

[32] 31 *Ann. Rev. Pub. Health* at 375–76.

[33] Peter Arcidiacono, et al., ''Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?'' (2005), *available at http://public.econ.duke.edu/~psarcidi/teensex.pdf.*

[34] G. Raymond et al., ''Population effect of increased access to emergency contraceptive pills: a systematic review,'' 109 Obstet. Gynecol. 181 (2007).

[35] William D. Mosher & Jo Jones, U.S. Dep't of HHS, CDC, National Center for Health Statistics, ''Use of Contraception in the United States: 1982–2008'' at 5 fig. 1, 23 *Vital and Health Statistics* 29 (Aug. 2010), available at *https://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.*

[36] Helen M. Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 404–05 & n.128 (2013), available at *http://digitalcommons.law.villanova.edu/vlr/vol58/iss3/2* (quoting Christopher Tietze, ''Unintended Pregnancies in the United States, 1970–1972,'' 11 *Fam. Plan. Persp.* 186, 186 n.* (1979) (''in 1972, 35.4 percent percent of all U.S. pregnancies were 'unwanted' or 'wanted later'''')).

[37] *Id.* (citing Lawrence B. Finer & Stanley K. Henshaw, ''Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001'' 38 *Persp. on Sexual Reprod. Health* 90 (2006) (''In 2001, 49 percent of pregnancies in the United States were unintended'')).

[38] See, for example, J.L Dueñas, et al., ''Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997–2007,'' 83 *Contraception* 82 (2011) (as use of contraceptives increased from 49 percent to 80 percent, the elective abortion rate more than doubled); D. Paton, ''The economics of family planning and underage conceptions,'' 21 *J. Health Econ.* 207 (2002) (data from the UK confirms an economic model which suggests improved family planning access for females under 16 increases underage sexual activity and has an ambiguous impact on underage conception rates); T. Raine et al., ''Emergency contraception: advance provision in a young, high-risk clinic population,'' 96 *Obstet. Gynecol.* 1 (2000) (providing advance provision of emergency contraception at family planning clinics to women aged 16–24 was associated with the usage of less effective and less consistently used contraception by other methods); M. Belzer et al., ''Advance supply of emergency contraception: a randomized trial in adolescent mothers,'' 18 *J. Pediatr. Adolesc. Gynecol.* 347 (2005) (advance provision of emergency contraception to mothers aged 13–20 was associated with increased unprotected sex at the 12-month follow up).

[39] NIH, ''Female Contraceptive Development Program (U01)'' (Nov. 5, 2013), available at *https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-14-024.html.* Thirty six percent of women in the United States are obese. *https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity.* Also see ''Does birth control raise my risk for health problems?'' and ''What are the health risks for smokers who use birth control?'' HHS Office on Women's Health, available at *https://www.womenshealth.gov/a-z-topics/birth-control-methods*; Skovlund, CW, ''Association of Hormonal Contraception with Depression,'' 73 *JAMA Psychiatry* 1154 (Nov. 1, 2016), available at *https://www.ncbi.nlm.nih.gov/pubmed/27680324.*

[40] Havrilesky, L.J, et al., ''Oral Contraceptive User for the Primary Prevention of Ovarian Cancer,'' Agency for Healthcare Research and Quality, Report No.: 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html.*

[41] *Id.*

potential quality-of-life impact of breast cancer and vascular events are considered.''[42]

In addition, in relation to several studies cited above, imposing a coverage Mandate on objecting entities whose plans cover many enrollee families who may share objections to contraception could, among some populations, affect risky sexual behavior in a negative way. For example, it may not be a narrowly tailored way to advance the Government interests identified here to mandate contraceptive access to teenagers and young adults who are not already sexually active and at significant risk of unintended pregnancy.[43]

Finally, evidence from studies that post-date the Mandate is not inconsistent with the observations the Departments make here. In 2016, HRSA awarded a 5-year cooperative agreement to the American College of Obstetricians and Gynecologists to develop recommendations for updated Women's Preventive Services Guidelines. The awardee formed an expert panel called the Women's Preventive Services Initiative that issued a report (the WPSI report).[44] After observing that ''[p]rivate companies are increasingly challenging the contraception provisions in the Affordable Care Act,'' the WPSI report cited studies through 2013 stating that application of HRSA Guidelines had applied preventive services coverage to 55.6 million women and had led to a 70 percent decrease in out-of-pocket expenses for contraceptive services among commercially insured women. *Id.* at 57–58. The WPSI report relied on a 2015 report of the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans,'' which estimated that persons who have private insurance coverage of preventive services without cost sharing includes 55.6 million women.[45]

As discussed above and based on the Departments' knowledge of litigation challenging the Mandate, during the time ASPE estimated the scope of preventive services coverage (2011–2013), houses of worship and integrated auxiliaries were exempt from the Mandate, other objecting religious nonprofit organizations were protected by the temporary safe harbor, and hundreds of accommodated self-insured church plan entities were not subject to enforcement of the Mandate through their third party administrators. In addition, dozens of for-profit entities that had filed lawsuits challenging the Mandate were protected by court orders pending the Supreme Court's resolution of *Hobby Lobby* in June 2014. It would therefore appear that the benefits recorded by the report occurred even though most objecting entities were not in compliance.[46] Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[47]

The Departments need not take a position on these empirical questions. Our review is sufficient to lead us to conclude that significantly more uncertainty and ambiguity exists in the record than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals as set forth herein, and that no compelling interest exists to counsel against us extending the exemption.

During public comment periods, some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions. The IOM similarly stated that ''the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain.'' IOM 2011 at 107. Consequently, some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes. Section 2713(a)(4) of the PHS Act does not, however, apply to non-preventive care provided solely for treatment of an existing condition. It applies only to ''such additional preventive care and screenings . . . as provided for'' by HRSA (Section 2713(a)(4) of the PHS Act). HRSA's Guidelines implementing this section state repeatedly that they apply to ''preventive'' services or care, and with respect to the coverage of contraception specifically, they declare that the methods covered are ''contraceptive'' methods as a ''Type of Preventive Service,'' and that they are to be covered only ''[a]s prescribed'' by a physician or other health care provider. *https://www.hrsa.gov/womensguidelines/* The contraceptive coverage requirement in the Guidelines also only applies for ''women with reproductive capacity.'' *https://www.hrsa.gov/womensguidelines/*; (80 FR 40318). Therefore, the Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that the FDA has approved for contraceptive use is prescribed in whole or in part for such use. The Guidelines and section 2713(a)(4) of the PHS Act do not require coverage of such drugs where they are prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[48] As discussed above, the last

[42] *Id.* Also, see Kelli Miller, ''Birth Control & Cancer: Which Methods Raise, Lower Risk,'' *The Am. Cancer Society,* (Jan. 21, 2016), available at *http://www.cancer.org/cancer/news/features/birth-control-cancer-which-methods-raise-lower-risk.*

[43] For further discussion, see Alvaré, 58 *Vill. L. Rev.* at 400–02 (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[44] ''WPSI 2016 Recommendations: Evidence Summaries and Appendices,'' at 54–64, *available at https://www.womenspreventivehealth.org/wp-content/uploads/2016/12/Evidence-Summaries-and-Appendices.pdf.*

[45] Available at *https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans*; also, see Abridged Report, available at *https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.*

[46] In addition, as in IOM 2011, the WPSI report bases its evidentiary conclusions relating to contraceptive coverage, use, unintended pregnancy, and health benefits, on conclusions that the phenomena are ''associated'' with the intended outcomes, without showing there is a causal relationship. For example, the WPSI report states that ''[c]ontraceptive counseling in primary care may increase the uptake of hormonal methods and [long-acting reversible contraceptives], although data on structured counseling in specialized reproductive health settings demonstrated no such effect.'' *Id.* at 63. The WPSI report also acknowledges that a large-scale study evaluating the effects of providing no-cost contraception had ''no randomization or control group.'' *Id.* at 63.

The WPSI report also identifies the at-risk population as young, low-income, and/or minority women: ''[u]nintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities.'' *Id.* at 58. The WPSI report acknowledges that many in this population are already served by Title X programs, which provide family planning services to ''approximately 1 million teens each year.'' *Id.* at 58. The WPSI report observes that between 2008 and 2011—before the contraceptive coverage requirement was implemented—unintended pregnancy decreased to the lowest rate in 30 years. *Id.* at 58. The WPSI report does not address how to balance contraceptive coverage interests with religious objections, nor does it specify the extent to which applying the Mandate among commercially insured at objecting entities serves to deliver contraceptive coverage to women most at risk of unintended pregnancy.

[47] See Michael J. New, ''Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes,'' 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

[48] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that ''there are demonstrated preventive health benefits

Continued

Administration decided to exempt houses of worship and their integrated auxiliaries from the Mandate, and to relieve hundreds of religious nonprofit organizations of their obligations under the Mandate and not further require contraceptive coverage to their employees. In several of the lawsuits challenging the Mandate, some religious plaintiffs stated that they do not object and are willing to cover drugs prescribed for the treatment of an existing condition and not for contraceptive purposes—even if those drugs are also approved by the FDA for contraceptive uses. Therefore, the Departments conclude that the fact that some drugs that are approved for preventive contraceptive purposes can also be used for exclusively non-preventive purposes to treat existing conditions is not a sufficient reason to refrain from expanding the exemption to the Mandate.

An additional consideration supporting the Departments' present view is that alternative approaches can further the interests the Departments previously identified behind the Mandate. As noted above, the Government already engages in dozens of programs that subsidize contraception for the low-income women identified by the IOM as the most at risk for unintended pregnancy. The Departments have also acknowledged in legal briefing that contraception access can be provided through means other than coverage offered by religious objectors, for example, through ''a family member's employer,'' ''an Exchange,'' or ''another government program.'' [49]

Many employer plan sponsors, institutions of education arranging student health coverage, and individuals enrolled in plans where their employers or issuers (as applicable) are willing to offer them a religiously acceptable plan, hold sincerely held religious beliefs against (respectively) providing, arranging, or participating in plans that comply with the Mandate either by providing contraceptive coverage or by using the accommodation. Because we have concluded that requiring such compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many such entities or individuals, and because we conclude requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest, we now believe that requiring such compliance led to the violation of RFRA in many instances. We recognize that this is a change of position on this issue, and we make that change based on all the matters discussed in this preamble.

B. Discretion To Provide Religious Exemptions

Even if RFRA does not compel the religious exemptions provided in these interim final rules, the Departments believe they are the most appropriate administrative response to the religious objections that have been raised. RFRA identifies certain circumstance under which government must accommodate religious exercise-when a government action imposes a substantial burden on the religious exercise of an adherent and imposition of that burden is not the least restrictive means of achieving a compelling government interest. RFRA does not, however, prescribe the accommodation that the government must adopt. Rather, agencies have discretion to fashion an appropriate and administrable response to respect religious liberty interests implicated by their own regulations. We know from *Hobby Lobby* that, in the absence of any accommodation, the contraceptive-coverage requirement imposes a substantial burden on certain objecting employers. We know from other lawsuits and public comments that many religious entities have objections to complying with the accommodation based on their sincerely held religious beliefs. Previously, the Departments attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA's requirements for imposing that burden.

Now, however, the Departments have reassessed the relevant interests and determined that, even if exemptions are not required by RFRA, they would exercise their discretion to address the substantial burden identified in *Hobby Lobby* by expanding the exemptions from the Mandate instead of revising accommodations previously offered. In the Departments' view, a broader exemption is a more direct, effective means of satisfying all bona fide religious objectors. This view is informed by the fact that the Departments' previous attempt to develop an appropriate accommodation did not satisfy all objectors. That previous accommodation consumed Departmental resources not only through the regulatory process, but in persistent litigation and negotiations. Offering exemptions as described in these interim final rules is a more workable way to respond to the substantial burden identified in *Hobby Lobby* and bring years of litigation concerning the Mandate to a close.

C. General Scope of Expanded Religious Exemptions

1. Exemption and Accommodation for Religious Employers, Plan Sponsors, and Institutions of Higher Education

For all of these reasons, and as further explained below, the Departments now believe it is appropriate to modify the scope of the discretion afforded to HRSA in the July 2015 final regulations to direct HRSA to provide the expanded exemptions and change the accommodation to an optional process if HRSA continues to otherwise provide for contraceptive coverage in the Guidelines. As set forth below, the expanded exemption encompasses non-governmental plan sponsors that object based on sincerely held religious beliefs, and institutions of higher education in their arrangement of student health plans. The accommodation is also maintained as an optional process for exempt employers, and will provide contraceptive availability for persons covered by the plans of entities that use it (a legitimate program purpose).

The Departments believe this approach is sufficiently respectful of religious objections while still allowing the Government to advance other interests. Even with the expanded exemption, HRSA maintains the discretion to require contraceptive coverage for nearly all entities to which the Mandate previously applied (since most plan sponsors do not appear to possess the requisite religious objections), and to reconsider those interests in the future where no covered objection exists. Other Government subsidies of contraception are likewise not affected by this rule.

---

from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act section 2713(a)(4) or the Guidelines require coverage of ''contraceptive'' methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead it was an observation that such drugs—generally referred to as ''contraceptives''—also have some alternate beneficial uses to treat existing conditions. For the purposes of these interim final rules, the Departments clarify here that our previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines.

[49] Brief for the Respondents at 65, *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016) (No. 14–1418).

2. Exemption for Objecting Individuals Covered by Willing Employers and Issuers

As noted above, some individuals have brought suit objecting to being covered under an insurance policy that includes coverage for contraceptives. See, for example, *Wieland* v. *HHS,* 196 F. Supp. 3d 1010 (E.D. Mo. 2016); *Soda* v. *McGettigan,* No. 15–cv–00898 (D. Md.). Just as the Departments have determined that the Government does not have a compelling interest in applying the Mandate to employers that object to contraceptive coverage on religious grounds, we have also concluded that the Government does not have a compelling interest in requiring individuals to be covered by policies that include contraceptive coverage when the individuals have sincerely held religious objections to that coverage. The Government does not have an interest in ensuring the provision of contraceptive coverage to individuals who do not wish to have such coverage. Especially relevant to this conclusion is the fact that the Departments have described their interests of health and gender equality as being advanced among women who ''want'' the coverage so as to prevent ''unintended'' pregnancy. (77 FR 8727).[50] No asserted interest is served by denying an exemption to individuals who object to it. No unintended pregnancies will be avoided or costs reduced by imposing the coverage on those individuals.

Although the Departments previously took the position that allowing individual religious exemptions would undermine the workability of the insurance system, the Departments now agree with those district courts that have concluded that an exemption that allows—but does not require—issuers and employers to omit contraceptives from coverage provided to objecting individuals does not undermine any compelling interest. See *Wieland,* 196 F. Supp. 3d at 1019–20; *March for Life,* 128 F. Supp. 3d at 132. The individual exemption will only apply where the employer and issuer (or, in the individual market, the issuer) are willing to offer a policy accommodating the objecting individual. As a result, the Departments consider it likely that where an individual exemption is invoked, it will impose no burdens on the insurance market because such burdens may be factored into the willingness of an employer or issuer to offer such coverage. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our lack of authority to enforce the accommodation with respect to self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[51] Furthermore, granting exemptions to individuals who do not wish to receive contraceptive coverage where the plan and, as applicable, issuer and plan sponsor are willing, does not undermine the Government's interest in ensuring the provision of such coverage to other individuals who wish to receive it. Nor do such exemptions undermine the operation of the many other programs subsidizing contraception. Rather, such exemptions serve the Government's interest in accommodating religious exercise. Accordingly, as further explained below, the Departments have provided an exemption to address the concerns of objecting individuals.

D. Effects on Third Parties of Exemptions

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 of the PHS Act requirements on grandfathered plans that cover millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including the various governmental programs discussed above. As the Government is under no constitutional obligation to fund contraception, *cf. Harris* v. *McRae,* 448 United States 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their religious beliefs. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) (''A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.'').[52]

That conclusion is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants ''to confer benefits on third parties.'' *Hobby Lobby,* 134 S. Ct. at 2781 n.37. The burdens imposed on such third parties may be relevant to the RFRA analysis, but they cannot be dispositive. ''Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).'' *Id.* Where, as here, contraceptives are readily accessible and, for many low income persons, are available at reduced cost or for free through various governmental programs, and contraceptive coverage may be available through State sources or family plans obtained through non-objecting employers, the Departments have determined that the expanded exemptions rather than accommodations are the appropriate response to the substantial burden that the Mandate has placed upon the religious exercise of many religious employers.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including prior interim final rules), public comments, and litigation throughout the Federal court system. The interim final rules seek to resolve this matter and the long-running litigation with respect to religious

[50] In this respect, the Government's interest in contraceptive coverage is different than its interest in persons receiving some other kinds of health coverage or coverage in general, which can lead to important benefits that are not necessarily conditional on the recipient's desire to use the coverage and the specific benefits that may result from their choice to use it.

