IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

COMMONWEALTH OF PENNSYLVANIA, Plaintiff-Appellee, v. PRESIDENT, UNITED STATES OF AMERICA et al., Defendants-Appellants, and LITTLE SISTERS OF THE POOR SAINTS PETER AND PAUL HOME, Intervenor-Defendant-Appellant.	Nos. 17-3752 and 18-1253

MOTION TO GOVERN FURTHER PROCEEDINGS

The federal defendants file this motion to govern further proceedings to address the appropriate disposition of this appeal in light of the issuance of final rules superseding the interim final rules challenged in this case. As we explain below, this Court should hold the appeal in abeyance pending disposition by the district court of Pennsylvania's anticipated motion for a preliminary injunction of the final rules.

STATEMENT

1. In October 2017, in an attempt to resolve ongoing litigation over the contraceptive-coverage mandate adopted pursuant to the Patient Protection and Affordable Care Act, the Departments of Health and Human Services, Labor, and the Treasury issued interim final rules expanding the regulatory exemption to the mandate. The interim rules expanded the existing religious exemption to a broader range of entities with sincere religious objections to providing contraceptive coverage, *see* 82 Fed. Reg. 47,792 (Oct. 13, 2017) (JA 442), and created a new exemption for certain entities with moral objections to providing such coverage, *see* 82 Fed. Reg. 47,838 (Oct. 13, 2017) (JA 486).

Invoking agency-specific statutory authority to issue interim final rules, 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92, as well as the Administrative Procedure Act's (APA's) general "good cause" exception to notice-and-comment requirements, 5 U.S.C. § 553(b), the agencies issued the rules without prior notice and comment. The agencies did, however, solicit comments for 60 days post-promulgation. *See* 82 Fed. Reg. at 47,792; 82 Fed. Reg. at 47,838.

2. Pennsylvania brought suit, challenging the interim rules. As relevant in this appeal, Pennsylvania claimed that the rules (1) failed to comply with the APA's notice-and-comment requirements; and (2) are arbitrary and capricious, an abuse of discretion, or otherwise contrary to law because they violate the Affordable Care Act and cannot be justified by the Religious Freedom Restoration Act (RFRA). *See* JA 110-113. Pennsylvania sought a preliminary injunction.

The federal government moved to dismiss Pennsylvania's suit, arguing, among other things, that Pennsylvania lacked standing to challenge the interim rules and that Pennsylvania had sued in the wrong venue. The government also separately opposed Pennsylvania's motion for injunctive relief, arguing that the interim rules were both procedurally and substantively valid and that equitable relief was unwarranted regardless. Without ruling on the government's motion to dismiss, the district court granted a preliminary injunction. As to justiciability, although the court ignored the government's venue objection, it rejected the objection to Pennsylvania's standing. *See* JA 19-23. On the merits, the court held that the agencies had neither statutory authority nor good cause to issue the rules without following

notice-and-comment procedures, *see* JA 25-35, and further held that the rules were substantively unlawful because neither the Affordable Care Act nor RFRA justified the expanded exemptions from the contraceptive-coverage mandate in light of the accommodation's availability, *see* JA 35-43. Finding that the equities warranted a preliminary injunction, *see* JA 43-50, the court issued an order prohibiting the agencies from "enforcing" the interim rules, JA 52.

The federal government and intervenor the Little Sisters of the Poor appealed, and the district court proceedings were stayed pending disposition of the appeal. *See* dkt. no. 73. The government and the Little Sisters filed their opening briefs on September 21, 2018; Pennsylvania has not yet filed its response brief.

3. After reviewing all the comments received on the interim rules, the agencies promulgated final rules superseding the interim rules. The final rules were made publicly available on the Federal Register's website on November 7, 2018, and were published in the Federal Register on November 15, 2018. *See* 83 Fed. Reg. 57,536 (Nov. 15, 2018) (religious exemption) (attached as Exhibit A); 83 Fed. Reg. 57,592 (Nov. 15, 2018) (moral exemption) (attached as Exhibit B).

The final rules finalize the exemptions provided in the interim rules. In response to public comments, the agencies made certain changes in the final rules to clarify the intended scope of the exemptions. *See* 83 Fed. Reg. at 57,537; 83 Fed. Reg. at 57,593. But the substance of the rules remains largely the same, and none of the changes is material to Pennsylvania's substantive claims in this case or the question of Pennsylvania's standing to bring those claims.

The final rules take effect on January 14, 2019. *See* 83 Fed. Reg. at 57,536; 83 Fed. Reg. at 57,592.

4. On November 9, 2018, the federal government submitted a letter notifying the Court that the agencies had promulgated final rules and proposing that the parties file motions to govern further proceedings.

5. On November 26, 2018, Pennsylvania filed a motion in district court to lift the stay of proceedings. *See* dkt. no. 81. Pennsylvania stated that if the motion is granted, the Commonwealth intends to seek leave to supplement its complaint to challenge the final rules and to seek a preliminary injunction of the final rules. *See id.* at 3.

ARGUMENT

Although the agencies have now issued final rules superseding the interim rules challenged by Pennsylvania, neither the case nor this appeal is moot. Considerations of judicial economy nevertheless warrant a brief abeyance while the district court addresses Pennsylvania's anticipated motion for a preliminary injunction of the final rules.

1. As an initial matter, Pennsylvania's standing to challenge the rules remains a threshold issue that this Court can address, notwithstanding the issuance of the final rules. Standing is a "core component" and an "essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Because standing is a threshold jurisdictional issue, *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998), a court may conclude that a case should be dismissed for lack of standing without first addressing whether the case has become moot. As the Supreme Court has made clear, while a federal court generally may not rule on the merits without first determining that it has subject-matter and personal jurisdiction, "there is no mandatory sequencing of

jurisdictional issues." *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 431 (2007) (internal quotation marks omitted). Instead, a court "has leeway to choose among threshold grounds for denying audience to a case on the merits." *Id.* (internal quotation marks omitted).