[51] Also, see *Real Alternatives,* 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) (''Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the Affordable Care Act) would be unworkable, it has not satisfied strict scrutiny.'' (citation and internal quotation marks omitted)).

[52] *Cf. also Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists,* 257 P.3d 181, 196 (Ariz. Ct. App. 2011) (''a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.'').

objections by extending the exemption under the HRSA Guidelines to encompass entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage, and by making the accommodation process optional for eligible organizations.

The Departments acknowledge that the foregoing analysis represents a change from the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlie the Mandate. These changes in policy are within the Departments' authority. As the Supreme Court has acknowledged, ''[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change.'' *Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125 (2016). This ''reasoned analysis'' requirement does not demand that an agency ''demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates''. *United Student Aid Funds, Inc.* v. *King,* 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)); also, see *New Edge Network, Inc.* v. *FCC,* 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that ''an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance'').

Here, for all of the reasons discussed above, the Departments have determined that the Government's interest in the application of contraceptive coverage requirements in this specific context to the plans of certain entities and individuals does not outweigh the sincerely held religious objections of those entities and individuals based on the analyses set forth above. Thus, these interim final rules amend the Departments' July 2015 final regulations to expand the exemption to include additional entities and persons that object based on sincerely held religious beliefs. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no such objection exists, and to the extent that section 2713 of the PHS Act applies. These interim final rules also maintain the existence of an accommodation process, but consistent with our expansion of the exemption, we make the process optional for eligible organizations. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[53]

A. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules modify the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) introductory text and (a)(1)(iv), so that they conform to the statutory text of section 2713 of the PHS Act.

B. Prefatory Language of the Exemption in 45 CFR 147.132

These interim final rules move the religious exemption from 45 CFR 147.131 to a new § 147.132 and expand it as follows. In the prefatory language of § 147.132, these interim final rules specify that not only are certain entities ''exempt,'' but the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such entities. This is an acknowledgement that section 2713(a)(4) of the PHS Act requires women's preventive services coverage only ''as provided for in comprehensive guidelines supported by the Health Resources and Services Administration.'' To the extent the HRSA Guidelines do not provide for or support the application of such coverage to exempt entities, the Affordable Care Act does not require the coverage. Section 147.132 not only describes the exemption of certain entities and plans, but does so by specifying that the HRSA Guidelines do not provide for, or support the application of, such coverage to exempt entities and plans.

C. General Scope of Exemption for Objecting Entities

In the new 45 CFR 147.132 as created by these interim final rules, these rules expand the exemption that was previously located in § 147.131(a). With respect to employers that sponsor group health plans, the new language of § 147.132(a)(1) introductory text and (a)(1)(i) provides exemptions for employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption created in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.132(a)(1) introductory text and (a)(1)(i), by specifying that ''[a] group health plan and health insurance coverage provided in connection with a group health plan'' is exempt ''to the extent the plan sponsor objects as specified in paragraph (a)(2),'' exempt the group health plans the sponsors of which object, and exempt their health insurance issuers from providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[54] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage,

[53] See *https://www.hrsa.gov/womensguidelines/* and *https://www.hrsa.gov/womensguidelines2016/index.html.*

[54] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. Also, see 45 CFR 147.200 (requiring disclosure of the ''exceptions, reductions, and limitations of the coverage,'' including group health plans and group & individual issuers).

otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.132(a) apply ''to the extent'' of the objecting entities' sincerely held religious beliefs. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.132(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsor has no qualifying objection. The objection of a health insurance issuer in § 147.132(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

D. Exemption of Employers and Institutions of Higher Education

The scope of the exemption is expanded for non-governmental plan sponsors and certain entities that arrange health coverage under these interim final rules. The Departments have consistently taken the position that section 2713(a)(4) of the PHS Act grants HRSA authority to issue Guidelines that provide for and support exemptions from a contraceptive coverage requirement. Since the beginning of rulemaking concerning the Mandate, HRSA and the Departments have repeatedly exercised their discretion to create and modify various exemptions within the Guidelines.[55]

The Departments believe the approach of these interim final rules better aligns our implementation of section 2713(a)(4) of the PHS Act with Congress' intent in the Affordable Care Act and throughout other Federal health care laws. As discussed above, many Federal health care laws and regulations provide exemptions for objections based on religious beliefs, and RFRA applies to the Affordable Care Act. Expanding the exemption removes religious obstacles that entities and certain individuals may face when they otherwise wish to participate in the health care market. This advances the Affordable Care Acts goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate. These rules also leave in place many Federal programs that subsidize contraceptives for women who are most at risk of unintended pregnancy and who may have more limited access to contraceptives.[56] These interim final rules achieve greater uniformity and simplicity in the regulation of health insurance by expanding the exemptions to include entities that object to the Mandate based on their sincerely held religious beliefs.

The Departments further conclude that it would be inadequate to merely attempt to amend the accommodation process instead of expand the exemption. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way ''seamless'' to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. The Departments have engaged in an effort to attempt to identify an accommodation that would eliminate the plaintiffs' religious objections, including seeking public comment through an RFI, but we stated in January 2017 that we were unable to develop such an approach at that time.

1. Plan Sponsors Generally

The expanded exemptions in these interim final rules cover any kind of non-governmental employer plan sponsor with the requisite objections but, for the sake of clarity, they include an illustrative, non-exhaustive list of employers whose objections qualify the plans they sponsor for an exemption.

Under these interim final rules, the Departments do not limit the Guidelines exemption with reference to nonprofit status or to sections 6033(a)(3)(A)(i) or (iii) of the Code, as previous rules have done. A significant majority of States either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[57] Although the practice of States is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor a statement about what the Federal Government may do consistent with RFRA or other limitations in federal law, such State practice can be informative as to the viability of broad protections for religious liberty. In this case, such practice supports the Departments' decision to expand the federal exemption, bringing the Federal Government's practice into greater alignment with the practices of the majority of the States.

2. Section 147.132(a)(1)(i)(A)

Despite not limiting the exemption to certain organizations referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, the exemption in these rules includes such organizations. Section 147.132(a)(1)(i)(A) specifies, as under the prior exemption, that the exemption covers ''a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order.'' In the preamble to rules setting forth the prior exemption at § 147.132(a), the Departments interpreted this same language used in those rules by declaring that ''[t]he final regulations continue to provide that the availability of the exemption or accommodation be determined on an employer by employer basis, which the Departments continue to believe best balances the interests of religious employers and eligible organizations and those of employees and their dependents.'' (78 FR 39886). Therefore, under the prior exemption, if an employer participated in a house of worship's plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not considered to be covered by the

[55] ''The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.'' *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837, 863–64 (1984).

[56] See, for example, Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[57] See Guttmacher Institute, ''Insurance Coverage of Contraceptives'' available at *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a ''plan established or maintained by a [house of worship].''

Under these interim final rules, however, the Departments intend that, when this regulation text exempts a plan ''established or maintained by'' a house of worship or integrated auxiliary, such exemption will no longer ''be determined on an employer by employer basis,'' but will be determined on a plan basis—that is, by whether the plan is a ''plan established or maintained by'' a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these interim final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the threshold of being integrated auxiliaries. Moreover, under this interpretation, houses of worship would not be faced with the potential prospect of services to which they have a religious objection being covered for employees of an associated employer participating in a plan they have established and maintain.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted participation in its health plan, but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior rule, to the extent that, in practice and as discussed elsewhere herein, it does not force contraceptive coverage to be provided on behalf of the plan participants of many religious organizations in a self-insured church plan exempt from ERISA—which are exempt in part because the plans are established and maintained by a church. (Section 3(33)(A) of ERISA) In several lawsuits challenging the Mandate, the Departments took the position that some plans established and maintained by houses of worship, but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government ''has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time.'' *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013). Therefore the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

3. Section 147.132(a)(1)(i)(B)

Section 147.132(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of plan sponsors that are nonprofit organizations.

4. Section 147.132(a)(1)(i)(C)

Under § 147.132(a)(1)(i)(C), the rules extend the exemption to the plans of closely held for-profit entities. This is consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby,* religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the Departments' argument to the contrary. (134 S. Ct. 2768–75) Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.[58]

5. Section 147.132(a)(1)(i)(D)

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. The Departments implicitly recognized the difficulty of providing an affirmative definition of closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely ''substantially similar'' to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. The exemptions in these interim final rules do not need to address this difficulty because they include both for-profit entities that are closely held and for-profit entities that are not closely held.[59] The mechanisms for determining whether a company has adopted and holds such principles or views is a matter of well-established State law with respect to corporate decision-making,[60] and the Departments expect that application of such laws would cabin the scope of this exemption.

In including entities in the exemption that are not closely held, these interim final rules provide for the possibility that some publicly traded entities may use the exemption. Even though the Supreme Court did not extend its holding in *Hobby Lobby* to publicly traded corporations (the matter could be resolved without deciding that question), the Court did instruct that RFRA applies to corporations because they are ''persons'' as that term is defined in 1 U.S.C. 1. Given that the definition under 1 U.S.C. 1 applies to any corporation, the Departments consider it appropriate to extend the exemption set forth in these interim final rules to for-profit corporations whether or not they are closely held. The Departments are generally aware that in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.[61] The fact that such a company is religious does not mean that it will have an objection to contraceptive coverage, and there are many fewer publicly traded companies than there are closely held ones. But our experience with closely held companies is that some, albeit a small minority, do have religious objections to contraceptive coverage. Thus we consider it possible, though very unlikely, that a religious publicly

[58] See Jennifer Haberkorn, ''Two years later, few Hobby Lobby copycats emerge,'' *Politico* (Oct. 11, 2016), available at *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627*.

[59] In the companion interim final rules published elsewhere in this **Federal Register**, the Departments provide an exemption on an interim final basis to closely held entities by using a negative definition: entities that do not have publicly traded ownership interests as defined by certain securities required to be registered under section 12 of the Securities Exchange Act of 1934. Although this is a more workable definition than set forth in our previous rules, we have determined that it is appropriate to offer the expanded religious exemptions to certain entities whether or not they have publicly traded ownership interests.

[60] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

[61] *See, e.g., Nasdaq.com,* ''4 Publicly Traded Religious Companies if You're Looking to Invest in Faith'' (Feb. 7, 2014), available at *http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665*.

traded company might have objections to contraceptive coverage. At the same time, we are not aware of any publicly traded entities that challenged the Mandate specifically either publicly or in court. The Departments agree with the Supreme Court that it is improbable that many publicly traded companies with numerous ''unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs'' and thereby qualify for the exemption. (134 S. Ct. at 2774)

6. Section 147.132(a)(1)(i)(E)

Under § 147.132(a)(1)(i)(E), the rules extend the exemption to the plans of any other non-governmental employer. The plans of governmental employers are not covered by the plan sponsor exemption of § 147.132(a)(1)(i). The Departments are not aware of reasons why it would be appropriate or necessary to offer religious exemptions to governmental employer plan sponsors in the United States with respect to the contraceptive Mandate. But, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and thus to provide health insurance coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these interim final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization.

7. Section 147.132(a)(1)(ii)

As in the previous rules, the plans of institutions of higher education that arrange student health insurance coverage will continue to be treated similarly to the way in which the plans of employers are treated, but for the purposes of such plans being exempt or electing the optional accommodation, rather than merely being eligible for the accommodation as in the previous rule. These interim final rules specify, in § 147.132(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor. As mentioned above, because the Affordable Care Act does not require institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or use the accommodation. Extending the exemption in these interim final rules may remove an obstacle to such entities deciding to offer student plans, thereby giving students another health insurance option.

E. Exemption for Issuers

These interim final rules extend the exemption, in § 147.132(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services.

The Departments are not currently aware of health insurance issuers that possess their own religious objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations are protected from being required to provide coverage or pay for abortions. See, for example, Consolidated Appropriations Act of 2017, Public Law 115–31, Div. H, Title V, Sec. 507(d). Congress also declared this year that ''it is the intent of Congress'' to include a ''conscience clause'' which provides exceptions for religious beliefs if the District of Columbia requires ''the provision of contraceptive coverage by health insurance plans.'' See *Id.* at Div. C, Title VIII, Sec. 808. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.132(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. As set forth in these interim final rules, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection. Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under 42 CFR 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include coverage for some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt. Issuers that hold religious objections should identify to plan sponsors the lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held religious beliefs, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to

continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4) of the PHS Act or related provisions for their failure to provide contraceptive coverage.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these interim final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these interim final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) of the PHS Act to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators under section 3(16) of ERISA and, therefore, would not normally act as plan administrators under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These interim final rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or continue, contracts as third party administrators of such plans. For these reasons, these interim final rules do not otherwise exempt third party administrators. The Departments solicit public comment, however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have religious beliefs implicated by the Mandate.

F. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.132(a)(2). That paragraph specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.132(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

G. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the ''individual exemption''). Section 147.132(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held religious beliefs. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. See *Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This ''individual exemption'' cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other Federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.[62] At the same time, this individual exemption ''does not undermine the governmental interests furthered by the contraceptive coverage requirement,'' [63] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

H. Optional Accommodation

Despite expanding the scope of the exemption, these rules also keep the accommodation process, but revise it so as to make it optional. In this way, objecting employers are no longer required to choose between direct compliance or compliance through the accommodation. These rules maintain the location of the accommodation process in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. These rules, by virtue of expanding the plan sponsor exemption beyond houses of worship and integrated auxiliaries that were

[62] See, for example, *Wieland,* 196 F. Supp. 3d at 1017, and *March for Life,* 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to ''forgo health insurance altogether.''

[63] 78 FR 39874.

previously exempt, and beyond religious nonprofit groups that were previously accommodated, and by defining eligible organizations for the accommodation with reference to those covered by the exemption, likewise expand the kinds of entities that may use the optional accommodation. This includes plan sponsors with sincerely held religious beliefs for the reasons described above. Consequently, under these interim final rules, objecting employers may make use of the exemption, or may choose to pursue the optional accommodation process. If an eligible organization pursues the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

The fees adjustment process for qualifying health issuers or third party administrators pursuant to 45 CFR 156.50 is not modified, and (as specified therein) requires for its applicability that an exception under OMB Circular No. A–25R be in effect as the Secretary of the Department of Health and Human Services requests.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these interim final rules and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. This revocation process applies both prospectively to eligible organizations who decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that were included in the accommodation prior to the effective date of these interim final rules either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. If contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the 1st day of the 1st plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act,[64] if applicable, to revoke its use of the accommodation process.

The Departments have eliminated the provision in the previous accommodation under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. Because any organization with a sincerely held religious objection to contraceptive coverage is now eligible for the optional accommodation under these interim final rules and is also exempt, the Departments believe there is minimal opportunity for mistake or misrepresentation by the organization, and the reliance provision is no longer necessary.

I. Definition of Contraceptive Services for the Purpose of These Rules

The interim final rules specify that when the rules refer to ''contraceptive'' services, benefits, or coverage, such terms include contraceptive or sterilization items, services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv). This was the case under the previous rules, as expressed in the preamble text of the various iterations of the regulations, but the Departments wish to make the scope clear by specifying it in the regulatory text.

J. Conclusion

The Departments believe that the Guidelines and the exemptions expanded herein will advance the limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for religious exemptions with respect to especially sensitive health care and health insurance requirements. These interim final rules leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. These interim final rules also maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines (in plans where Congress applied section 2713 of the PHS Act) if no objection exists. The Departments believe this array of programs and requirements better serves the interest of providing contraceptive coverage while protecting the conscience rights of entities that have sincerely held religious objections to some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

V. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; 79 FR 51092).

Section 553(b) of the Administrative Procedure Act (APA) requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated

[64] See also 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to continue to update the Guidelines.

Dozens of lawsuits over the Mandate have been pending for nearly 5 years. The Supreme Court remanded several of those cases more than a year ago, stating that on remand ''[w]e anticipate that the Courts of Appeals will allow the parties sufficient time to resolve any outstanding issues between them''. *Zubik,* 136 S. Ct. at 1560. During that time, Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days. Those status reports have informed the courts that the parties were in discussions, and about the RFI issued in late 2016 and its subsequent comment process and the FAQ the Departments issued indicating that we could not find a way at that time to amend the accommodation process so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. Since then, several courts have issued orders setting more pressing deadlines. For example, on March 10, 2017, the United States Court of Appeals for the Seventh Circuit ordered that, by May 1, 2017, ''the court expects to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions. In the event no agreement is reported on or before May 1, 2017, the court will plan to schedule oral argument on the merits of the case on short notice after that date''. The Departments submitted a status report but were unable to set forth their specific position because this interim final rule was not yet on public display. Instead, the Departments informed the Court that we ''are now considering whether further administrative action would be appropriate''. In response, the court extended the deadline to June 1, 2017, again declaring the court expected ''to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions''. The Departments were again unable to set forth their position in that status report, but were able to state that the ''Departments of Health and Human Services, Labor, and the Treasury are engaged in rulemaking to reconsider the regulations at issue here,'' citing *https://www.reginfo.gov/public/do/eoDetails?rrid=127381*.

As discussed above, the Departments have concluded that, in many instances, requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncomplaince has violated RFRA. Good cause exists to issue the expanded exemption in these interim final rules in order to cure such violations (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters.

The Departments have also been subject to temporary injunctions protecting many religious nonprofit organizations from being subject to the accommodation process against their wishes, while many other organizations are fully exempt, have permanent court orders blocking the contraceptive coverage requirement, or are not subject to section 2713 of the PHS Act and its enforcement due to Congress' limited application of that requirement. Good cause exists to change the Departments' previous rules to direct HRSA to bring its Guidelines in accord with the legal realities and remove the threat of a future violation of religious beliefs, including where such violations are contrary to Federal law.

Other objecting entities similarly have not had the protection of court injunctions. This includes some nonprofit entities that have sued the Departments, but it also includes some organizations that do not have lawsuits pending against us. For example, many of the closely held for-profit companies that brought the array of lawsuits challenging the Mandate leading up to the decision in *Hobby Lobby* are not protected by injunctions from the current rules, including the requirement that they either fully comply with the Mandate or subject themselves to the accommodation. Continuing to apply the Mandate's regulatory burden on individuals and organizations with religious beliefs against it could serve as a deterrent for citizens who might consider forming new entities—nonprofit or for-profit—and to offering health insurance in employer-sponsored plans or plans arranged by institutions of higher education. Delaying the protection afforded by these interim final rules would be contrary to the public interest because it would serve to extend for many months the harm caused to all entities and individuals with religious objections to the Mandate. Good cause exists to provide immediate resolution to this myriad of situations rather than leaving them to continued uncertainty, inconsistency, and cost during litigation challenging the previous rules.

These interim final rules provide a specific policy resolution that courts have been waiting to receive from the Departments for more than a year. If the Departments were to publish a notice of proposed rulemaking instead of these interim final rules, many more months could pass before the current Mandate is lifted from the entities receiving the expanded exemption, during which time those entities would be deprived of the relief clearly set forth in these interim final rules. In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and by what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed.

As the United States Court of Appeals for the D.C. Circuit stated with respect to an earlier interim final rule promulgated with respect to this issue in *Priests for Life* v. *U.S. Department of Health and Human Services,* 772 F.3d 229, 276 (D.C. Cir. 2014), vacated on other grounds, *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016), ''[S]everal reasons support HHS's decision not to engage in notice and comment here''. Among other things, the Court noted that ''the agency made a good cause finding in the rule it issued''; that ''the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues''; that ''HHS will expose its interim rule to notice and comment before its permanent implementation''; and that ''delay in implementation of the rule would interfere with the prompt availability of contraceptive coverage and delay the implementation of the alternative opt-out for religious objectors''. *Id.* at 277.

Delaying the availability of the expanded exemption would delay the ability of those organizations and individuals to avail themselves of the relief afforded by these interim final rules. Good cause is supported by

providing relief for entities and individuals for whom the Mandate operates in violation of their sincerely held religious beliefs, but who would have to experience that burden for many more months under the prior regulations if these rules are not issued on an interim final basis. Good cause is also supported by the effect of these interim final rules in bringing to a close the uncertainty caused by years of litigation and regulatory changes made under section 2713(a)(4) of the PHS Act. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

Delaying the availability of the expanded exemption would also increase the costs of health insurance. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover contraception. They wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. They are refraining from making those changes—and therefore are continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. Issuing these rules on an interim final basis is necessary in order to help reduce the costs of health insurance for such entities and their plan participants.

These interim final rules also set forth an optional accommodation process, and expand eligibility for that process to a broader category of entities. Delaying the availability of the optional accommodation process would delay the ability of organizations that do not now qualify for the accommodation, but wish to opt into it, to be able to do so and therefore to provide a mechanism for contraceptive coverage to be provided to their employees while the organization's religious objections are accommodated.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final rules effective immediately upon filing at the Office of the Federal Register.

VI. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an ''economically significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of $100 million or more in any 1 year, and therefore do not meet the definition of ''economically significant'' under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations to expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, and to revise the accommodation process to make it optional for eligible organizations. The expanded exemption would apply to individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action is taken, among other reasons, to provide for participation in the health insurance market by certain entities or individuals free from penalties for violating sincerely held religious beliefs opposed to providing or receiving coverage of contraceptive services, and to resolve many of the lawsuits that have been filed against the Departments.

2. Anticipated Effects

The Departments assess this interim final rule together with a companion interim final rule concerning moral but non-religious conscientious objections to contraception, published elsewhere in this **Federal Register**. Regarding entities that are extended an exemption, absent expansion of the exemption the Guidelines would require many of these entities and individuals to either: Pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which some entities also believe entangles them in the provision of such objectionable coverage; or, pay tax penalties or be

subject to other adverse consequences for non-compliance with these requirements. These interim final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections and exempting them—on the basis of such objections—from the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption immediately, a notice will need to be sent to enrollees (either by the entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during a plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these interim final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be $51,990.

The Departments estimate that these interim final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their newly exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation that were not provided access to it previously. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations on issuers and third party administrators serving the fewer number of entities that will newly opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation.

These interim final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. The Departments do not have sufficient data to determine the actual effect of these rules on plan participants and beneficiaries, including for costs they may incur for contraceptive coverage, nor of unintended pregnancies that may occur. As discussed above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- how many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby,* several objecting entities still provide coverage for 14 of the 18 women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- how many women will be covered by plans of entities using their newly exempt status.
- which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- the degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- the degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- the degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- the extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

The Departments have access to sources of information discussed in the following paragraphs that are relevant to this issue, but those sources do not provide a full picture of the impact of these interim final rules.

First, the prior rules already exempted certain houses of worship and their integrated auxiliaries. Further, as discussed above, the prior accommodation process allows hundreds of additional religious nonprofit organizations in self-insured church plans that are exempt from ERISA to file a self-certification or notice that relieves not only themselves but, in effect, their third party administrators of any obligation to provide contraceptive coverage or payments. Although in the latter case, third party administrators are legally permitted to provide the coverage, several self-insured church plans themselves have expressed an objection in litigation to allowing such contraceptive coverage to be provided, and according to information received during litigation, it appears that such contraceptive coverage has not been provided. In addition, a significant portion of the lawsuits challenging the Mandate were brought by a single firm representing Catholic dioceses and related entities covered by their diocese-sponsored plans. In that litigation, the Departments took the position that, where those diocese-sponsored plans are self-insured, those plans are likely church plans exempt from ERISA.[65] For the purposes of considering whether the expanded exemption in these rules affects the persons covered by such diocese-sponsored plans, the Departments continue to assume that such plans are similar to other objecting entities using self-insured church plans with respect to their third party administrators being unlikely to provide contraceptive coverage to plan participants and beneficiaries under the previous rule. Therefore the

[65] See, for example, Brief in Opp. To Pls.' Mot. for Prelim. Inj., *Brandt* v. *Burwell,* No. 2:14–cv–681–AJS, doc. #23 (W.D. Pa. filed June 10, 2014) (arguing that ''plaintiffs have not established an injury in fact to the degree plaintiffs have a self-insured church plan,'' based on the fact that ''the same law firm representing the plaintiffs here has suggested in another similar case that all 'Catholic entities like the Archdiocese participate in ''church plans.'' '); *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013) (''because plaintiffs' self-insured plans are church plans, their third party administrators would not be required to provide contraceptive coverage'').

Departments estimate that these interim final rules have no significant effect on the contraceptive coverage of women covered by plans of houses of worship and their integrated auxiliaries, entities using a self-insured church plan, or church dioceses sponsoring self-insured plans.

It is possible that an even greater number of litigating or accommodated plans might have made use of self-insured church plan status under the previous accommodation. Notably, one of the largest nonprofit employers that had filed suit challenging the Mandate had, under these prior rules, shifted most of their employees into self-insured church plans, and the Departments have taken the position that various other employers that filed suit were eligible to assume self-insured church plan status.[66] The Supreme Court's recent decision in *Advocate Health Care Network,* while not involving this Mandate, also clarifies certain circumstances under which religious hospitals may be eligible for self-insured church plan status. See 137 S. Ct. at 1656–57, 1663 (holding that a church plan under ERISA can be a plan not established and maintained by a church, if it is maintained by a principal-purpose organization).

Second, when the Departments previously created the exemption, expanded its application, and provided an accommodation (which, as mentioned, can lift obligations on self-insured church plans for hundreds of nonprofit organizations), we concluded that no significant burden or costs would result at all. (76 FR 46625; 78 FR 39889.) We reached this conclusion despite the impact, just described, whereby the previous rule apparently lead to women not receiving contraceptive coverage through hundreds of nonprofit entities using self-insured church plans. We also reached this conclusion without counting any significant burden or cost to some women covered in the plans of houses of worship or integrated auxiliaries that might want contraceptive coverage. This conclusion was based in part on the assertion, set forth in previous regulations, that employees of houses of worship and integrated auxiliaries likely share their employers' opposition to contraception. Many other religious nonprofit entities, however, both adopt and implement religious principles with similar fervency. For the reasons discussed above, the Departments no longer believe we can distinguish many of the women covered in the plans of religious nonprofit entities from the women covered in the plans of houses of worship and integrated auxiliaries regarding which the Departments assumed share their employers' objection to contraception, nor from women covered in the plans of religious entities using self-insured church plans regarding which we chose not to calculate any anticipated effect even though we conceded we were not requiring their third party administrators to provide contraceptive coverage. In the estimates and assumptions below, we include the potential effect of these interim rules on women covered by such entities, in order to capture all of the anticipated effects of these rules.

Third, these interim final rules extend the exemption to for-profit entities. Among the for-profit employers that filed suit challenging the Mandate, the one with the most employees was *Hobby Lobby.*[67] As noted above, and like some similar entities, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of various contraceptive services: 14 of 18 FDA-approved women's contraceptive and sterilization methods.[68] (134 S. Ct. at 2766.) The effect of expanding the exemption to for-profit entities is therefore mitigated to the extent many of the persons covered by such entities' plans may receive coverage for at least some contraceptive services. No publicly traded for-profit entities have filed lawsuits challenging the Mandate. The Departments agree with the Supreme Court's expectation in this regard: ''it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable''. *Hobby Lobby,* 134 S. Ct. at 2774. Therefore, although publicly traded entities could make use of exempt status under these interim final rules, the Departments do not expect that very many will do so, as compared to the 87 religious closely held for-profit entities that brought litigation challenging the Mandate (some of which might be content with the accommodation).

Fourth, the Departments have a limited amount of information about entities that have made use of the accommodation process as set forth in the previous rules. HHS previously estimated that 209 entities would make use of the accommodation process. That estimate was based on HHS's observation in its August 2014 interim final rules and July 2015 final regulations that there were 122 eligible entities that had filed litigation challenging the accommodation process, and 87 closely held for-profit entities that had filed suit challenging the Mandate in general. (79 FR 51096; 80 FR 41336). The Departments acknowledged that entities that had not litigated might make use of the accommodation, but we stated we did not have better data to estimate how many might use the accommodation overall.

After issuing those rules, the Departments have not received complete data on the number of entities actually using the accommodation, because the accommodation does not require many accommodated entities to submit information to us. Our limited records indicate that approximately 63 entities have affirmatively submitted notices to HHS to use the accommodation. This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. We have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being

[66] See *https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf.*; see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

[67] Verified Complaint ¶ 34, *Hobby Lobby Stores, Inc., et al.* v. *Sebelius,* No. 5:12–cv–01000–HE (Sept. 12, 2012 W.D. Okla.) (13,240 employees).

[68] By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, *https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf*, Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). See 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: Sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives (''the Pill''—combined pill); oral contraceptives (''the Pill''—extended/continuous use/combined pill); oral contraceptives (''the Mini Pill''—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and ''[t]he pill and female sterilization have been the two most commonly used methods since 1982.'' See Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or we were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage. Our records also indicate that 60 plans used the contraceptive user fees adjustments in the 2015 plan year, the last year for which we have data. This includes only self-insured plans, and it includes some plans that self-certified through submitting notices and other plans that, presumably, self-certified through the EBSA form 700.

These sets of data are not inconsistent with our previous estimate that 209 entities would use the accommodation, but they indicate that some non-litigating entities used the accommodation, and some litigating entities did not, possibly amounting to a similar number. For this reason, and because we do not have more complete data available, we believe the previous estimate of 209 accommodated entities is still the best estimate available for how many entities have used the accommodation under the previous rule. This assumes that the number of litigating entities that did not use the accommodation is approximately the same as the number of non-litigating entities that did use it.

In considering how many entities will use the voluntary accommodation moving forward—and how many will use the expanded exemption—we also do not have specific data. We expect the 122 nonprofit entities that specifically challenged the accommodation in court to use the expanded exemption. But, as noted above, we believe a significant number of them are not presently participating in the accommodation, and that some nonprofit entities in self-insured church plans are not providing contraceptive coverage through their third party administrators even if they are using the accommodation. Among the 87 for-profit entities that filed suit challenging the Mandate in general, few if any filed suit challenging the accommodation. We do not know how many of those entities are using the accommodation, how many may be complying with the Mandate fully, how many may be relying on court injunctions to do neither, or how many will use the expanded exemption moving forward. Among entities that never litigated but used the accommodation, we expect many but not all of them to continue using the accommodation, and we do not have data to estimate how many such entities there are or how many will choose either option.

Overall, therefore, without sufficient data to estimate what the estimated 209 previously accommodated entities will do under these interim final rules, we assume that just over half of them will use the expanded exemption, and just under half will continue their accommodated status under the voluntary process set forth in these rules. Specifically, we assume that 109 previously accommodated entities will make use of their exempt status, and 100 will continue using the accommodation. This estimate is based in part on our view that most litigating nonprofit entities would prefer the exemption to the accommodation, but that many of either have not been using the accommodation or, if they have been using it, it is not providing contraceptive coverage for women in their plans where they participate in self-insured church plans. This estimate is also consistent with our lack of knowledge of how many for-profit entities were using the accommodation and will choose the exemption or the accommodation, given that many of them did not bring legal challenges against the accommodation after *Hobby Lobby.* This estimate is further consistent with our view, explained in more detail below, that some entities that are using the accommodation and did not bring litigation will use the exemption, but many accommodated, non-litigating entities—including the ones with the largest relative workforces among accommodated entities—will continue using the accommodation. The Departments recognize that we do not have better data to estimate the effects of these interim final rules on such entities.

In addition to these factors, we recognize that the expanded exemption and accommodation are newly available to religious for-profit entities that are not closely held and some other plan sponsors. As explained above, the Departments believe religious for-profit entities that are not closely held may exist, or may wish to come into being. HHS does not anticipate that there will be significant number of such entities, and among those, we believe that very few if any will use the accommodation. All of the for-profit entities that have challenged the Mandate have been religious closely held entities.

It is also possible that religious nonprofit or closely held for-profit entities that were already eligible for the accommodation but did not previously use it will opt into it moving forward, but because they could have done so under the previous rules, their opting into the accommodation is not caused by these rules.