Thus, in *Common Cause of Pennsylvania v. Pennsylvania*, 558 F.3d 249, 256 n.2 (3d Cir. 2009), this Court decided an appeal on the ground that the plaintiffs lacked standing without considering whether their claims were moot. Other courts of appeals have likewise dismissed cases or appeals on the basis of standing without considering mootness. *See Nicklaw v. CitiMortgage, Inc.*, 839 F.3d 998, 1000 (11th Cir. 2016); *Staker v. Wells Fargo Bank, N.A. (In re Staker)*, 550 F. App'x 580, 582 (10th Cir. 2013); *National Comm. for the New River, Inc. v. FERC*, 433 F.3d 830, 832 n.1 (D.C. Cir. 2005); *Myers Investigative & Sec. Servs., Inc. v. United States*, 275 F.3d 1366, 1369 (Fed. Cir. 2002); *In re VMS Ltd. P'ship Sec. Litig.*, 976 F.2d 362, 366 n.7 (7th Cir. 1992).

This Court could adopt that approach here, particularly since the final rules do not materially alter the question of Pennsylvania's standing. Pennsylvania's lawsuit challenges on various grounds the

expanded exemptions in the interim rules, alleging, for example, that these exemptions "are inconsistent with the Affordable Care Act's requirement that group health plans and insurers provide women with preventive care as provided for in guidelines issued by the HRSA [Health Resources and Services Administration]." JA 112 ¶ 170. Pennsylvania contends that the Commonwealth and its residents will be injured because Pennsylvania employers are likely to use the expanded exemptions under the interim rules and, as a result, Pennsylvania women will lose employer-sponsored contraceptive coverage and turn to state-funded programs. *See* JA 106-107 ¶¶ 129-136 (asserting fiscal injury to the Commonwealth); *see also* JA 108 ¶ 140 (asserting quasi-sovereign interest in protecting citizens' well-being).

The final rules finalize those exemptions in substantially the same form and thus do not materially alter the question of Pennsylvania's standing. As our opening brief explains, Pennsylvania's allegations of economic injury are far too speculative to demonstrate standing, as Pennsylvania has not identified a single woman who will lose contraceptive coverage (let alone who will then be eligible for and seek state-funded services) as a result of the religious or moral exemptions.

See Fed. Br. 23-31. And Pennsylvania's alternative attempt to assert *parens patriae* standing to protect the well-being of its residents is squarely foreclosed by Supreme Court precedent. *See* Fed. Br. 31-35.

2. For the same reason that it is appropriate to determine standing regardless of whether the case is moot—namely, that the substance of the rules remains largely unchanged, such that the same standing issue persists—the case is not moot, because the same substantive merits claims persist as well. A case does not become moot when, as here, a challenged regulation is altered in an "insignificant respect" given the scope of the challenge. *Northeast Fla. Chapter of the Associated Gen. Contractors of Am. v. City of Jacksonville*, 508 U.S. 656, 661-62 & n.3 (1993) (holding that case was not moot where challenged ordinance was replaced by "sufficiently similar" ordinance after Court granted certiorari); *see also Nextel West Corp. v. Unity Township*, 282 F.3d 257, 261-64 (3d Cir. 2002) (holding that amendment "did not sufficiently alter" the challenged ordinance to moot the case). "[A] superseding statute or regulation moots a case only to the extent that it removes challenged features of the prior law." *Naturist Soc'y, Inc. v. Fillyaw*, 958 F.2d 1515, 1520 (11th Cir. 1992).

As explained above, the final rules do not remove the "challenged features" of the interim rules. *Naturist Soc'y*, 958 F.2d at 1520. And because "the 'gravamen of [Pennsylvania's] complaint [about the interim rules] remains," Pennsylvania's substantive challenges to the rules are not moot. *Nextel*, 282 F.3d at 262 (quoting *Northeastern Fla. Chapter*, 508 U.S. at 662); *see also American Freedom Def. Initiative v. Washington Metro. Area Transit Auth.*, 901 F.3d 356, 361-62 (D.C. Cir. 2018); *Associated Gen. Contractors of Am. v. California Dep't of Transp.*, 713 F.3d 1187, 1193-94 (9th Cir. 2013).[1]

[1] The final rules, when they take effect, will moot Pennsylvania's procedural challenge to the interim rules (*i.e.*, the Commonwealth's claim that the agencies improperly issued the interim rules without prior notice and comment). *See Safari Aviation Inc. v. Garvey*, 300 F.3d 1144, 1150 (9th Cir. 2002) (Because "the life of the interim rule is over, no purpose is served by reviewing its rulemaking procedures."); *cf. Natural Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 758-59 & n.15 (3d Cir. 1982) (challenge to agency's failure to comply with notice-and-comment procedures in indefinitely postponing effectiveness of previously promulgated rule not moot notwithstanding subsequent notice-and-comment rulemaking postponing that rule, where court could order that postponed rule be reinstated and made effective as of originally scheduled effective date and such relief would "change the status quo" and affect "compliance obligations"). That Pennsylvania's procedural claim is moot, however, does not mean that the entire *case* is moot.

3. For these reasons, the government is entitled to proceed with its appeal despite the issuance of the final rules. Nonetheless, because Pennsylvania has requested that the district court proceedings be reopened so that the Commonwealth can seek a preliminary injunction of the final rules, considerations of judicial economy warrant a brief abeyance of this appeal. We anticipate that the district court proceedings will be resolved expeditiously, as the reasoning of the district court's prior decision that the interim rules were substantively unlawful, *see* JA 35-43, also appears to apply to the final rules. And because briefing has not yet been completed and oral argument has not yet occurred in this appeal, a short abeyance is likely to allow consolidation of this appeal with an anticipated appeal from the district court's preliminary-injunction ruling concerning the final rules, without material delay in this appeal.

CONCLUSION

For the foregoing reasons, the Court should hold this appeal in abeyance pending disposition by the district court of Pennsylvania's anticipated motion for a preliminary injunction of the final rules.

Respectfully submitted,

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NOVEMBER 2018

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I hereby certify that this motion complies with the requirements of Rule 27(d)(1)(E) because it has been prepared in 14-point Century Schoolbook, a proportionally spaced font, and that it complies with the type-volume limitation of Rule 27(d)(2)(A), because it contains 2,007 words, according to the count of Microsoft Word.