Without any data to estimate how many of any entities newly eligible for and interested in using the accommodation might exist, HHS assumes for the purposes of estimating the anticipated effect of these rules that less than 10 entities (9) will do so. Therefore, we estimate that 109 entities will use the voluntary accommodation moving forward, 100 of which were already using the previous accommodation, and that 109 entities that have been using the previous accommodation will use the expanded exemption instead.

Fifth, in attempting to estimate the anticipated effect of these interim final rules on women receiving contraceptive coverage, the Departments have limited information about the entities that have filed suit challenging the Mandate. Approximately 209 entities have brought suit challenging the Mandate over more than 5 years. They have included a broad range of nonprofit entities and closely held for-profit entities. We discuss a number of potentially relevant points:

First, the Departments do not believe that out-of-pocket litigation costs have been a significant barrier to entities choosing to file suit. Based on the Departments' knowledge of these cases through public sources and litigation, nearly all the entities were represented pro bono and were subject to little or no discovery during the cases, and multiple public interest law firms publicly provided legal services for entities willing to challenge the Mandate.[69] (It is noteworthy, however, that such pro bono arrangements and minimization of discovery do not eliminate 100 percent of the time costs of participating in litigation or, as discussed in more detail below, the potential for negative

[69] See, for example, Catholic Diocese of Pittsburgh, ''Award-winning attorney 'humbled' by recognition,'' *Pittsburgh Catholic* (''Jones Day is doing the cases 'pro bono,' or voluntarily and without payment.'') (quoting Paul M. Pohl, Partner, Jones Day), available at *http://diopitt.org/pittsburgh-catholic/award-winning-attorney-humbled-recognition*; ''Little Sisters Fight for Religious Freedom,'' *National Review* (Oct. 2, 2013) (''the Becket Fund for Religious Liberty is representing us pro bono, as they do all their clients.'') (quoting Sister Constance Veit, L.S.P., communications director for the Little Sisters of the Poor), available at *http://www.nationalreview.com/article/360103/little-sisters-fight-religious-freedom-interview*; Suzanne Cassidy, ''Meet the major legal players in the Conestoga Wood Specialties Supreme Court case,'' *LancasterOnline* (Mar. 25, 2014) (''Cortman and the other lawyers arguing on behalf of Conestoga Wood Specialties and Hobby Lobby are offering their services pro bono.''), available at *http://lancasteronline.com/news/local/meet-the-major-legal-players-in-the-conestoga-wood-specialties/article_302bc8e2-b379-11e3-b669-001a4bcf6878.html.*

publicity. Both concerns could have dissuaded participation in lawsuits, and the potential for negative publicity may also dissuade participation in the expanded exemptions.)

Second, prior to the Affordable Care Act, the vast majority of entities already covered contraception, albeit not always without cost-sharing The Departments do not have data to indicate why entities that did not cover contraception prior to the Affordable Care Act chose not to cover it. As noted above, however, the Departments have maintained that compliance with the contraceptive Mandate is cost-neutral to issuers, which indicates that no significant financial incentive exists to omit contraceptive coverage. As indicated by the report by HHS ASPE discussed above, we have assumed that millions of women received preventive services after the Mandate went into effect because nearly all entities complied with the Guidelines. We are not aware of expressions from most of those entities indicating that they would have sincerely held religious objections to complying with the Mandate, and therefore that they would make use of the expanded exemption provided here.

Third, omitting contraceptive coverage has subjected some entities to serious public criticism and in some cases organized boycotts or opposition campaigns that have been reported in various media and online outlets regarding entities that have filed suit. The Departments expect that even if some entities might not receive such criticism, many entities will be reluctant to use the expanded exemption unless they are committed to their views to a significant degree.

Overall, the Departments do not know how many entities will use the expanded exemption. We expect that some non-litigating entities will use it, but given the aforementioned considerations, we believe it might not be very many more. Moreover, many litigating entities are already exempt or are not providing contraceptive coverage to women in their plans due to their participating in self-insured church plans, so the effect of the expanded exemption among litigating entities is significantly lower than it would be if all the women in their plans were already receiving the coverage.

To calculate the anticipated effects of this rule on contraceptive coverage among women covered by plans provided by litigating entities, we start by examining court documents and other public sources.[70] These sources provide some information, albeit incomplete, about how many people are employed by these entities. As noted above, however, contraceptive coverage among the employees of many litigating entities will not be affected by these rules because some litigating entities were exempt under the prior rule, while others were or appeared to be in self-insured church plans so that women covered in their plans were already not receiving contraceptive coverage.

Among litigating entities that were neither exempt nor likely using self-insured church plans, our best estimate based on court documents and public sources is that such entities employed approximately 65,000 persons, male and female.[71] The average number of workers at firms offering health benefits that are actually covered by those benefits is 62 percent.[72] This amounts to approximately 34,000 employees covered under those plans. DOL estimates that for each employee policyholder, there is approximately one dependent.[73] This amounts to approximately 68,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—compose 20.2 percent of the general population.[74] In addition, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[75] Therefore, we estimate that approximately 7,221 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that have filed lawsuits challenging the Mandate, where those plans are neither exempt under the prior rule nor are self-insured church plans.

We also estimate that for the educational institutions objecting to the Mandate as applied to student coverage that they arranged, where the entities were neither exempt under the prior rule nor were their student plans self-insured, such student plans likely covered approximately 3,300 students. On average, we expect that approximately half of those students (1,650) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. We expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, we assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 3,300. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, we assume they are. Therefore, for the purposes of this estimate, we assume that the effect of these expanded exemptions on student plans of litigating entities includes 3,300 women. Assuming that 44.3 perecent of such women use contraception covered by the Guidelines,[76] we estimate that

[70] Where complaints, affidavits, or other documents filed in court did not indicate the number of employees that work for an entity, and that entity was not apparently exempt as a house of worship or integrated auxiliary, and it was not using the kind of plan that we have stated in litigation qualifies for self-insured church plan status (see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013)), we examined employment data contained in some IRS form W–3's that are publicly available online for certain nonprofit groups, and looked at other Web sites discussing the number of people employed at certain entities.

[71] In a small number of lawsuits, named plaintiffs include organizations claiming to have members that seek an exemption. We have very little information about the number, size, and types of entities those members. Based on limited information from those cases, however, their membership appears to consist mainly, although not entirely, of houses of worship, integrated auxiliaries, and participants in self-insured plans of churches. As explained above, the contraceptive coverage of women covered by such plans is not likely to be affected by the expanded exemption in these rules. However, to account for plans subject to contraceptive coverage obligations among those members we have added 10,000 to our estimate of the number of persons among litigants that may be impacted by these rules.

[72] See Kaiser Family Foundation and Health Research and Educational Trust, ''Employer Health Benefits: 2017 Annual Survey'' at 57, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[73] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[74] United States Census Bureau, ''Age and Sex Composition: 2010'' (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies ''for all women with reproductive capacity.'' *https://www.hrsa.gov/womensguidelines/*; also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, ''Contraceptive Use in the United States'' (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[75] See *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states* (reporting that of 60,877,000 women aged 15–44, 26,945,000 use women's contraceptive methods covered by the Guidelines).

[76] It would appear that a smaller percentage of college-aged women use contraception—and use more expensive methods such as long acting methods or sterilization—than among other women of childbearing age. *See* NCHS Data Brief, ''Current Contraceptive Status Among Women Aged 15–44: United States, 2011–2013'' (Dec. 2014), available at

Continued

1,462 of those women would be affected by these rules.

Together, this leads the Departments to estimate that approximately 8,700 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted above, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do we know how many would have alternative contraceptive access from a parent's or spouse's plan, or from Federal, State, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

Sixth, in a brief filed in the *Zubik* litigation, the Departments stated that ''in 2014, [HHS] provided user-fee reductions to compensate TPAs for making contraceptive coverage available to more than 600,000 employees and beneficiaries,'' and that ''[t]hat figure includes both men and women covered under the relevant plans.'' [77] HHS has reviewed the information giving rise to that estimate, and has received updated information for 2015. In 2014, 612,000 persons were covered by plans claiming contraceptive user fees adjustments, and in 2015, 576,000 persons were covered by such plans. These numbers include all persons in such plans, not just women of childbearing age.

HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly 100,000 persons each, and several others cover approximately 40,000 persons each. In other words, these plans were proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

There are two reasons to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.[78] Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these interim final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.[79] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[80] (The Departments take no view on the status of these particular plans under ERISA, but simply make this observation for the purpose of seeking to estimate the impact of these interim final rules.) Nevertheless, overall it seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these interim final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations these interim final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these interim final rules. The Departments begin with the 8,700 women of childbearing age that use contraception who we estimate will be affected by use of the expanded exemption among litigating entities. In addition to that number, we calculate the following number of women affected by accommodated entities using the expanded exemption. As noted above, approximately 576,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2014. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, we do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, we assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer sponsored insurance, 56.1 percent are covered by self-insured plans and 43.9 percent are covered by fully insured plans.[81] Therefore, corresponding to the 576,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 451,000 persons were covered by fully insured plans using the accommodation. This yields an estimate of 1,027,000 covered persons of all ages and sexes in plans using the previous accommodation.

As discussed below, and recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the prior rule

https://www.cdc.gov/nchs/data/databriefs/db173.pdf.

[77] Brief of Respondents at 18–19 & n.7, *Zubik* v. *Burwell,* No. 14–1418, et al. (U.S. filed Feb. 10, 2016). The actual number is 612,487.

[78] See, for example, *https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule* (''HHS has now established an accommodation that will allow our ministries to continue offering health insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.'') In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it ''is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia.'' Comments on CMS–9968–ANPRM (dated June 15, 2012).

[79] See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, *Advocate Health Care Network,* Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) (''CHA members have relied for decades that the 'church plan' exemption contained in'' ERISA.).

[80] See supra note 66.

[81] ''Health Insurance Coverage Bulletin'' Table 3A, page 15. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

will continue to opt into it under these interim final rules. Notably, however, the data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As also cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these interim final rules would not impact the contraceptive coverage their employees receive. We do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. We assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data. Based on these assumptions and without better data available, we assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, we assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.

Applying these percentages to the total number of 1,027,000 persons we estimate are covered in accommodated plans, we estimate that approximately 257,000 persons previously covered in accommodated plans will be covered in the 109 plans that use the expanded exemption, and 770,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, 20.2 percent of these persons are women of childbearing age, which amounts to approximately 51,900 women of childbearing age in previously accommodated plans that we estimate will use the expanded exemption. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that we expect approximately 23,000 women that use contraception covered by the Guidelines to be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 8,700 women in plans of litigating entities that may be affected by these rules. Based on our limited information from the litigation and accommodation notices, we expect that the overlap is significant. Nevertheless, in order to estimate the possible effects of these rules, we assume there is no overlap between these two numbers, and therefore that these interim final rules would affect the contraceptive costs of approximately 31,700 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these interim final rules is less than 0.1 percent of the 55.6 million women in private plans that HHS ASPE estimated [82] receive preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the prior accommodation process, the total user fee adjustment amount for self-insured plans for the 2015 benefit year was $33 million. These adjustments covered the cost of contraceptive coverage provided to women participants and beneficiaries in self-insured plans where the employer objected and made use of the accommodation, and where an authorizing exception under OMB Circular No. A–25R was in effect as the Secretary of the Department of Health and Human Services requests. Nine percent of that amount was attributable to administrative costs and margin, according to the provisions of 45 CFR 156.50(d)(3)(ii). Thus the amount of the adjustments attributable to the cost of contraceptive services was about $30 million. As discussed above, in 2015 that amount corresponded to 576,000 persons covered by such plans. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age—that is, approximately 116,000 women. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, which includes 51,400 women in those plans. Therefore, entities using contraceptive user fees adjustments received approximately $584 per year per woman of childbearing age that use contraception covered by the Guidelines and are covered in their plans.

As discussed above, the Departments estimate that the expanded exemptions will impact the contraceptive costs of approximately 31,700 women of childbearing age that use contraception covered by the Guidelines. At an average of $584 per year, the financial transfer effects attributable to the interim final rules on those women would be approximately $18.5 million.[83] [84]

To account for uncertainty in the estimate, we conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these interim final rules.

As noted above, the HHS ASPE report estimated that 55.6 million women aged 15 to 64 and covered by private insurance had preventive services coverage under the Affordable Care Act. Approximately 16.2 percent of those women were enrolled in plans on exchanges or were otherwise not covered by employer sponsored insurance, so only 46.6 million women aged 15 to 64 received the coverage through employer sponsored private insurance plans.[85] In addition, some of those private insurance plans were offered by government employers, encompassing approximately 10.5 million of those women aged 15 to 64.[86]

[82] Available at *https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans*; also, see Abridged Report, available at *https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf*.

[83] As noted above, the Departments have taken the position that providing contraceptive coverage is cost neutral to issuers. (78 FR 39877). At the same time, because of the up-front costs of some contraceptive or sterilization methods, and because some entities did not cover contraception prior to the Affordable Care Act, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent.

[84] Describing this impact as a transfer reflects an implicit assumption that the same products and services would be used with or without the rule. Such an assumption is somewhat oversimplified because the interim final rules shift cost burden to consumption decision-makers (that is, the women who choose whether or not to use the relevant contraceptives) and thus can be expected to lead to some decrease in use of the affected drugs and devices and a potential increase in pregnancy—thus leading to a decrease and an increase, respectively, in medical expenditures.

[85] Available at *https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf*.

[86] The ASPE study relied on Census data of private health insurance plans, which included plans sponsored by either private or public sector

Continued

The expanded exemption in these interim final rules does not apply to government plan sponsors. Thus we estimate that the number of women aged 15 to 64 covered by private sector employer sponsored insurance who receive preventive services coverage under the Affordable Care Act is approximately 36 million.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.[87] The 6 percent may have included approximately 2.16 million of the women aged 15–64 covered by employer sponsored insurance plans in the private sector. According to Census data, 59.9 percent of women aged 15 to 64 are of childbearing age (aged 15 to 44), in this case, 1.3 million. And as noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore we estimate that 574,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.[88]

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for conscientious reasons, or for other reasons. Despite our lack of information about their motives, we attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, we estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby,* where the Court observed that ''HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable''. 134 S. Ct. at 2774. The Departments are aware of several Federal health care conscience laws[89] that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but we are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while we consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions we agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.[90] That means that only approximately 394,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, these interim final rules build on existing rules that already exempt houses of worship and integrated auxiliaries and, as explained above, effectively remove obligations to provide contraceptive coverage within objecting self-insured church plans. These rules will therefore not effect transfers to women in the plans of such employers. In attempting to estimate the number of such employers, we consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the

employers. See Table 2, notes 2 & 3 (explaining the scope of private plans and government plans for purposes of Table 2), available at *https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-250.pdf*.

According to data tables from the Medical Expenditure Panel Survey (MEPS) of the Agency for Healthcare Research and Quality of HHS (*https://meps.ahrq.gov/mepsweb/*), State and local governments employ 19,297,960 persons; 99.2 percent of those employers offer health insurance; and 67.4 percent of employees that work at such entities where insurance is offered are enrolled in those plans, amounting to 12.9 million persons enrolled. DOL estimates that in the public sector, for each policyholder there is an average of slightly less than one dependent. ''Health Insurance Coverage Bulletin'' Table 4, page 21. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf*. Therefore, State and local government employer plans cover approximately 24.8 million persons of all ages. Census data indicates that on average, 12 percent of persons covered by private insurance plans are aged 65 and older. Using these numbers, we estimate that State and local government employer plans cover approximately 21.9 million persons under age 65.

The Federal Government has approximately 8.2 million persons covered in its employee health plans. According to information we received from the Office of Personnel Management, this includes 2.1 million employees having 3.2 million dependents, and 1.9 million retirees (annuitants) having 1 million dependents. We do not have information about the ages of these policyholders and dependents, but for the purposes of this estimate we assume the annuitants and their dependents are aged 65 or older and the employees and their dependents are under age 65, so that the Federal Government's employee health plans cover 5.3 million persons under age 65.

Thus, overall we estimate there are 27.2 million persons under age 65 enrolled in private health insurance sponsored by government employers. Of those, 38.3 percent are women aged 15–64, that is, 10.5 million.

[87] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2010 Annual Survey'' at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf*.

[88] Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these interim final rules.