/s/ Karen Schoen
Karen Schoen
Counsel for the Federal Government

CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2018, I electronically filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the Third Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Karen Schoen
Karen Schoen
Counsel for the Federal Government

EXHIBIT A

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9840]

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–F2]

RIN 0938–AT54

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: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, interim final rules concerning religious exemptions and accommodations regarding coverage of certain preventive services issued in the **Federal Register** on October 13, 2017. These 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, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an ''accommodation'' process 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 regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, at (301) 492–4305 or *marketreform@cms.hhs.gov* for the 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; William Fischer, 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, 1–866–444–EBSA (3272) or visit the Department of Labor's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47792), ''Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (the Religious IFC). The rules are necessary to expand the protections for the sincerely held religious objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, a requirement that was created by HHS through guidance promulgated by the Health Resources and Services Administration (HRSA) (hereinafter ''Guidelines''), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules maintain a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's Guidelines. The changes being finalized to these rules will ensure that proper respect is afforded to sincerely held religious objections in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Expanded Religious Exemptions to the Contraceptive Coverage Requirement

These rules finalize exemptions provided in the Religious IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held religious beliefs opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's Guidelines. The rules finalize exemptions to the same types of organizatons and individuals for which exemptions were provided in the Religious IFC: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals. The rules also finalize the regulatory restatement in the Religious IFC of language from section 2713(a) and (a)(4) of the Public Health Service Act.

In response to public comments, various changes are made to clarify the intended scope of the language in the Religious IFC. The prefatory language to the exemptions is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to clarify that, where an exemption encompasses a plan or coverage established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, the exemption applies to each employer, organization, or plan sponsor that adopts the plan. Language is also added to clarify that the exemptions apply to non-governmental entities, including as the exemptions apply to institutions of higher education. The Departments revise the exemption applicable to health insurance issuers to make clear that 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. The Departments also restructure the provision describing the religious objection for entities. That provision specifies that the entity objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for either: coverage or payments for some or all contraceptive services; or, a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The final rule specifies that the individual exemption ensures that the HRSA Guidelines do not 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 group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. Optional Accommodation

These rules also finalize provisions from the Religious IFC that maintain the accommodation process as an optional process for entities that qualify for the exemption. Under that process, entities can choose to use the accommodation process so that contraceptive coverage to which they object is omitted from their plan, but their issuer or third party administrator, as applicable, will arrange for the persons covered by their plan to receive contraceptive coverage or payments.

In response to public comments, these final rules make technical changes to the accommodation regulations maintained in parallel by HHS, the Department of Labor, and the Department of the Treasury. The Departments modify the regulations governing when an entity, that was using or will use the accommodation, can revoke the accommodation and operate under the exemption. The modifications set forth a transitional

rule as to when entities currently using the accommodation may revoke it and use the exemption by giving 60-days notice pursuant to Public Health Service Act section 2715(d)(4) and 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), and 29 CFR 2590.715–2715(b). The modifications also express a general rule that, in plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

The Departments also modify the Religious IFC by adding a provision that existed in rules prior to the Religious IFC, namely, that if an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable contraceptive coverage requirement from HRSA's Guidelines if the issuer complies with the obligations under this section applicable to such issuer. Likewise, the rule adds pre-existing ''reliance'' language deeming an issuer serving an accommodated organization compliant with the contraceptive coverage requirement if the issuer relies reasonably and in good faith on a representation by an organization as to its eligibility for the accommodation and the issuer otherwise complies with the accommodation regulation, and likewise deeming a group health plan compliant with the contraceptive coverage requirement if it complies with the accommodation regulation.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	The purpose of this provision is to ensure that the regulatory language that restates section 2713(a) and (a)(4) of the Public Health Service Act mirrors the language of the statute. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.
Expanded religious exemptions.	Expanding religious exemptions to the contraceptive coverage requirement will relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their religious beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage or using the accommodation in violation of their sincerely held religious beliefs.	We estimate there will be transfer costs where women previously receiving contraceptive coverage from employers will no longer receive that coverage where the employers use the expanded exemptions. Even after the public comment period, we have very limited data on what the scale of those transfer costs will be. We estimate that in no event will they be more than $68.9 million. We estimate that, where entities using the accommodation revoke it to use the exemption, the cost to industry of sending notices of revocation to their policy holders will be $112,163.
Optional accommodation regulations.	Maintaining the accommodation as an optional process will ensure that contraceptive coverage is made available to many women covered by plans of employers that object to contraceptive coverage but not to their issuers or third party administrators arranging for such coverage to be provided to their plan participants.	We estimate that, by expanding the types of organizations that may use the accommodation, some entities not currently using it will opt into it. When doing so they will incur costs of $677 to send a self-certification or notice to their issuer or third party administrator, or to HHS, to commence operation of the accommodation. We estimate that entities that newly make use of the accommodation as the result of these rules, or their issuers or third party administrators, will incur costs of $311,304 in providing their policy holders with notices indicating that contraceptive coverage or payments are available to them under the accommodation process.

B. Background

Over many decades, Congress has protected conscientious objections, including those based on religious beliefs, in the context of health care and human services including health coverage, even as it has sought to promote and expand access to health services.[1] In 2010, Congress enacted the

[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 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (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. E, 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. E, Sec. 808 (regarding any requirement for ''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. I, (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

Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended the PPACA. As amended by HCERA, the PPACA is known as the Affordable Care Act (ACA).

The ACA 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. The ACA 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), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter ''section 2713(a)(4)''), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, ''with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by'' HRSA's Guidelines.

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same time period, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, ''the Departments'') [3] have promulgated regulations to guide HRSA in exercising its discretion to allow exemptions to those requirements, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments defined the scope of permissible exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Many individuals and entities brought legal challenges to 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 (''RFRA''). Several of those cases went to the Supreme Court. *See, for example, Burwell* v. *Hobby Lobby Stores, Inc.,* 134 S. Ct. 2751 (2014); *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016).

The Departments most recently solicited public comments on these issues again in two interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017: the regulations (82 FR 47792) that are being finalized with changes here, and regulations (82 FR 47838) concerning moral objections (the Moral IFC), which are being finalized with changes in companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Religious IFC, the Departments explained several reasons why it was appropriate to reevaluate the religious exemptions and accommodations for the contraceptive Mandate and to take into account the religious beliefs of certain employers concerning that Mandate. The Departments also sought public comment on those modifications. The Departments considered, among other things, Congress's history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; protection of the free exercise of religion in the First Amendment and, by Congress, in RFRA; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); previously submitted public comments;

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); 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] The references in this document to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to ''Contraceptive Methods and Counseling'' as ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header ''Contraception,'' to: ''the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures,'' ''contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),'' and ''instruction in fertility awareness-based methods, including the lactation amenorrhea method.'' *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[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] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, 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.*

and the extensive litigation over the contraceptive Mandate.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Religious IFC, with changes based on comments as indicated herein.[5]

II. Overview, Analysis, and Response to Public Comments

We provided a 60-day public comment period for the Religious IFC, which closed on December 5, 2017. The Departments received over 56,000 public comment submissions, which are posted at *www.regulations.gov*.[6] Below, the Departments provide an overview of the general comments on the final regulations, and address the issues raised by commenters.

These rules expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules finalize the accommodation process, which was previously established in response to objections of religious organizations that were not protected by the original exemption, as an optional process for any exempt entities. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[7]

A. The Departments' Authority To Mandate Coverage and Provide Religious Exemptions

The Departments received conflicting comments on their legal authority to provide the expanded exemptions and accommodation for religious beliefs. Some commenters agreed that the Departments are legally authorized to provide the expanded exemptions and accommodation, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing religious exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the exemptions that existed prior to the Religious IFC, but not to expand them.

Some commenters who argued that section 2713(a)(4) does not allow for exemptions said that the previous exemptions for houses of worship and integrated auxiliaries, and the previous accommodation process, were set forth in the ACA itself, and therefore were acceptable while the expanded exemptions in the Religious IFC were not. This is incorrect. The ACA does not prescribe (or prohibit) the previous exemptions for house of worship and the accommodation processes that the Departments issued through regulations.[8] The Departments, therefore, find it appropriate to use the regulatory process to issue these expanded exemptions and accommodation, to better address concerns about religious exercise.

The Departments conclude that legal authority exists to provide the expanded exemptions and accommodation for religious beliefs set forth in these final rules. These rules concern section 2713 of the PHS Act, as also incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes.[9]

Where it applies, section 2713(a)(4) requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' Guidelines developed by HHS through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS, as the administering agency of HRSA, and to all three agencies, as the administering agencies of the statutes by which the Guidelines are enforced, to shape that development. *See* 26 U.S.C. 9834; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38,409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable Guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must ''provide for'' and ''support'' the application of Guidelines that it chooses to adopt. HRSA's authority to support ''comprehensive guidelines'' involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only ''as provided for in comprehensive guidelines supported by [HRSA].'' That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word ''as'' in the phrase ''as provided for,'' it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase ''as you like it.'' [10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See, e.g.*, 42 U.S.C. 1395x (''The Secretary shall establish procedures to make beneficiaries and providers aware

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[5] The Department of the Treasury and the Internal Revenue Service (IRS) published proposed and temporary regulations as part of the joint rulemaking of the Religious IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules. The Department of the Treasury and IRS are finalizing their proposed regulations.

[6] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2014-0115* and *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=7525&dct=PS&D=IRS-2017-0016.* Some of those submissions included form letters or attachments that, while not separately tabulated at *regulations.gov*, together included comments from, or were signed by, hundreds of thousands of separate persons. The Departments reviewed all of the public comments and attachments.

[7] *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), and 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), and (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[8] The ACA also does not require that contraceptives be covered under the preventive services provisions.

[9] 26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92.

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (''[u]sed to indicate by comparison the way something happens or is done'').

of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.'') (emphasis added). Thus, the inclusion of ''as'' in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has been granted discretion in supporting how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word ''as'' is missing from the other three provisions in PHS Act section 2713(a). Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require ''evidence-based'' or ''evidence-informed'' coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The religious objections at issue here, and in regulations providing exemptions from the inception of the Mandate in 2011, are considerations that, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines ''exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,'' and ''it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.'' *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a specific statutory mandate that contraceptives must be covered or that they be covered without any exemptions or exceptions, supports the conclusion that the Departments are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The conclusions on which these final rules are based are consistent with the Departments' interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4)'s grant of authority to include broad discretion regarding the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrators of self-insured church plans. *See* 80 FR 41323. Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. During prior rulemakings, the Departments also disagreed with commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or as incorporated into ERISA and the Code, and who contended instead that we must enforce the Guidelines on the broadest spectrum of group health plans as possible. *See, e.g.,* 2012 final regulations at 77 FR 8726.

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require coverage of preventive services for every type of plan that is subject to the ACA. *See, e.g.,* 76 FR 46623. On the contrary, Congress carved out an exemption from PHS Act section 2713 (and from several other provisions) for grandfathered plans. In contrast, grandfathered plans do have to comply with many of the other provisions in Title I of the ACA—provisions referred to by the previous Administration as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include (from the PHS Act) 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 and annual dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group health insurance markets, and requires them to provide rebates to policyholders if that medical loss ratio is not met. (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.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, ''there is no legal requirement that grandfathered plans ever be phased out.'' *Hobby Lobby,* 134 S. Ct. at 2764 n.10.

Some commenters argue that Executive Order 13535's reference to

[11] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' Henry J Kaiser Family Foundation (Sept. 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions to the Mandate in the Guidelines. The Departments, however, believe these final regulations are consistent with Executive Order 13535. Issued upon the signing of the ACA, Executive Order 13535 specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect holders of religious beliefs from certain requirements in health care contexts. While the Executive Order 13535 does not require the expanded exemptions in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws that protect religious beliefs, and are consistent with the Executive Order's intent that the ACA would be implemented in accordance with the conscience protections set forth in those laws.

The extent to which RFRA provides authority for these final rules is discussed below in section II.C., The First Amendment and the Religious Freedom Restoration Act.

B. Availability and Scope of Religious Exemptions

Some commenters supported the expanded exemptions and accommodation in the Religious IFC, and the entities and individuals to which they applied. They asserted the expanded exemptions and accommodation are appropriate exercises of discretion and are consistent with religious exemptions Congress has provided in many similar contexts. Some further commented that the expanded exemptions are necessary under the First Amendment or RFRA. Similarly, commenters stated that the accommodation was an inadequate means to resolve religious objections, and that the expanded exemptions are needed. They objected to the accommodation process because it was another method to require compliance with the Mandate. They contended its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and that such coverage flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to the religious objections that organizations would not have with an expanded exemption.