[89] For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

[90] John Asker, et al., ''Corporate Investment and Stock Market Listing: A Puzzle?'' 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at *https://doi.org/10.1093/rfs/hhu077*. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, ''The number of publicly-traded US companies is down 46% in the past two decades,'' *Yahoo! Finance* (Aug. 8, 2016), available at *https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html*.

United States,[91] 197 Catholic dioceses,[92] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[93] Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so we use the number of schools to estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention. It covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[94] Christian Brothers is a plan that covers Catholic organizations. It covers Catholic churches and integrated auxiliaries, which are estimated above, but also it has said in litigation that it also covers about 500 additional entities that are not exempt as churches. In total, therefore, we estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous rules. We do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include ''churches, mission-sending agencies, hospitals, educational institutions and other related ministries.'' Using that ratio, we estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 would be of childbearing age, and 32,100 would use contraceptives covered by the Guidelines. Therefore, we estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous rules nor were participants in self-insured church plans that oppose contraceptive coverage, covered 362,100 women aged 15 to 44 that use contraceptives covered by the Guidelines. As noted above, we estimate an average annual expenditure on contraceptive products and services of $584 per user. That would amount to $211.5 million in potential transfer impact among entities that did not cover contraception pre- Affordable Care Act for any reason.

We do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these interim final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous rules on this matter, we are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, we believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 120,000 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these interim final rules. Consequently, as explained below, we believe that the potential impact of these interim final rules falls substantially below the $100 million threshold for economically significant and major rules.

First, as mentioned, we are not aware of information that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or religious beliefs specifically, as opposed to having done so for other reasons. Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees. Also, avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts, all provide reasons for some employers not to return to pre-Affordable Care Act lack of contraceptive coverage. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.[95] Furthermore, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

In addition, not all sincerely held conscientious objections to contraceptive coverage are likely to be held by persons with religious beliefs as distinct from persons with sincerely held non-religious moral convictions, whose objections would not be encompassed by these interim final rules.[96] We do not have data to indicate, among entities that did not cover contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, which ones did so based on religious beliefs and which ones did so instead based on non-religious moral convictions. Among the general public, polls vary about religious beliefs but one prominent poll shows that 89 percent of Americans say they believe in God, while 11 percent say they do not or are agnostic.[97] Therefore, we estimate that for every ten entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, one did so based on sincerely held non-religious moral convictions, and therefore are not affected by the expanded exemption provided by these interim final rules for religious beliefs.

Based on our estimate of an average annual expenditure on contraceptive products and services of $584 per user,

[91] Roman Catholic Diocese of Reno, ''Diocese of Reno Directory: 2016–2017,'' available at *http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf.*

[92] Wikipedia, ''List of Catholic dioceses in the United States,'' available at *https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.*

[93] National Catholic Educational Association, ''Catholic School Data,'' available at *http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.*

[94] Guidestone Financial Resources, ''Who We Serve,'' available at *https://www.guidestone.org/AboutUs/WhoWeServe.*

[95] On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered ''yes'' or ''don't know'' to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule's effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

[96] Such objections may be encompassed by companion interim final rules published elsewhere in this **Federal Register**. Those rules, however, as an interim final matter, are more narrow in scope than these rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

[97] Gallup, ''Most Americans Still Believe in God'' (June 14–23, 2016), available at *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

the effect of the expanded exemptions on 120,000 women would give rise to approximately $70.1 million in potential transfer impact. This falls substantially below the $100 million threshold for economically significant and major rules. In addition, as noted above, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent, yielding a potential transfer of $63.8 million.

We request comment on all aspects of the preceding regulatory impact analysis, as well as on how to attribute impacts to this interim final rule and the companion interim final rule concerning exemptions provided based on sincerely held (non-religious) moral convictions published elsewhere in this **Federal Register**.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments anticipate that there will be more entities reluctantly using the existing accommodation that will choose to operate under the newly expanded exemption, than entities that are not currently eligible to use the accommodation that will opt into it. The effect of this rule will therefore be that fewer overall adjustments are made to the Federally facilitated Exchange user fees for entities using the accommodation process, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect, than would have occurred under the previous rule if this rule were not finalized. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities, and in many cases will relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization, the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

However, we are requesting an emergency review of the information collection referenced later in this section. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we have submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting an emergency review and approval under both 5 CFR 1320.13(a)(2)(i) and (iii) of the implementing regulations of the PRA in order to implement provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). In accordance with 5 CFR 1320.13(a)(2)(i), we believe public harm is reasonably likely to ensue if the normal clearance procedures are followed. The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information. Similarly, in accordance with 5 CFR 1320.13(a)(2)(iii), we believe the use of normal clearance procedures is reasonably likely to cause a statutory or court ordered deadline to be missed. Many cases have been on remand for over a year from the Supreme Court, asking the Departments and the parties to resolve this matter. These interim final rules extend exemptions to entities, which involves no collection of information and which the Departments have statutory authority to do by the use of interim final rules. If the information collection involved in the amended accommodation process is not approved on an emergency basis, newly exempt entities that wish to opt into the amended accommodation process might not be able to do so until normal clearance procedures are completed.

A description of the information collection provisions implicated in these interim final rules is given in the following section with an estimate of the annual burden. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.[98]

a. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under

[98] May 2016 National Occupational Employment and Wage Estimates United States found at *https://www.bls.gov/oes/current/oes_nat.htm.*

these interim final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these interim final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations. The burden related to the notice to HHS is currently approved under OMB Control Number 0938–1248 and the burden related to the self-certification (EBSA Form 700) is currently approved under OMB control number 0938–1292.

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these interim final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party administrator). As explained above, HHS assumes that, among the 209 entities we estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes, as it did in its August 2014 interim final rules, that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.[99] HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour,[100] 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour,[101] 5 minutes for legal counsel at a cost of $134.50 per hour,[102] and 5 minutes by a senior executive at a cost of $186.88 per hour [103]) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately $74.96 for a total hour burden of approximately 7.5 hours with an equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

HHS estimates that each self-certification or notice to HHS will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be $0.54. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately $2.70 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so each will account for $1.35 of the cost burden.

b. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language set forth previously by HHS or substantially similar language. The burden for this ICR is currently approved under OMB control number 0938–1292.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at $55.68 per hour) [104] and 15 minutes of management review (at $117.40 per hour) [105] to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately $85.03. The total burden for all issuers or third party administrators will be 136 hours, with an equivalent cost of $9,268. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 68 burden hours with an equivalent cost of $4,634, with approximately 55 respondents.

As discussed above, the Departments estimate that 770,000 persons will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. It is not known how many persons will be covered in the plans of the 9 entities newly using the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity, we estimate that all 109 accommodated entities will encompass 839,300 covered persons. We assume that sending one notice to each participant will satisfy the need to send the notices to all participants and dependents. Among persons covered by plans, approximately 50.1 percent are participants and 49.9 percent are

[99] For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

[100] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84, *https://www.bls.gov/oes/current/oes436011.htm.*

[101] Occupation code 11–3111 for Compensation and Benefits Managers with mean hourly wage $61.01, *https://www.bls.gov/oes/current/oes113111.htm.*

[102] Occupation code 23–1011 for Lawyers with mean hourly wage $67.25, *https://www.bls.gov/oes/current/oes231011.htm.*

[103] Occupation code11–1011 for Chief Executives with mean hourly wage $93.44, *https://www.bls.gov/oes/current/oes111011.htm.*

[104] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84.

[105] Occupation code 11–1021 General and Operations Managers with mean hourly wage $58.70.

dependents.[106] For 109 entities, the total number of notices will be 420,490. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[107] Therefore, approximately 194,687 notices will be mailed. HHS estimates that each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54. The total cost for sending approximately 194,687 notices by mail is approximately $105,131. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $52,565 of the cost burden.

c. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to cause the notification to be sent (the issuer or third party administrator can send the notice on behalf of the entity). For the purpose of calculating ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke it fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of $117.40 per hour,[108] 30 minutes for legal counsel at a cost of $134.50 per hour [109], 1 hour for clerical labor at a cost of $55.68 per hour [110]). The burden per respondent will be 2 hours with an equivalent cost of $181.63; for 109 entities, the total burden will be 218 hours with an equivalent cost of approximately $19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an equivalent cost of approximately $9,899.

As discussed above, HHS estimates that there are 257,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[111] As before, we use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 128,757 notices will be sent, of which 59,615 notices will be mailed. HHS estimates that each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54. The total cost for sending approximately 59,615 notices by mail is approximately $32,192. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 64,379 notices, with an equivalent cost of approximately $16,096.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
Self-Certification or Notices to HHS	0938—NEW	*5	5	0.83	3.75	$89.95	$337.31	$338.66
Notice of Availability of Separate Payments for Contraceptive Services.	0938—NEW	*55	210,245	1.25	68.13	68.02	4,634.14	57,199.59
Notice of Revocation of Accommodation	0938—NEW	*55	64,379	2.00	109	90.82	9,898.84	25,994.75
Total		*115	274,629	4.08	180.88		14,870.29	83,533.00

*The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

We are soliciting comments on all of the information collection requirements contained in these interim final rules. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938–1292 and 0938–1248. HHS is requesting a new OMB control number that will ultimately contain the approval for the new information collection requirements contained in these interim

[106] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[107] According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the Internet outside of work. According to a Pew Research Center survey, 61 percent of Internet users use online banking, which is used as the proxy for the number of Internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

[108] Occupation code 11–1021 for General and Operations Managers with mean hourly wage $58.70, *https://www.bls.gov/oes/current/oes111021.htm.*

[109] Occupation code 23–1011 for Lawyers with mean hourly wage $67.25, *https://www.bls.gov/oes/current/oes231011.htm.*

[110] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84, *https://www.bls.gov/oes/current/oes436011.htm.*

[111] In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, we indicated that we do not know the extent to which the number of women in accommodated plans affected by these rules overlap with the number of women in plans offered by litigating entities that will be affected by these rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

final rules as well as the related requirements currently approved under 0938–1292 and 0938–1248. In an effort to consolidate the number of information collection requests, we will formally discontinue the control numbers 0938–1292 and 0938–1248 once the new information collection request associated with these interim final rules is approved.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov*. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

These interim final rules amend the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer who revokes their accommodation. DOL submitted the ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. In an effort to consolidate the number of information collection requests, DOL will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once the ICR is approved DOL will discontinue 1210–0152. A copy of the information collection request may be obtained free of charge on the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001*. This approval will allow respondents to temporarily utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden.

Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur $0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 420,489 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke its use and will therefore be required to cause the Notice of Revocation of Accommodation to be sent (the issuer or third party administrator can send the notice on behalf of the entity). These entities will spend approximately two hours in preparation time and incur $0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 128,757 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114 [112] (combined with HHS total is 227).

Total Responses: 274,628 (combined with HHS total is 549,255).

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: $68,662 (combined with HHS total is $137,325).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, ''[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications.'' In addition, agencies are directed to ''take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market.'' These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting

[112] Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

costs.[113] Therefore, this interim final rule is considered an Executive Order 13771 deregulatory action.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''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 one year.'' The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflater for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

G. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VII. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* [Reserved]. For further guidance, see § 54.9815–2713T(a)(1) introductory text.

* * * * *

(iv) [Reserved]. For further guidance, see § 54.9815–2713T(a)(1)(iv).

* * * * *

■ 3. Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of § 54.9815–2713 and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i)–(iii) [Reserved]. For further guidance, see § 54.9815–2713(a)(1)(i) through (iii).

[113] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of § 54.9815–2713 as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

(2)–(c) [Reserved]. For further guidance, see § 54.9815–2713(a)(2) through (c).

(d) *Effective/Applicability date.* (1) Paragraphs (a) through (c) of this section are applicable beginning on April 16, 2012, except—

(2) Paragraphs (a)(1) introductory text and (a)(1)(iv) of this section are effective on October 6, 2017.

(e) *Expiration date.* This section expires on October 6, 2020.

■ 4. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) through (f) [Reserved]. For further guidance, see § 54.9815–2713AT.

(b)

■ 5. Section 54.9815–2713AT is added to read as follows:

§ 54.9815–2713AT Accommodations in connection with coverage of preventive health services (temporary).

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give sixty-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group

health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): ''Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].''

(e) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(g) *Expiration date.* This section expires on October 6, 2020.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 2590.715–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 8. Section 2590.715–2713A is revised to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its exempt status under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under § 2510.3–16 of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715–2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) for plan participants and beneficiaries

for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): ''Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer].''

(e) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 2590.715–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131 and 147.132, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132.

* * * * *

■ 11. Section 147.131 is revised to read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process.

(d) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Deparement of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) ''Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments . If you have any questions about this notice, contact [contact information for health insurance issuer].''

(f) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 12. Add § 147.132 to read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to ''plan participants and beneficiaries'' will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(c) *Definition.* For the purposes of this section, reference to ''contraceptive'' services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21851 Filed 10–6–17; 11:15 am]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P; 6325–64–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9828]

RIN 1545–BN91

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9925–IFC]

RIN 0938–AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs or moral convictions. These interim final rules expand exemptions to protect moral convictions for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the United States Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also provide certain morally objecting entities access to the voluntary "accommodation" process regarding such coverage. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES:

Effective date: These interim final rules are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by "Preventive Services," may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9925–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9925–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492–4305 or *marketreform@cms.hhs.gov* for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the context of legal requirements touching on certain sensitive health care issues—including health coverage of contraceptives—Congress has a consistent history of supporting conscience protections for moral convictions alongside protections for religious beliefs, including as part of its efforts to promote access to health services.[1] Against that backdrop,

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their "religious beliefs or moral convictions"); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS,

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, "with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by" HRSA (the "Guidelines"). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, "the Departments"),[3] exercised both the discretion granted to HHS through HRSA, its component, in PHS Act section 2713(a)(4), and the authority granted to the Departments as administering agencies (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92) to issue regulations to guide HRSA in carrying out that provision. Through rulemaking, including three interim final rules, the Departments exempted and accommodated certain religious objectors, but did not offer an exemption or accommodation to any group possessing non-religious moral objections to providing coverage for some or all contraceptives. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the "contraceptive Mandate," or the "Mandate") as being inconsistent with various legal protections. These challenges included lawsuits brought by some non-religious organizations with sincerely held moral convictions inconsistent with providing coverage for some or all contraceptive services, and those cases continue to this day. Various public comments were also submitted asking the Departments to protect objections based on moral convictions.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as: The interests served by the existing Guidelines, regulations, and accommodation process;[4] the extensive litigation; Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017); Congress' history of providing protections for moral convictions alongside religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under PHS Act section 2713(a)(4); the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; and the history of the regulatory process and comments submitted in various requests for public comments (including in the Departments' 2016 Request for Information). Elsewhere in this issue of the **Federal Register**, the Departments published, contemporaneously with these interim final rules, companion interim final rules expanding exemptions to protect sincerely held religious beliefs in the context of the contraceptive Mandate.

In light of these considerations, the Departments issue these interim final rules to better balance the Government's interest in promoting coverage for contraceptive and sterilization services with the Government's interests in providing conscience protections for individuals and entities with sincerely held moral convictions in certain health care contexts, and in minimizing burdens imposed by our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, "[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact" and that "[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the Department of Health and Human Services (HHS)." Those laws protect objections based on moral convictions in addition to religious beliefs.

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS

and Education, and Related Agencies Appropriations Act), Public Law 115–31 (protecting any "health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of "the provision of contraceptive coverage by health insurance plans" in the District of Columbia, "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions."); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions"); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their "religious or conscientious commitment to offer only natural family planning"); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on "religious beliefs or moral objections"); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on "conscience" as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on "religious beliefs or moral convictions"); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by "aliens" due to "religious beliefs or moral convictions"); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on "moral or religious convictions"); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their "religious or moral objection").

[2] This document's references to "contraception," "contraceptive," "contraceptive coverage," or "contraceptive services" generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

[3] Note, however, that in sections under headings listing only two of the three Departments, the term "Departments" generally refers only to the two Departments listed in the heading.

[4] In this IFR, we generally use "accommodation" and "accommodation process" interchangeably.