Several other commenters asserted that the exemptions in the Religious IFC are too narrow and called for there to be no mandate of contraceptive coverage. Some of them contended that HRSA should not include contraceptives in their women's preventive services Guidelines because fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of preventive health services. They also contended that contraceptives can pose medical risks for women and that studies do not show that contraceptive programs reduce abortion rates or rates of unintended pregnancies. Some commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacients and, therefore, violate federal conscience protections such as the Weldon Amendment, *see* section 507(d) of Public Law 115–141.

Other commenters contended that the expanded exemptions are too broad. In general, these commenters supported the inclusion of contraceptives in the Guidelines, contending they are a necessary preventive service for women. Some said that the Departments should not exempt various kinds of entities such as businesses, health insurance issuers, or other plan sponsors that are not nonprofit entities. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318). Some commenters said the Departments should not expand the exemptions, but simply expand or adjust the accommodation process to resolve religious objections to the Mandate and accommodation. Some commenters contended that even the previous regulations allowing an exemption and accommodation were too broad, and said that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible.

After consideration of the comments, the Departments are finalizing the provisions of the Religious IFC without contracting the scope of the exemptions and accommodation set forth in the Religious IFC. Since HRSA issued its Guidelines in 2011, the Departments have recognized that religious exemptions from the contraceptive Mandate are appropriate. The details of the scope of such exemptions are discussed in further detail below. In general, the Departments conclude it is appropriate to maintain the exemptions created by the Religious IFC to avoid instances where the Mandate is applied in a way that violates the religious beliefs of certain plan sponsors, issuers, or individuals. The Departments do not believe the previous exemptions are adequate, because some religious objections by plan sponsors and individuals were favored with exemptions, some were not subjected to contraceptive coverage if they fell under the indirect exemption for certain self-insured church plans, and others had to choose between the Mandate and the accommodation even though they objected to both. The Departments wish to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage. The lack of a congressional mandate that contraceptives be covered, much less that they be covered without religious exemptions, has also informed the Departments' decision to expand the exemptions. And Congress's decision not to apply PHS Act section 2713 to grandfathered plans has likewise informed the Departments' decision whether exemptions to the contraceptive Mandate are appropriate.

Congress has also established a background rule against substantially burdening sincere religious beliefs except where consistent with the stringent requirements of the Religious Freedom Restoration Act. And Congress has consistently provided additional, specific exemptions for religious beliefs in statutes addressing federal requirements in the context of health care and specifically concerning issues such as abortion, sterilization, and contraception. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive coverage Mandate by the exercise of agency discretion, that we also include exemptions for the protection of religious beliefs in certain cases. The expanded exemptions finalized in these rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. They are also consistent with the intent of Executive Order 13535 (March 24, 2010), which was issued upon the signing of the ACA and 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 Public Law 111–8) remain intact'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.''

Some commenters argued that Congress's failure to explicitly include

religious exemptions in PHS Act section 2713 itself is indicative of an intent that such exemptions not be included, but the Departments disagree. As noted above, Congress also failed to require contraceptive coverage in PHS Act section 2713. And the commenters' argument would negate not just these expanded exemptions, but the previous exemptions for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting religious beliefs in the context of certain federal health care requirements.

If there is to be a federal contraceptive mandate that fails to include some—or, in the views of some commenters, any—religious exemptions, the Departments do not believe it is appropriate for us to impose such a regime through discretionary administrative measures. Instead, such a serious imposition on religious liberty should be created, if at all, by Congress, in response to citizens exercising their rights of political participation. Congress did not prohibit religious exemptions under this Mandate. It did not even require contraceptive coverage under the ACA. It left the ACA subject to RFRA, and it specified that additional women's preventive services will only be required coverage as provided for in Guidelines supported by HRSA. Moreover, Congress legislated in the context of the political consensus on conscientious exemptions for health care that has long been in place. Since *Roe* v. *Wade* in 1973, Congress and the states have consistently offered religious exemptions for health care providers and others concerning issues such as sterilization and abortion, which implicate deep disagreements on scientific, ethical, and religious (and moral) concerns. Indeed over the last 44 years, Congress has repeatedly expanded religious exemptions in similar cases, including to contraceptive coverage. Congress did not purport to deviate from that approach in the ACA. Thus, we conclude it is appropriate to specify in these final rules, that, if the Guidelines continue to maintain a contraceptive coverage requirement, the expanded exemptions will apply to those Guidelines and their enforcement.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for religious beliefs in the context of certain Federal health care requirements. Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held religious beliefs to the extent the Guidelines otherwise include contraceptive coverage.[12] These exemptions do not prohibit any services, nor do they authorize employers to prohibit employees from obtaining any services. The Religious IFC and these final rules simply refrain from imposing the federal Mandate that employers and health insurance issuers cover contraceptives in their health plans where compliance with the Mandate would violate their sincerely held religious beliefs. And though not necessary to the Departments' decision here, the Departments note that the Church Amendments explicitly protect entities and that several subsequent federal conscience statutes have protected against federal mandates in health coverage.

The Departments note that their decision is also consistent with state practice. 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.[13] Although the practice of states is not a limit on the discretion delegated to HRSA by the ACA, nor is it a statement about what the federal government may do consistent with RFRA or other limitations or protections embodied in federal law, such state practices can inform the Departments' view that it is appropriate to protect religious liberty as an exercise of agency discretion.

The Departments decline to adopt the suggestion of some commenters to use these final rules to revoke the contraceptive Mandate altogether, such as by declaring that HHS through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). Although previous regulations were used to authorize religious exemptions and accommodations to the imposition of the Guidelines' coverage of contraception, the issuance of the Guidelines themselves in 2011 describing what items constitute recommended women's preventive services, and the update to those recommendations in December 2016, did not occur through the regulations that preceded the 2017 Religious IFC and these final rules. The Guidelines' specification of which women's preventive services were recommended were issued, not by regulation, but directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The Departments decline to accept the invitation of some commenters to use these rules to specify whether HRSA includes contraceptives in the Guidelines at all. Instead the Departments conclude it is appropriate for these rules to continue to focus on restating the statutory language of PHS Act section 2713 in regulatory form, and delineating what exemptions and accommodations apply if HRSA lists contraceptives in its Guidelines. Some commenters said that if contraceptives are not removed from the Guidelines entirely, some entities or individuals with religious objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in the Religious IFC and these final rules cover a broad range of entities and individuals. The Departments are not aware of specific groups or individuals whose religious beliefs would still be substantially burdened by the Mandate after the issuance of these final rules.

Some commenters asserted that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions.

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

[13] *See* Guttmacher Institute, ''Insurance Coverage of Contraceptives'', The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These rules focus on what religious exemptions and accommodations shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacients.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content of, and the process for developing and updating, the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov.*

The Departments conclude that it would be inadequate to merely attempt to amend or expand the accommodation process instead of expanding the exemption. In the past, the Departments had stated in our regulations and court briefs that the previous accommodation process required contraceptive coverage or payments in a way that is ''seamless'' with the coverage provided by the objecting employer. As a result, in significant respects, that previous accommodation process did not actually accommodate the objections of many entities, as many entities with religious objections have argued. The Departments have attempted to identify an accommodation process that would eliminate the religious objections of all plaintiffs, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but we stated in January 2017 that we were unable to develop such an approach at that time.[14] The Departments continue to believe that, because of the nature of the accommodation process, merely amending that accommodation process without expanding the exemptions would not adequately address religious objections to compliance with the Mandate. Instead, we conclude that the most appropriate approach to resolve these concerns is to expand the exemptions as set forth in the Religious IFC and these final rules, while maintaining the accommodation as an option for providing contraceptive coverage, without forcing entities to choose between compliance with either the Mandate or the accommodation and their religious beliefs.

Comments considering the appropriateness of exempting certain specific kinds of entities or individuals are discussed in more detail below.

C. The First Amendment and the Religious Freedom Restoration Act

Some commenters said that the Supreme Court ruled that the exemptions to the contraceptive Mandate, which the Departments previously provided to houses of worship and integrated auxiliaries, were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but exemptions beyond those are not. But in *Hobby Lobby* and *Zubik,* the Supreme Court did not decide whether the exemptions previously provided to houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate to other organizations unless RFRA prohibits the Departments from doing so. Moreover, the previous church exemption, which applied automatically to all churches whether or not they had even asserted a religious objection to contraception, 45 CFR 147.141(a), is not tailored to any plausible free-exercise concerns. The Departments decline to adopt the view that RFRA does not apply to other religious organizations, and there is no logical explanation for how RFRA could require the church exemption but not this expanded religious exemption, given that the accommodation is no less an available alternative for the former than the latter.

Commenters disagreed about the scope of RFRA's protection in this context. Some commenters said that the expanded exemptions and accommodation are consistent with RFRA. Some also said that they are required by RFRA, as the Mandate imposes substantial burdens on religious exercise and fails to satisfy the compelling-interest and least-restrictive-means tests imposed by RFRA. Other commenters, however, contended that the expanded exemptions and accommodation are neither required by, nor consistent with, RFRA. In this vein, some argued that the Departments have a compelling interest to deny religious exemptions, that there is no less restrictive means to achieve its goals, or that the Mandate or its accommodation process do not impose a substantial burden on religious exercise.

For the reasons discussed below, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden. Here, after further consideration of these issues and review of the public comments, the Departments have determined that a broader exemption, rather than a mere accommodation, is the appropriate response.

In addition, with respect to religious employers, the Departments conclude that, without finalizing the expanded exemptions, and therefore requiring certain religiously objecting entities to choose between the Mandate, the accommodation, or penalties for noncompliance—or requiring objecting individuals to choose between purchasing insurance with coverage to which they object or going without insurance—the Departments would violate their rights under RFRA.

1. Discretion To Provide Religious Exemptions

In the Religious IFC, we explained that even if RFRA does not compel the Departments to provide the religious exemptions set forth in the IFC, the Departments believe the exemptions are the most appropriate administrative response to the religious objections that have been raised.

The Departments received conflicting comments on this issue. Some commenters agreed that the Departments have administrative discretion to address the religious objections even if the Mandate and accommodation did not violate RFRA. Other commenters expressed the view that RFRA does not provide such discretion, but only allows exemptions when RFRA requires exemptions. They contended that RFRA does not require exemptions for entities covered by the expanded exemptions of the Religious IFC, but that subjecting those entities to the accommodation satisfies RFRA, and therefore RFRA provides the Departments with no additional authority to exempt those entities. Those commenters further contended that because, in their view, section 2713(a)(4) does not authorize the

[14] *See* Departments of Labor, Health and Human Services, and the Treasury, ''FAQs About Affordable Care Act Implementation Part 36,'' (Jan. 9, 2017), *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* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

expanded exemptions, no statutory authority exists for the Departments to finalize the expanded exemptions.

As discussed above, the Departments disagree with the suggestions of commenters that section 2713(a)(4) does not authorize the Departments to adopt the expanded exemptions. Nevertheless, the Departments note that the expanded exemptions for religious objectors also rest on an additional, independent ground: The Departments have determined that, in light of RFRA, an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*. Indeed, with respect to at least some objecting entities, an expanded exemption, as opposed to the existing accommodation, is required by RFRA. The Departments disagree with commenters who contend RFRA does not give the Departments discretion to offer these expanded exemptions.

The Departments' determination about their authority under RFRA rests in part on the Departments' reassessment of the interests served by the application of the Mandate in this specific context. Although the Departments previously took the position that the application of the Mandate to objecting employers was narrowly tailored to serve a compelling governmental interest, as discussed below the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Particularly under those circumstances, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement or instead to attempt to create an accommodation that would mitigate the burden. And here, the Departments have determined that a broader exemption rather than the existing accommodation is the appropriate response. That determination is informed by the Departments' reassessment of the relevant interests, as well as by their desire to bring to a close the more than five years of litigation over RFRA challenges to the Mandate.

Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive Mandate, pursuant to *Hobby Lobby*—neither RFRA nor the ACA *prescribes* the remedy by which the government must eliminate that burden, where any means of doing so will require departing from the ACA to some extent (on the view of some commenters, with which the Departments disagree, that section 2713(a)(4) does not itself authorize the Departments to recognize exceptions). The prior administration *chose* to do so through the complex accommodation it created, but nothing in RFRA or the ACA compelled that novel choice or prohibits the current administration from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. After all, on the theory that section 2713(a)(4) allows for no exemptions, the accommodation also departed from section 2713(a)(4) in the sense that employers were not themselves offering contraceptive coverage, and the ACA did not require the Departments to choose that departure rather than the expanded exemptions as the exclusive method to satisfy their obligations under RFRA to eliminate the substantial burden imposed by the Mandate. The agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA. *See* 82 FR at 47798; *see also Ricci* v. *DeStefano,* 557 U.S. 586, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban). Indeed, if the Departments had simply adopted an expanded exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because they should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result now based merely on path dependence.

Although the foregoing analysis is independently sufficient, additional support for this view is provided by the Departments' conclusion, as explained more fully below, that an expanded exemption is required by RFRA for at least some objectors. In the Religious IFC, the Departments reaffirmed their conclusion that there is not a way to satisfy all religious objections by amending the accommodation, (82 FR at 47800), a conclusion that was confirmed by some commenters (and the continued litigation over the accommodation).[15] Some commenters agreed the religious objections could not be satisfied by amending the accommodation without expanding the exemptions, because if the accommodation requires an objecting entity's issuer or third party administrator to provide or arrange contraceptive coverage for persons covered by the plan because they are covered by the plan, this implicates the objection of entities to the coverage being provided through their own plan, issuer, or third party administrator. Other commenters contended the accommodation could be modified to satisfy RFRA concerns without extending exemptions to objecting entities, but they did not propose a method of modifying the accommodation that would, in the view of the Departments, actually address the religious objections to the accommodation.

In the Departments' view, after considering all the comments and the preceding years of contention over this issue, it is appropriate to finalize the expanded exemptions rather than merely attempt to change the accommodation to satisfy religious objections. This is because if the accommodation still delivers contraceptive coverage through use of the objecting employer's plan, issuer, or third party administrator, it does not address the religious objections. If the accommodation could deliver contraceptive coverage independent and separate from the objecting employer's plan, issuer, and third party administrator, it could possibly address the religious objections, but there are two problems with such an approach. First, it would effectively be an exemption, not the accommodation as it has existed, so it would not be a reason not to offer the expanded exemptions finalized in these rules. Second, although (as explained above) the Departments have authority to provide exemptions to the Mandate, the Departments are not aware of the authority, or of a practical mechanism, for using section 2713(a)(4) to require contraceptive coverage be provided

[15] *See* RFI, 81 FR 47741 (July 26, 2016); Departments of Labor, Health and Human Services, and the Treasury, ''FAQs, About Affordable Care Act Implementation Part 36,'' (Jan. 9, 2017), *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* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

specifically to persons covered by an objecting employer, other than by using the employer's plan, issuer, or third party administrator, which would likely violate some entities' religious objections. The Departments are aware of ways in which certain persons covered by an objecting employer might obtain contraceptive coverage through other governmental programs or requirements, instead of through objecting employers' plans, issuers, or third party administrators, and we mention those elsewhere in this rule. But those approaches do not involve the accommodation, they involve the expanded exemptions, plus the access to contraceptives through separate means.

2. Requiring Entities To Choose Between Compliance With the Contraceptive Mandate or the Accommodation Violated RFRA in Many Instances

Before the Religious IFC, the Departments had previously contended that the Mandate did not impose a substantial burden on entities and individuals under RFRA; that it was supported by a compelling government interest; and that it was, in combination with the accommodation, the least restrictive means of advancing that interest. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with sincerely held religious objections, that argument was rejected in *Hobby Lobby,* which held that the Mandate imposes a substantial burden and was not the least restrictive means of achieving any compelling governmental interest. *See* 134 S. Ct. at 2775–79. In the Religious IFC, the Departments revisited its earlier conclusions and reached a different view, concluding that requiring compliance through the Mandate or accommodation constituted a substantial burden on the religious exercise of many entities or individuals with religious objections, did not serve a compelling interest, and was not the least restrictive means of serving a compelling interest, so that requiring such compliance led to the violation of RFRA in many instances. (82 FR at 47806).

In general, commenters disagreed about this issue. Some commenters agreed with the Departments, and with some courts, that requiring entities to choose between the contraceptive Mandate and its accommodation violated their rights under RFRA, because it imposed a substantial burden on their religious exercise, did not advance a compelling government interest, and was not the least restrictive means of achieving such an interest. Other commenters contended that requiring compliance either with the Mandate or the accommodation did not violate RFRA, agreeing with some courts that have concluded the accommodation does not substantially burden the religious exercise of organizations since, in their view, it does not require organizations to facilitate contraceptive coverage except by submitting a self-certification form or notice, and requiring compliance was the least restrictive means of advancing the compelling interest of providing contraceptive access to women covered by objecting entities' plans.

The Departments have examined further, including in light of public comments, the issue of whether requiring compliance with the combination of the contraceptive Mandate and the accommodation process imposes a substantial burden on entities that object to both, and is the least restrictive means of advancing a compelling government interest. The Departments now reaffirm the conclusion set forth in the Religious IFC, that requiring certain religiously objecting entities or individuals to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA.

a. Substantial Burden

The Departments concur with the description of substantial burdens expressed recently by the Department of Justice:

> A governmental action substantially burdens an exercise of religion under RFRA if it bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice.
>
> Because the government cannot second-guess the reasonableness of a religious belief or the adherent's assessment of the connection between the government mandate and the underlying religious belief, the substantial burden test focuses on the extent of governmental compulsion involved. In general, a government action that bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, will qualify as a substantial burden on the exercise of religion.[16]

The Mandate and accommodation under the previous regulation forced certain non-exempt religious entities to choose between complying with the Mandate, complying with the accommodation, or facing significant penalties. Various entities sincerely contended, in litigation or in public comments, that complying with either the Mandate or the accommodation was inconsistent with their religious observance or practice. The Departments have concluded that withholding an exemption from those entities has imposed a substantial burden on their exercise of religion, either by compelling an act inconsistent with that observance or practice, or by substantially pressuring the adherents to modify such observance or practice. To this extent, the Departments believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing substantial burden, to the burdens that an entity faces when it opposes, on the basis of its religious beliefs, complying with the Mandate or participating in the accommodation process, and is subject to penalties or disadvantages that would have applied in this context if it chose neither. *See also Sharpe Holdings,* 801 F.3d at 942. Likewise, reconsideration of these issues has also led the Departments to conclude that the Mandate imposes a substantial burden on the religious beliefs of an individual employee who opposes coverage of some (or all) contraceptives in his or her plan on the basis of his or her religious beliefs, 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 the Mandate requires that employer or issuer to provide a plan that covers all FDA-approved contraceptives. The Departments disagree with commenters that contend the accommodation did not impose a substantial burden on religiously objecting entities, and agree with other commenters and some courts and judges that concluded the accommodation can be seen as imposing a substantial burden on religious exercise in many instances.

b. 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 concluded, after reassessing the relevant interests and, in light of the public comments received, that it does not. This is based on several independent reasons.