Act requires coverage without cost sharing for "such additional" women's preventive care and screenings "as provided for" and "supported by" guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

The Departments have consistently interpreted section 2713(a)(4)'s of the PHS Act grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act reference to "comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph" to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines "supported by the Health Resources and Services Administration for purposes of this paragraph," the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from "the other guidelines referenced in section 2713(a), which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients." *Id.* Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4), the Departments have previously promulgated regulations defining the scope of permissible religious exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority delegated to the Departments as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. The Congress did not intend to require entirely uniform coverage of preventive services. (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 for grandfathered plans. This exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include: Section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime limits; section 2712, which prohibits rescissions of health insurance coverage; section 2714, which extends dependent coverage until age 26; and section 2718, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." *Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that "longstanding Federal laws to protect conscience . . . remain intact," including laws that protect religious beliefs and moral convictions from certain requirements in the health care context. Although the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect conscience regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in consideration of the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS Act.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, "Clinical Preventive Services for Women, Closing the Gaps" (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation, pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[6]

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of "contraceptives" certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,[7] the IOM's recommendation included

[5] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[6] Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings "with respect to women," the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[7] FDA's guide "Birth Control: Medicines To Help You," specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and "may also work . . . by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason distinct from whether they also oppose contraception or sterilization. One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He stated that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by section 2713(a)(1) through (3) of the PHS Act leads to lower rates of disability or disease and increased rates of well-being, such that the IOM should recommend additional services to be included under Guidelines issued under section 2713(a)(4) of the PHS Act. He further stated that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and that "the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy." He also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] IOM 2011 at 231–32. In its response to Dr. LoSasso, the other 15 committee members stated in part that "At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions."

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM. *https://www.hrsa.gov/womensguidelines/* The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (hereinafter "the Mandate").

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules. (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specified that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.[9] The 2011 interim final rules only offered the exemption to a narrow scope of employers, and only if they were religious. As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some "States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services." (76 FR 46623). Several comments were submitted asking that the exemption include those who object to contraceptive coverage based on non-religious moral convictions, including pro-life, non-profit advocacy organizations.[10]

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of "religious employer" in the 2011 interim final rules without modification (2012 final regulations).[11] (77 FR 8725). The exemption did not require exempt employers to file any certification form or comply with any other information collection process.

Contemporaneously with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).[12] The temporary safe harbor did not include nonprofit organizations that had an objection to contraceptives based on moral convictions but not religious beliefs, nor did it include for-profit entities of any kind. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve "two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services." (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer—(1) have the inculcation of religious values as its purpose; (2) primarily employ persons who share its religious tenets; and (3) primarily serve persons who share its religious tenets. The proposed expanded

[8] The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

[9] The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011. (76 FR 46621).

[10] *See, for example,* Americans United for Life ("AUL") Comment on CMA–9992–IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496.*

[11] The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

[12] Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: *http://www.lb7.uscourts.gov/documents/12cv3932.pdf.* The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

definition still encompassed only religious entities.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations "may be less likely than" employees of exempt houses of worship and integrated auxiliaries to share their employer's faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization's plan—and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries. The proposed accommodation process was not to be offered to non-religious nonprofit organizations, nor to any for-profit entities. Public comments again included the request that exemptions encompass objections to contraceptive coverage based on moral convictions and not just based on religious beliefs.[14] On August 15, 2012, the Departments extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations "does not undermine the governmental interests furthered by the contraceptive coverage requirement." (78 FR 39874). However, like the 2013 NPRM, the July 2013 regulations assumed that "[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection" to contraceptives. *Id.*

The July 2013 regulation also finalized an accommodation for eligible organizations, which were then defined to include solely organizations that are religious. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization's plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the HHS Secretary requests and an authorizing exception under OMB Circular No. A–25R is in effect.[15] With respect to fully insured group health plans, the issuer was expected to bear the cost of such payments,[16] and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations. The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. Religious for-profit entities won various court decisions leading to the Supreme Court's ruling in *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[17]

On August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of HHS that an eligible organization had religious objections to coverage of all or a subset of contraceptive services (79 FR 51092). In response to *Hobby Lobby*, the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption; neither added a certification requirement for

[13] The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

[14] *See, for example,* AUL Comment on CMS–9968–P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115.*

[15] *See also* 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally-facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.

[16] "[P]roviding payments for contraceptive services is cost neutral for issuers." (78 FR 39877).

[17] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. *See* 134 S. Ct. at 2774.

exempt entities; and neither encompassed objections based on non-religious moral convictions.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

Meanwhile, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik* v. *Burwell*. On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik*, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases "in light of the substantial clarification and refinement in the positions of the parties" that had been filed in supplemental briefs. 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would "allow the parties sufficient time to resolve any outstanding issues between them." *Id.* The Court also specified that "the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice" while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, meetings were held between attorneys for the Government and for the plaintiffs in those cases. The Departments also issued a Request for Information ("RFI") on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016. Those comments included the request that the exemption be expanded to include those who oppose the Mandate for either religious "or moral" reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.[18]

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations asserted that they believe some methods classified by FDA as contraceptives may have an abortifacient effect and therefore, in their view, are morally equivalent to abortion. These organizations have neither received an exemption from the Mandate nor do they qualify for the accommodation. For example, the organization that since 1974 has sponsored the annual March for Life in Washington, DC (March for Life), filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, (77 FR 8727), March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who "want" the coverage so as to prevent "unintended" pregnancy. March for Life contended that because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and therefore doing so was arbitrary and capricious in violation of the APA. March for Life further contended that because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on our assumption that such entities are relatively more likely than other religious nonprofits to have employees that share their views against contraception), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and therefore violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real Alternatives, Inc.* v. *Burwell*, 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the Federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims (not specifically ruling on the APA claim), and issued a permanent injunction against the Departments that is still in place. *March for Life* v. *Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, Federal district and appellate courts in Pennsylvania disagreed with the reasoning from *March for Life* and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives*, 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. *Id.* at *18.

On December 20, 2016, HRSA updated the Guidelines via its Web site, *https://www.hrsa.gov/womensguidelines2016/index.html*. HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the

[18] *See, for example, https://www.regulations.gov/document?D=CMS-2016-0123-54142; see also https://www.regulations.gov/document?D=CMS-2016-0123-54218* and *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

contraceptive method). They also specified, for the first time, that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process, nor did they extend the exemption or accommodation process to organizations or individuals that oppose certain forms of contraception (and coverage thereof) on moral grounds.

On January 9, 2017, the Departments issued a document entitled, "FAQs About Affordable Care Act Implementation Part 36." [19] The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. The Departments did not adopt the approach requested by certain commenters, cited above, to expand the exemption to include those who oppose the Mandate for moral reasons.

On May 4, 2017, the President issued Executive Order 13798, "Promoting Free Speech and Religious Liberty." Section 3 of that order declares, "Conscience Protections with Respect to Preventive-Care Mandate. The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code."

II. Expanded Exemptions and Accommodations for Moral Convictions

These interim final rules incorporate conscience protections into the contraceptive Mandate. They do so in part to bring the Mandate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues, cognizant that Congress neither required the Departments to impose the Mandate nor prohibited them from providing conscience protections if they did so. Specifically, these interim final rules expand exemptions to the contraceptive Mandate to protect certain entities and individuals that object to coverage of some or all contraceptives based on sincerely held moral convictions but not religious beliefs, and these rules make those exempt entities eligible for accommodations concerning the same Mandate.

A. Discretion To Provide Exemptions Under Section 2713(a)(4) of the PHS Act and the Affordable Care Act

The Departments have consistently interpreted HRSA's authority under section 2713(a)(4) of the PHS Act to allow for exemptions and accommodations to the contraceptive Mandate for certain objecting organizations. Section 2713(a)(4) of the PHS Act gives HRSA discretion to decide whether and in what circumstances it will support Guidelines providing for additional women's preventive services coverage. That authority includes HRSA's discretion to include contraceptive coverage in those Guidelines, but the Congress did not specify whether or to what extent HRSA should do so. Therefore, section 2713(a)(4) of the PHS Act allows HRSA to not apply the Guidelines to certain plans of entities or individuals with religious or moral objections to contraceptive coverage, and by not applying the Guidelines to them, to exempt those entities from the Mandate. These rules are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Our protection of conscience in these interim final rules is consistent with the structure and intent of the Affordable Care Act. The Affordable Care Act refrains from applying section 2713(a)(4) of the PHS Act to millions of women in grandfathered plans. In contrast, we anticipate that conscientious exemptions to the Mandate will impact a much smaller number of women. President Obama emphasized in signing the Affordable Care Act that "longstanding Federal law to protect conscience"—laws with conscience protections encompassing moral (as well as religious) objections—specifically including (but not limited to) the Church Amendments (42 U.S.C. 300a–7), "remain intact." Executive Order 13535. Nothing in the Affordable Care Act suggests Congress' intent to deviate from its long history, discussed below, of protecting moral convictions in particular health care contexts. The Departments' implementation of section 2713(a)(4) of the PHS Act with respect to contraceptive coverage is a context similar to those encompassed by many other health care conscience protections provided or supported by Congress. This Mandate concerns contraception and sterilization services, including items believed by some citizens to have an abortifacient effect—that is, to cause the destruction of a human life at an early stage of embryonic development. These are highly sensitive issues in the history of health care regulation and have long been shielded by conscience protections in the laws of the United States.

B. Congress' History of Providing Exemptions for Moral Convictions

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on nearly 50 years of statutory law and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health insurance coverage. Congress very recently expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808, Public Law 115–31 (May 5, 2017). In support of these interim final rules, we consider it significant that Congress' most recent statement on the prospect of Government mandated contraceptive coverage specifically intends that a conscience clause be included to protect moral convictions.

The many statutes listed in Section I-Background under footnote 1, which show Congress' consistent protection of moral convictions alongside religious beliefs in the Federal regulation of health care, includes laws such as the 1973 Church Amendments, which we discuss at length below, all the way to the 2017 Consolidated Appropriations Act discussed above. Notably among those laws, the Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w–

[19] Available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf*.

22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"). The Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.

C. The Church Amendments' Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations. These sections of the United States Code are known as the Church Amendments, named after their primary sponsor Senator Frank Church (D–Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions. Among other things, the amendments protect the recipients of certain Federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object "on the basis of religious beliefs or moral convictions," and they prohibit recipients of certain Federal health funds from discriminating against any personnel "because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions" (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to "any lawful health service," or to "any part of a health service program." (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute "any lawful health service" or a "part of a health service program." As such, the protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court's decision in *Roe* v. *Wade*, 410 U.S. 113 (1973). Even though the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens must facilitate its exercise. Thus, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared "Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles." 410 U.S. at 144 & n.38 (1973). Likewise in *Roe*'s companion case, *Doe* v. *Bolton*, the Court observed that, under State law, "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions "obviously . . . afford appropriate protection." *Id.* at 198. As an Arizona court later put it, "a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either." *Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains relevant discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe* v. *Wade* but also an instance where a Federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D–IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record is particularly relevant to this discussion:

> Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.
>
> One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.
>
> As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?
>
> Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words "or moral"?
>
> Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words "or moral conviction" were added after "religious belief." I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.
>
> Mr. STEVENSON. The Senator's suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18.

As the debate proceeded, Senator Church went on to quote *Doe* v. *Bolton*'s reliance on a Georgia statute that stated "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 119 Congr. Rec. at S5722 (quoting 410 U.S. at 197–98). Senator Church added, "I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations." *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D–WI) asked whether, "if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, 'We are not going to bother with this kind of procedure in this hospital,' would the pending amendment permit that?" 119 Congr. Rec. at S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C–NY), speaking in support of the amendment, added the following perspective:

> Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the

recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic] [20] to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words "moral conviction," because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. at S5723.

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R–MA) [21] likewise observed that "the right of conscience has long been recognized in the parallel situation in which the individual's right to conscientious objector status in our selective service system has been protected" and "expanded by the Supreme Court to include moral conviction as well as formal religious belief." 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, "We are concerned here only with the right of moral conscience, which has always been a part of our national tradition." *Id.* at 4149.

These first of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion: See 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31;
- Protections for entities and individuals that object to providing or covering contraceptives: See id. at Div. C, Title VIII, Sec. 808; id. at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act); and id. at Div. I, Title III; and
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives: See 42 U.S.C. 290bb–36; 42 U.S.C. 14406; 42 U.S.C. 18113; and 42 U.S.C. 1396a(w)(3).

The Departments believe that the intent behind Congress' protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports our decision in these interim final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

D. Court Precedents Relevant to These Expanded Exemptions

The legislative history of the protection of moral convictions in the first Church Amendments shows that Members of Congress saw the protection as being consistent with Supreme Court decisions. Not only did Senator Church cite the abortion case *Doe* v. *Bolton* as a parallel instance of conscience protection, but he also spoke of the Supreme Court generally giving "comparable treatment to deeply held moral convictions." Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court's protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh* v. *United States*, 398 U.S. 333 (1970), which the Supreme Court decided just 3 years earlier.

Welsh involved what is perhaps the Government's paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on "religious training and belief," that protection would also extend to avowedly non-religious objections to war held with the same moral strength. *Id.* at 343. The Court declared, "[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to that filled by . . . God' in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a 'religious' conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions."

The Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in these interim final rules. Neither these interim final rules, nor the Church Amendments or other Federal health care conscience statutes, define "moral convictions" (nor do they define "religious beliefs"). But in issuing these interim final rules, we seek to use the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the "individual deeply and sincerely holds"; (2) "that are purely ethical or moral in source and content; (3) "but that nevertheless impose upon him a duty"; (4) and that "certainly occupy in the life of that individual a place parallel to that filled by . . . God' in traditionally religious persons," such that one could say "his beliefs function as a religion in his life." (398 U.S. at 339–40). As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises "capriciously." Instead, along with the requirement that protected moral convictions must be "sincerely held," this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby*, Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan's opinion in *Welsh*, 398 U.S. at 357–58, in support of her statement that "[s]eparating moral convictions from religious beliefs would be of questionable legitimacy." 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious

[20] The Senator might have meant "[forced] . . . against his will."

[21] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

beliefs constitute an illegitimate "separat[ion]" of moral convictions, nor do we assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress' intent in the Church Amendments and in later Federal conscience statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

E. Conscience Protections in Regulations and Among the States

The tradition of protecting moral convictions in certain health contexts is not limited to Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[22] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs when they have determined that it is appropriate to do so in particular circumstances. The Equal Employment Opportunity Commission has consistently protected "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views" alongside religious views under the "standard [] developed in *United States* v. *Seeger*, 380 U.S. 163 (1965) and [*Welsh*]." (29 CFR 1605.1). The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so "is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics." (28 CFR 26.5).[23]

Forty-five States have health care conscience protections covering objections to abortion, and several of those also cover sterilization or contraception.[24] Most of those State laws protect objections based on "moral," "ethical," or "conscientious" grounds in addition to "religious" grounds. Particularly in the case of abortion, some Federal and State conscience laws do not require any specified motive for the objection. (42 U.S.C. 238n). These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts.

The contraceptive Mandate implicates that governmental interest. Many persons and entities object to this Mandate in part because they consider some forms of FDA-approved contraceptives to be abortifacients and morally equivalent to abortion due to the possibility that some of the items may have the effect of preventing the implantation of a human embryo after fertilization. Based on our knowledge from the litigation, all of the current litigants asserting purely non-religious objections share this view, and most of the religious litigants do as well. The Supreme Court, in describing family business owners with religious objections, explained that "[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions." *Hobby Lobby*, 134 S. Ct. at 2751. Outside of the context of abortion, as cited above, Congress has also provided health care conscience protections pertaining to sterilization, contraception, and other health care services and practices.

F. Founding Principles

The Departments also look to guidance from the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. As quoted above, in supporting protecting conscience based on non-religious moral convictions, Senator Buckley declared "[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred." Rep. Heckler similarly stated that "the right of moral conscience . . . has always been a part of our national tradition." This tradition is reflected, for example, in a letter President George Washington wrote saying that "[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of citizenship."[25] Thomas Jefferson similarly declared that "[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority."[26] Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience "the most sacred of all property," and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that "the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed."[27]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context. We do not suggest that the specific protections offered in this rule would also be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These interim final rules do not address in any way how the Government would balance its interests with respect to

[22] *See, for example*, 42 CFR 422.206 (declaring that the general Medicare Advantage rule "does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds."); 42 CFR 438.102 (declaring that information requirements do not apply "if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds"); 48 CFR 1609.7001 ("health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs."); 48 CFR 352.270–9 ("Non-Discrimination for Conscience" clause for organizations receiving HIV or Malaria relief funds).

[23] *See also* 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA's request will depend in part on "[c]ultural, religious, or moral objections to the request").

[24] According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). "Refusing to Provide Health Services" (June 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services*.

[25] From George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790), available at *https://founders.archives.gov/documents/Washington/05-06-02-0135*.

[26] Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809), available at *https://founders.archives.gov/documents/Jefferson/99-01-02-9714*.

[27] James Madison, "Essay on Property" (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

other health services not encompassed by the contraceptive Mandate.[28] Instead we highlight this tradition of respect for conscience from our Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4) of the PHS Act, while protecting conscience in the exercise of moral convictions. We believe that these interim final rules are consistent both with the American tradition of respect for conscience and with Congress' history of providing conscience protections in the kinds of health care matters involved in this Mandate.

G. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in the expanded exemptions and accommodations of these rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for "religious" beliefs, but for "conscience." We interpret that term to include moral convictions and not just religious beliefs. Likewise, President Trump's first Executive Order, EO 13765, declared that "the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." This Mandate imposes both a cost, fee, tax, or penalty, and a regulatory burden, on individuals and purchasers of health insurance that have moral convictions opposed to providing contraceptive coverage. These interim final rules exercise the Departments' discretion to grant exemptions from the Mandate to reduce and relieve regulatory burdens and promote freedom in the health care market.

[28] As the Supreme Court stated in *Hobby Lobby*, the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

H. Litigation Concerning the Mandate

The sensitivity of certain health care matters makes it particularly important for the Government to tread carefully when engaging in regulation concerning those areas, and to respect individuals and organizations whose moral convictions are burdened by Government regulations. Providing conscience protections advances the Affordable Care Act's goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to cover procedures that the owners "could not in good conscience" cover, such as abortion, "HHS would effectively exclude these people from full participation in the economic life of the Nation." 134 S. Ct. at 2783. That would be a serious outcome. As demonstrated by litigation and public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that some of those items may cause early abortions. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) of the PHS Act in a way that respects the moral convictions of our citizens so that they are more free to engage in "full participation in the economic life of the Nation." These expanded exemptions do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. *See March for Life* v. *Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court recently affirmed a district court ruling that allows the previous regulations to be imposed in a way that violates the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives*, 2017 WL 3324690. Our litigation of these cases has led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The organizations that have sued seeking a moral exemption have all adopted moral tenets opposed to contraception and hire only employees who share this view. It is reasonable to conclude that employees of these organizations would therefore not benefit from the Mandate. As a result, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, and our requirement to comply with permanent injunctive relief currently imposed in *March for Life*, provide substantial reasons for the Departments to protect moral convictions through these interim final rules. Even though, as discussed below, we assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, we know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, we consider it appropriate to issue the protections set forth in these interim final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so we, too, believe that "our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government" in this situation.

I. The Departments' Rebalancing of Government Interests

For additional discussion of the Government's balance of interests concerning religious beliefs issued contemporaneously with these interim final rules, see the related document published by the Department elsewhere in this issue of the **Federal Register**. There, we acknowledge that the Departments have changed the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlying it, and we assert that we now believe the Government's legitimate interests in providing for contraceptive coverage do not require us to violate sincerely held religious beliefs while implementing the Guidelines. For parallel reasons, the Departments believe Congress did not set forth—and we do not possess—interests that require us to violate sincerely held moral convictions in the course of generally requiring contraceptive coverage. These changes in policy are

within the Departments' authority. As the Supreme Court has acknowledged, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125 (2016). This "reasoned analysis" requirement does not demand that an agency "demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." *United Student Aid Funds, Inc.* v. *King,* 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)); *see also New Edge Network, Inc.* v. *FCC,* 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").[29]

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. In addition to the apparent fact that many entities with non-religious moral objections to the Mandate appear to only hire persons that share those objections, Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 requirements on grandfathered plans benefitting millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including through various other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, and which these interim final rules leave unchanged.[30] As the Government is under no constitutional obligation to fund contraception, *cf. Harris* v. *McRae,* 448 U.S. 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their moral convictions. *Cf. Rust* v. *Sullivan,* 500 U.S. 173, 192–93 (1991) ("A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.").

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. Our expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant Federal law, the Departments have determined that expanding the exemptions to include protections for moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to take advantage of these exemptions and accommodations may be small, we believe that it is important formally to codify such protections for objections based on moral conviction, given the long-standing recognition of such protections in health care and health insurance context in law and regulation and the particularly sensitive nature of these issues in the health care context. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including 3 previous interim final rules), public comments, and the long-running litigation from non-religious moral objectors to the Mandate, as well as the information contained in the companion interim final rules issued elsewhere in this issue of the **Federal Register**. These interim final rules seek to resolve these matters by directing HRSA, to the extent it requires coverage for certain contraceptive services in its Guidelines, to afford an exemption to certain entities and individuals with sincerely held moral convictions by which they object to contraceptive or sterilization coverage, and by making the accommodation process available for certain organizations with such convictions.

For all of the reasons discussed and referenced above, the Departments have determined that the Government's interest in applying contraceptive coverage requirements to the plans of certain entities and individuals does not outweigh the sincerely held moral objections of those entities and individuals. Thus, these interim final rules amend the regulations amended in both the Departments' July 2015 final regulations and in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

These interim final rules expand those exemptions to include additional entities and persons that object based on sincerely held moral convictions. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no objection specified in the regulations exists, and if section 2713 of the PHS Act otherwise applies. These interim final rules also maintain the existence of an accommodation process as a voluntary option for organizations with moral objections to contraceptive coverage, but consistent with our expansion of the exemption, we expand eligibility for the accommodation to include organizations with sincerely held moral convictions concerning contraceptive coverage. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[31]

[29] *See also Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.,* 467 U.S. 837, 863–64 (1984) ("The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.")

[30] *See, for example,* Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[31] *See https://www.hrsa.gov/womensguidelines/* and *https://www.hrsa.gov/womensguidelines2016/index.html.*

1. Exemption for Objecting Entities Based on Moral Convictions

In the new 45 CFR 147.133 as created by these interim final rules, we expand the exemption that was previously located in § 147.131(a), and that was expanded in § 147.132 by the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

With respect to employers that sponsor group health plans, § 147.133(a)(1) and (a)(1)(i) provide exemptions for certain employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held moral convictions.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption in § 147.133(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.133(a)(1) and (a)(1)(i), by specifying that "[a] group health plan and health insurance coverage provided in connection with a group health plan" is exempt "to the extent the plan sponsor objects as specified in paragraph (a)(2)," exempt the group health plans the sponsors of which object, and exempt their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[32] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures should reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.133(a) apply "to the extent" of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.133(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsors have no qualifying objection. The objection of a health insurance issuer in § 147.133(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

2. Exemption of Certain Plan Sponsors

The rules cover certain kinds of non-governmental employer plan sponsors with the requisite objections, and the rules specify which kinds of entities qualify for the exemption.

Under these interim final rules, the Departments do not limit the exemption with reference to nonprofit status as previous rules have done. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities without regard to whether they operate as nonprofits or for-profit entities. In addition, a significant majority of states either impose no contraceptive coverage requirement, or offer broader exemptions than the exemption contained in the July 2015 final regulations.[33] States also generally protect moral convictions in health care conscience laws, and they often offer those protections whether or not an entity operates as a nonprofit.[34] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor is it a statement about what the Federal Government may do consistent with other protections or limitations in federal law, such state practice can be informative as to the viability of offering protections for conscientious objections in particularly sensitive health care contexts. In this case, the existence of many instances where conscience protections are offered, or no underlying mandate of this kind exists that could violate moral convictions, supports the Departments' decision to expand the Federal exemption concerning this Mandate as set forth in these interim final rules.

Section 147.133(a)(1)(i)(A) of the rules specifies that the exemption includes the plans of a plan sponsor that is a nonprofit organization with sincerely held moral convictions.

Section 147.133(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of a plan sponsor that is a for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

Extending the exemption to certain for-profit entities is consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the

[32] *See, for example*, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. *See also* 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group & individual issuers).

[33] *See* Guttmacher Institute, "Insurance Coverage of Contraceptives" (Aug. 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives*.

[34] *See, for example*, Guttmacher Institute, "Refusing to Provide Health Services" (Aug. 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services*.

Departments' argument to the contrary. 134 S. Ct. 2768–75. Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.[35] The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held moral convictions, is a matter of well-established State law with respect to corporate decision-making,[36] and the Departments expect that application of such laws would cabin the scope of this exemption.

The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. Any such positive definition runs up against the myriad state differences in defining such entities, and potentially intrudes into a traditional area of state regulation of business organizations. The Departments implicitly recognized the difficulty of defining closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely "substantially similar" to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. Instead of attempting to positively define closely held businesses for the purpose of this rule, the Departments consider it much more clear, effective, and preferable to define the category negatively by reference to one element of our previous definition, namely, that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

In this way, these interim final rules differ from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in § 147.132(a)(1)—those extend to for-profit entities whether or not they are closely held or publicly traded. The Departments seek public comment on whether the exemption in § 147.133(a)(1)(i) for plan sponsors with moral objections to the Mandate should be finalized to encompass all of the types of plan sponsors covered by § 147.132(a)(1)(i), including publicly traded corporations with objections based on sincerely held moral convictions, and also non-federal governmental plan sponsors that may have objections based on sincerely held moral convictions.

In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without precluding publicly traded and governmental entities from using those protections. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. The Coats-Snowe Amendment likewise provides certain protections for health care entities and postgraduate physician training programs that choose not to perform, refer for, or provide training for abortions, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 238n).

The Weldon Amendment[37] provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions, and the statute does not limit those protections based on whether the entity is publicly traded or governmental. The Affordable Care Act provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing, and the statute similarly does not limit those protections based on whether the entity is publicly traded or governmental. (42 U.S.C. 18113).[38]

Sections 1395w–22(j)(3)(B) and 1396u–2(b)(3) of 42 U.S.C. protect organizations that offer Medicaid and Medicare Advantage managed care plans from being required to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds, and those paragraphs do not further specify that publicly traded entities do not qualify for the protections. Congress' most recent statement on Government requirements of contraceptive coverage specified that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808. Congress expressed no intent that such a conscience should be limited based on whether the entity is publicly traded.

At the same time, the Departments lack significant information about the need to extend the expanded exemption further. We have been subjected to litigation by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, and we have been sued by closely held for-profit entities expressing religious objections. This combination of different types of plaintiffs leads us to believe that there may be a small number of closely held for-profit entities that would seek to use an exemption to the contraceptive Mandate based on moral convictions. The fact that many closely held for-profit entities brought challenges to the Mandate has led us to offer protections that would include publicly traded entities with religious objections to the Mandate if such entities exist. But the combined lack of any lawsuits challenging the Mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity, leads us to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so in

[35] See Jennifer Haberkorn, "Two years later, few Hobby Lobby copycats emerge," *Politico* (Oct. 11, 2016), available at *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627*.

[36] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

[37] Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. 115–31.

[38] The lack of the limitation in this provision may be particularly relevant since it is contained in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—are promulgated.

a way parallel to the protections set forth in § 147.132(a)(1)(i). We agree with the Supreme Court that it is improbable that many publicly traded companies with numerous "unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs" (or moral convictions) and thereby qualify for the exemption. *Hobby Lobby,* 134 S. Ct. at 2774. We are also not aware of other types of plan sponsors (such as non-Federal governmental entities) that might possess moral objections to compliance with the Mandate, including whether some might consider certain contraceptive methods as having a possible abortifacient effect. Nevertheless, we would welcome any comments on whether such corporations or other plan sponsors exist and would benefit from such an exemption.

Despite our a lack of complete information, the Departments know that nonprofit entities have challenged the Mandate, and we assume that a closely held business might wish to assert non-religious moral convictions in objecting to the Mandate (although we anticipate very few if any will do so). Thus we have chosen in these interim final rules to include them in the expanded exemption and thereby remove an obstacle preventing such entities from claiming an exemption based on non-religious moral convictions. But we are less certain that we need to use these interim final rules to extend the expanded exemption for moral convictions to encompass other kinds of plan sponsors not included in the protections of these interim final rules. Therefore, with respect to plan sponsors not included in the expanded exemptions of § 147.133(a)(1)(i), and non-federal governmental plan sponsors that might have moral objections to the Mandate, we invite public comment on whether to include such entities when we finalize these rules at a later date.

The Departments further conclude that it would be inadequate to merely provide entities access to the accommodation process instead of to the exemption where those entities object to the Mandate based on sincerely held moral convictions. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way "seamless" to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. This has led many religious groups to challenge the accommodation in court, and we expect similar challenges would come from organizations objecting to the accommodation based on moral convictions if we offered them the accommodation but not an exemption. When we took that narrow approach with religious nonprofit entities it led to multiple cases in many courts that we needed to litigate to the Supreme Court various times. Although objections to the accommodation were not specifically litigated in the two cases brought by nonprofit non-religious organizations (because we have not even made them eligible for the accommodation), those organizations made it clear that they and their employees strongly oppose coverage of certain contraceptives in their plans and in connection with their plans.

3. Exemption for Institutions of Higher Education

The plans of institutions of higher education that arrange student health insurance coverage will be treated similarly to the way that plans of employers are treated for the purposes of such plans being exempt or accommodated based on moral convictions. These interim final rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

The Departments are not aware of institutions of higher education that arrange student coverage and object to the Mandate based on non-religious moral convictions. We have been sued by several institutions of higher education that arrange student coverage and object to the Mandate based on religious beliefs. We believe the existence of such entities with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible so that we should provide protections for them in these interim final rules. But based on a lack of information about such entities, we assume that none will use the exemption concerning student coverage at this time.

4. Exemption for Issuers

These interim final rules extend the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection (whether the objection is based on moral convictions, as set forth in these rules, or on religious beliefs, as set forth in exemptions created by the companion interim final rules published elsewhere in this issue of the **Federal Register**). Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt.

Under the rules as amended, issuers with objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions, and issuers with sincerely held religious beliefs could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Issuers that hold moral objections should identify to plan sponsors the

lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Protecting issuers that object to offering contraceptive coverage based on sincerely held moral convictions will help preserve space in the health insurance market for certain issuers so that exempt plan sponsors and individuals will be able to obtain coverage.

The Departments are not currently aware of health insurance issuers that possess their own religious or moral objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations from being required to provide coverage or pay for abortions. *See, for example,* Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31. The most recently enacted Consolidated Appropriations Act declares that Congress supports a "conscience clause" to protect moral convictions concerning "the provision of contraceptive coverage by health insurance plans." *See id.* at Div. C, Title VIII, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. The Departments solicit public comment; however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have moral convictions implicated by the Mandate.[39]

5. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.133(a)(2). That section specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.133(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) for coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held moral convictions.

6. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the "individual exemption"). Section 147.133(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan and/or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held moral convictions. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' moral convictions, or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the sincerely held moral objections of individual employees by offering them plans that omit contraception, even if those governmental entities do not object to offering contraceptive coverage in general.

This "individual exemption" cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held moral convictions.[40] At the same

[39] The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for business entities. Because the issuer exemption operates more narrowly than the exemption for business plan sponsors operates, in the ways described here, and exists in part to help preserve market options for objecting plan sponsors, the Departments consider it appropriate to not draw such a distinction among issuers.

[40] This prospect has been raised in cases of religious individuals—see, for example, *Wieland,*

Continued

time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement," [41] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered. In addition, because the individual exemption only operates when the employer and/or issuer, as applicable, are willing, the exemption will not undermine any governmental interest in the workability of the insurance market, because we expect that any workability concerns will be taken into account in the decision of whether to be willing to offer the individual morally acceptable coverage.

For similar reasons, we have changed our position and now believe the individual exemption will not undermine any Government interest in uniformity in the health insurance market. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. The Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our accommodation of self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[42]

With respect to operationalizing this provision of these rules, as well as the similar provision protecting individuals with religious objections to purchasing insurance that covers some or all contraceptives, in the interim final rules published elsewhere in this issue of the **Federal Register**, the Departments note that a plan sponsor or health insurance issuer is not required to offer separate and different benefit package options, or separate and different forms of policy, certificate, or contract of insurance with respect to those individuals who object on moral bases from those who object on religious bases. That is, a willing employer or issuer may offer the same benefit package option or policy, certificate, or contract of insurance—which excludes the same scope of some or all contraceptive coverage—to individuals who are exempt from the Mandate because of their moral convictions (under these rules) or their religious beliefs (under the regulations as amended by the interim final rules pertaining to religious beliefs).

7. Optional Accommodation

In addition to expanding the exemption to those with sincerely held moral convictions, these rules also expand eligibility for the optional accommodation process to include employers with objections based on sincerely held moral convictions. This is accomplished by inserting references to the newly added exemption for moral convictions, 45 CFR 147.133, into the regulatory sections where the accommodation process is codified, 45 CFR 147.131, 26 CFR 54.9815–2713AT, and 29 CFR 2590.715–2713A. In all other respects the accommodation process works the same as it does for entities with objections based on sincerely held religious beliefs, as described in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

The Departments are not aware of entities with objections to the Mandate based on sincerely held moral convictions that wish to make use of the optional accommodation, and our present assumption is that no such entities will seek to use the accommodation rather than the exemption. But if such entities do wish to use the accommodation, making it available to them will both provide contraceptive coverage to their plan participants and respect those entities' objections. Because entities with objections to the Mandate based on sincerely held non-religious moral convictions have not previously had access to the accommodation, they would not be in a position to revoke their use of the accommodation at the time these interim final rules are issued, but could do so in the future under the same parameters set forth in the accommodation regulations.

8. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules insert references to 45 CFR 147.133 into the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713T(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv).

9. Conclusion

The Departments believe that the Guidelines, and the expanded exemptions and accommodations set forth in these interim final rules, will advance the legitimate but limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for moral exemptions with respect to various health care matters. These interim final rules maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines if no regulatorily recognized exemption exists (and in plans where Congress applied section 2713 of the PHS Act). As cited above, these interim final rules also leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. The Departments believe this array of programs and requirements better serves the interests of providing contraceptive coverage while protecting the moral convictions of entities and individuals concerning coverage of some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

IV. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; and 79 FR 51092).

Section 553(b) of the APA requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior

196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130—where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to "forgo health insurance altogether."

[41] 78 FR 39874.

[42] *See also Real Alternatives*, 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) ("Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny." (citation and internal quotation marks omitted)).

to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to so continue to update the Guidelines.

Two lawsuits have been pending for several years by entities raising non-religious moral objections to the Mandate.[43] In one of those cases, the Departments are subject to a permanent injunction and the appeal of that case has been stayed since February 2016. In the other case, Federal district and appeals courts ruled in favor of the Departments, denying injunctive relief to the plaintiffs, and that case is also still pending. Based on the public comments the Departments have received, we have reason to believe that some similar nonprofit entities might exist, even if it is likely a small number.[44]

For entities and individuals facing a burden on their sincerely held moral convictions, providing them relief from Government regulations that impose such a burden is an important and urgent matter, and delay in doing so injures those entities in ways that cannot be repaired retroactively. The burdens of the existing rules undermine these entities' and individuals' participation in the health care market because they provide them with a serious disincentive—indeed a crisis of conscience—between participating in or providing quality and affordable health insurance coverage and being forced to violate their sincerely held moral convictions. The existence of inconsistent court rulings in multiple proceedings has also caused confusion and uncertainty that has extended for several years, with different federal courts taking different positions on whether entities with moral objections are entitled to relief from the Mandate. Delaying the availability of the expanded exemption would require entities to bear these burdens for many more months. Continuing to apply the Mandate's regulatory burden on individuals and organizations with moral convictions objecting to compliance with the Mandate also serves as a deterrent for citizens who might consider forming new entities consistent with their moral convictions and offering health insurance through those entities.

Moreover, we separately expanded exemptions to protect religious beliefs in the companion interim final rules issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. Because Congress has provided many statutes that protect religious beliefs and moral convictions similarly in certain health care contexts, it is important not to delay the expansion of exemptions for moral convictions set forth in these rules, since the companion rules provide protections for religious beliefs on an interim final basis. Otherwise, our regulations would simultaneously provide and deny relief to entities and individuals that are, in the Departments' view, similarly deserving of exemptions and accommodations consistent, with similar protections in other federal laws. This could cause similarly situated entities and individuals to be burdened unequally.

In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and to what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. As noted above, the public comments in response to both the RFI and various prior rulemaking proceedings included specific requests that the exemptions be expanded to include those who oppose the Mandate for either religious or "moral" reasons.[45] In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

As the U.S. Court of Appeals for the D.C. Circuit stated with respect to an earlier IFR promulgated with respect to this issue in *Priests for Life* v. *U.S. Department of Health and Human Services*, 772 F.3d 229, 276 (D.C. Cir. 2014), *vacated on other grounds, Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016), "[S]everal reasons support HHS's decision not to engage in notice and comment here." Among other things, the Court noted that "the agency made a good cause finding in the rule it issued"; that "the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues"; that "HHS will expose its interim rule to notice and comment before its permanent implementation"; and that not proceeding under interim final rules would "delay the implementation of the alternative opt-out for religious objectors." *Id.* at 277. Similarly, not proceeding with exemptions and accommodations for moral objectors here would delay the implementation of those alternative opt-outs for moral objectors.

Delaying the availability of the expanded exemption could also increase the costs of health insurance for some entities. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover

[43] *March for Life*, 128 F. Supp. 3d 116; *Real Alternatives*, 867 F.3d 338.

[44] *See, for example,* Americans United for Life ("AUL") Comment on CMA–9992–IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496*, and AUL Comment on CMS–9968–P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115*.

[45] *See, for example, http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496, http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115, https://www.regulations.gov/document?D=CMS-2016-0123-54142, https://www.regulations.gov/document?D=CMS-2016-0123-54218*, and *https://www.regulations.gov/document?D=CMS-2016-0123-46220*.

contraception. As such, they may wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. To the extent that entities with objections to the Mandate based on moral convictions but not religious beliefs fall into this category, they may be refraining from making those changes—and therefore may be continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. We are not aware of the extent to which such entities exist, but 17 percent of all covered workers are in grandfathered health plans, encompassing tens of millions of people.[46] Issuing these rules on an interim final basis reduces the costs of health insurance and regulatory burdens for such entities and their plan participants.

These interim final rules also expand access to the optional accommodation process for certain entities with objections to the Mandate based on moral convictions. If entities exist that wish to use that process, the Departments believe they should be able to do so without the delay that would be involved by not offering them the optional accommodation process by use of interim final rules. Proceeding otherwise could delay the provision of contraceptive coverage to those entities' employees.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final rules effective immediately upon filing for public inspection at the Office of the Federal Register.

V. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an "economically significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations and do so in conjunction with the amendments made in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. These interim final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process to make entities with such convictions eligible to use it. The expanded exemption would apply to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to providing coverage for some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action is taken, among other reasons, to provide for conscientious participation in the health insurance market free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to resolve lawsuits that have been filed against the Departments by some such entities, and to avoid similar legal challenges.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these interim final rules, they believe it to be small.

With respect to the expanded exemption for nonprofit organizations, as noted above the Departments are aware of two small nonprofit

[46] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017*.

organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the coverage.[47] Based on comments submitted in response to prior rulemakings on this subject, we believe that at least one other similar entity exists. However, we do not know how many similar entities exist. Lacking other information we assume that the number is small. Without data to estimate the number of such entities, we believe it to be less than 10, and assume the exemption will be used by nine nonprofit entities.

We also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with our conclusion in previous rules that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (*See* 76 FR 46625 and 78 FR 39889). We reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception, and without even requiring that such entities actually oppose contraception in order to be exempt (in contrast, the expanded exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to the coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, we relied on our assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is supported with respect to the expanded exemption for nonprofit organizations. To our knowledge, the vast majority of organizations objecting to the Mandate assert religious beliefs. The only nonprofit organizations of which we are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these interim final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under our previous rules that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[48] Although we are unable to find sufficient data on this issue, we believe that there are far fewer non-religious moral nonprofit organizations opposed to contraceptive coverage than there are churches with religious objections to such coverage. Based on our limited data, we believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose the coverage. Therefore, we expect that the expanded exemption for nonprofit entities will have no effect of reducing contraceptive coverage to employees who want that coverage.

These interim final rules expand the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and they make exempt entities with moral objections eligible to use the accommodation. The Departments are not aware of either kind of entity. We believe the number of entities that object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education, and appear to hold objections that we assume would likely lead them to reject the accommodation process. Therefore, for the purposes of estimating the anticipated effect of these interim final rules on contraceptive coverage of women who wish to receive such coverage, we assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on similar reasons to those given above for why the exemptions and accommodations are extended to other entities. We invite public comment on whether and how many such entities will make use of these interim final rules.

The expanded exemption for issuers will not result in a distinct effect on contraceptive coverage for women who wish to receive it because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein. The expanded exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The expanded moral exemption would also cover for-profit entities that do not have publicly traded ownership interests, and that have non-religious moral objections to the Mandate. The Departments are not aware of any for-profit entities that possess non-religious moral objections to the Mandate. However, scores of for-profit entities have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—both were nonprofit. Among the general public polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.[49] Among non-religious persons, only a very small percentage appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.[50] Combined, this suggests that 0.2 percent of Americans at most[51] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. We have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral

[47] Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

[48] *Cf., for example,* Gallup, "Americans, Including Catholics, Say Birth Control Is Morally OK," (May 22, 2012) ("Eighty-two percent of U.S. Catholics say birth control is morally acceptable"), available at *http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx.*

[49] Gallup, "Most Americans Still Believe in God" (June 14–23, 2016), available at *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

[50] Pew Research Center, "Where the Public Stands on Religious Liberty vs. Nondiscrimination" at page 26 (Sept. 28, 2016), available at *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[51] The study defined religiously "unaffiliated" as agnostic, atheist or "nothing in particular" (*id.* at 8), as distinct from several versions of Protestants, or Catholics. "Nothing in particular" might have included some theists.

convictions set forth in these interim final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, we assume that some similar for-profit entities with non-religious moral objections exist. But we expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities that do not have publicly traded ownership interests and that have objections to the Mandate based on sincerely held moral convictions, we expect that fewer than 10 entities, if any, will do so—we assume nine for-profit entities will use the exemption in these interim final rules.

The expanded exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.[52] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known what size the for-profit employers will be that might claim this exemption, but as discussed above these interim final rules do not include publicly traded companies (and we invite public comments on whether to do so in the final rules), and both of the two nonprofit entities that challenged the Mandate included fewer than five policyholders in each entity. Therefore we assume the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For nine entities, the total number of policyholders would be 81. DOL estimates that for each policyholder, there is approximately one dependent.[53] This amounts to 162 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—comprise 20.2 percent of the general population.[54] This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.[55] Thus we estimate that 15 women may incur contraceptive costs due to for-profit entities using the expanded exemption provided in these interim final rules.[56] In the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, within health plans that cover contraception, is $584. Consequently, we estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded exemption in these interim final rules is approximately $8,760.

The Departments estimate that these interim final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will use the accommodation, although we wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, we do not anticipate that these interim final rules will result in any burden from such entities revoking their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the rules expanded exemptions. The Departments acknowledge uncertainty in the estimate and therefore conducted a second analysis using an alternative framework, which is set forth in the companion interim final rule concerning religious beliefs issued contemporaneously with this interim final rule and published elsewhere in this issue of the **Federal Register**. Under either estimate, this interim final rule is not economically significant.

We reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

We request comment on all aspects of the preceding regulatory impact analysis.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments estimate that the likely effect of these interim final rules will be that entities will use the exemption and not the accommodation. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public

[52] "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf*Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance

[53] "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[54] U.S. Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." *https://www.hrsa.gov/womensguidelines/; see also* 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. *See,* Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[55] *See https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[56] We note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion—and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to some or all contraceptives and/or sterilization, the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We estimate that these interim final rules will not result in additional burdens not accounted for as set forth in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. As discussed there, regulations covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burdens related to those ICRs are currently approved under OMB Control Numbers 0938–1248 and 0938–1292. These interim final rules amend the accommodation regulations to make entities with moral objections to the Mandate eligible to use the same accommodation processes. The Departments will update the forms and model notices regarding these processes to reflect that entities with sincerely held moral convictions are eligible organizations.

As discussed above, however, we assume that no entities with non-religious moral objections to the Mandate will use the accommodation, and we know that no such entities were eligible for it until now, so that they do not possess accommodated status to revoke. Therefore we believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1248 and 0938–1292, as described in the interim final rules concerning religious beliefs issued contemporaneously with these interim final rules.

We are soliciting comments on all of the possible information collection requirements contained in these interim final rules, including those discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, for which these interim final rules provide eligibility to entities with objections based on moral convictions. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938–1292 and 0938–1248.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov.* PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these interim final rules make entities with certain moral convictions eligible for the accommodation, we assume that no entities will use it rather than the exemption, and such entities were not previously eligible for the accommodation so as to revoke it. Therefore we believe these interim final rules do not involve additional burden not accounted for under OMB control number 1210–0150.

Regarding the ICRs discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, the forms for which would be used if any entities with moral objections used the accommodation process in the future, DOL submitted those ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. OMB approved the ICRs under the emergency clearance process. In an effort to consolidate the number of information collection requests, DOL indicated it will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once

the ICR is approved, DOL indicated it will discontinue 1210–0152. OMB approved the ICR under control number 1210–0150 through [DATE]. A copy of the information collection request may be obtained free of charge on the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001*. This approval allows respondents temporarily to utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden. Contemporaneously with the publication of these interim final rules, DOL will publish a notice in the **Federal Register** informing the public of its intention to extend the OMB approval.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, "[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." In addition, agencies are directed to "take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market." These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting costs.[57] Therefore, this interim final rule is considered an EO 13771 deregulatory action.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "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 one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VI. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

[57] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713T [Amended]

■ 2. Section 54.9815–2713T, as added elsewhere in this issue of the **Federal Register**, is amended in paragraph (a)(1)(iv) by removing the reference "147.131 and 147.132" and adding in its place the reference "147.131, 147.132, and 147.133".

§ 54.9815–2713AT [Amended]

■ 3. Section 54.9815–2713AT, as added elsewhere in this issue of the **Federal Register**], is amended—

■ a. In paragraph (a)(1) by removing "or (ii)" and adding in its place "or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)";

■ b. In paragraph (a)(2) by removing the reference "147.132(a)" and adding in its place the reference "147.132(a) or 147.133(a)";

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ d. In paragraph (b)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ f. In paragraph (c)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133"; and

■ g. In paragraph (c)(2) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133".

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

§ 2590.715–2713 [Amended]

■ 4. Section 2590.715–2713, as amended elsewhere in this issue of the **Federal Register**], is further amended in paragraph (a)(1)(iv) by removing the reference "147.131 and 147.132" and adding in its place the reference "147.131, 147.132, and 147.133".

§ 2590.715–2713A [Amended]

■ 5. Section 2590.715–2713A, as revised elsewhere in this issue of the **Federal Register**], is further amended—

■ a. In paragraph (a)(1) by removing "(ii)" and adding in its place "(ii), or 45 CFR 147.133(a)(1)(i) or (ii)";

■ b. In paragraph (a)(2) by removing the reference "147.132(a)" and adding in its place the reference "147.132(a) or 147.133(a)";

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ d. In paragraph (b)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ f. In paragraph (c)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133"; and

■ g. In paragraph (c)(2) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133".

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 6. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

§ 147.130 [Amended]

■ 7. Section 147.130, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraphs (a)(1) introductory text and (a)(1)(iv) by removing the reference "§§ 147.131 and 147.132" and adding in its place the reference "§§ 147.131, 147.132, and 147.133".

§ 147.131 [Amended]

■ 8. Section 147.131, as revised elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (c)(1) by removing the reference "(ii)" and adding in its place the reference "(ii), or 45 CFR 147.133(a)(1)(i) or (ii)".

■ b. In paragraph (c)(2) by removing the reference "§ 147.132(a)" and adding in its place the reference "§ 147.132(a) or 147.133"; and

■ c. In paragraphs (d)(1)(ii) introductory text, (d)(1)(ii)(B) and (d)(2) by removing the reference "§ 147.132" and to adding in its place the reference "§ 147.132 or 147.133".

■ 9. Add § 147.133 to read as follows:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus

the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21852 Filed 10–6–17; 11:15 am]

BILLING CODE 4830–01–P; 4510–029–P; 4120–01–P; 6325–64–P