First, as discussed above, the structure of section 2713(a)(4) and the ACA evince a desire by Congress to

[16] *See* Federal Law Protections for Religious Liberty, 82 FR 49668, 49669 (Oct. 26, 2017).

grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4). This informs the Departments' assessment of whether the interest in mandating the coverage constitutes a compelling interest, as doing so imposes a substantial burden on religious exercise. As the Department of Justice has explained, ''[t]he strict scrutiny standard applicable to RFRA is exceptionally demanding,'' and ''[o]nly those interests of the highest order can outweigh legitimate claims to the free exercise of religion, and such interests must be evaluated not in broad generalities but as applied to the particular adherent.'' [17]

Second, since the day the contraceptive Mandate came into effect in 2011, the Mandate has not applied in many circumstances. To begin, the ACA does not apply the Mandate, or any part of the preventive services coverage requirements, to grandfathered plans. To continue, the Departments under the last Administration provided exemptions to the Mandate and expanded those exemptions through multiple rulemaking processes. Those rulemaking processes included an accommodation that effectively left employees of many non-exempt religious nonprofit entities without contraceptive coverage, in particular with respect to self-insured church plans exempt from ERISA. Under the previous accommodation, once a self-insured church plan filed a self-certification or notice, the accommodation relieved it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would generally have transferred the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments recognized that they 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 health insurance issuers, but does not apply 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 of those plans to provide such coverage, led to significant disparity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

Third party administrators for some, but not all, religious nonprofit organizations were subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they administer a self-insured church plan. Notably, many of those nonprofit organizations were not houses of worship or integrated auxiliaries. Under section 3(33)(C) of ERISA, organizations whose employees participate in self-insured church plans need not be churches so long as they are controlled by or ''share[ ] common religious bonds and convictions with'' a church or convention or association of churches. The effect is that many similar religious organizations were being treated differently with respect to their employees receiving contraceptive coverage based solely on whether organization employees participate in a church plan.

This arrangement encompassed potentially hundreds of religious non-profit organizations that were not covered by the exemption for houses of worship and integrated auxiliaries. For example, the Departments were sued by two large self-insured church plans—Guidestone and Christian Brothers.[18] Guidestone is a plan organized by the Southern Baptist convention that covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not. Christian Brothers is a plan that covers Catholic churches and integrated auxiliaries and has said in litigation that it covers about 500 additional entities that are not exempt as churches. In several other lawsuits challenging the Mandate, the previous Administration 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).

Third, the Departments now believe the administrative record on which the Mandate rested was—and remains—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. The Mandate is not narrowly tailored to advance the government's interests and appears both overinclusive and underinclusive. It includes some entities where a contraceptive coverage requirement seems unlikely to be effective, such as religious organizations of certain faiths, which, according to commenters, primarily hire persons who agree with their religious views or make their dedication to their religious views known to potential employees who are expected to respect those views. The Mandate also does not apply to a significant number of entities encompassing many employees and for-profit businesses, such as grandfathered plans. And it does not appear to target the population defined, at the time the Guidelines were developed, as being the most at-risk of unintended pregnancy, that is, ''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.'' [19] Rather than focusing on this group, the Mandate is a broad-sweeping requirement across employer-provided coverage and the individual and group health insurance markets.

The Department received conflicting comments on this issue. Some commenters agreed that the government does not have a compelling interest in applying the Mandate to objecting religious employers. They noted that the expanded exemptions will impact only a small fraction of women otherwise affected by the Mandate and argued that refusing to provide those exemptions would fail to satisfy the compelling interest test. Other commenters, however, argued that the government has a broader interest in the Mandate because all women should be considered at-risk of unintended pregnancy. But the Institute of Medicine (IOM), in discussing whether contraceptive coverage is needed, provided a very specific definition of the population of women most at-risk of unintended pregnancy.[20] The Departments believe it is appropriate to consider the government's interest in

[17] *Id.* at 49670.

[18] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[19] Institute of Medicine, ''Clinical Preventive Services for Women: Closing the Gaps'' at 102 (2011).

[20] Id.

the contraceptive coverage requirement using the definition that formed the basis of that requirement and the justifications the Departments have offered for it since 2011. The Mandate, by its own terms, applies not just to women most at-risk of unintended pregnancy as identified by the IOM, but applies to any non-grandfathered ''group health plan and a health insurance issuer offering group or individual health insurance coverage.'' PHS Act section 2713(a). Similarly, the exemptions and accommodation in previous rules, and the expanded exemptions in these rules, do not apply only to coverage for women most at-risk of unintended pregnancy, but to plans where a qualifying objection exists based on sincerely held religious beliefs without regard to the types of women covered in those plans. Seen in this light, the Departments believe there is a serious question whether the administrative record supports the conclusion that the Mandate, as applied to religious objectors encompassed by the expanded exemptions, is narrowly tailored to achieve the interests previously identified by the government. Whether and to what extent it is certain that an interest in health is advanced by refraining from providing expanded religious exemptions is discussed in more detail below in section II.F., Health Effects of Contraception and Pregnancy.

Fourth, the availability of contraceptive coverage from other possible sources—including some objecting entities that are willing to provide some (but not all) contraceptives, or from other governmental programs for low-income women—detracts from the government's interest to refuse to expand exemptions to the Mandate. The Guttmacher Institute recently published a study that concluded, ''[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy,'' and ''there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.'' [21] In discussing why they did not see such an effect from the Mandate, the authors suggested that ''[p]rior to the implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use. In addition, cost is not the only barrier to accessing a full range of method options,'' and ''[t]he fact that income is not associated with use of most other methods [besides male sterilization and withdrawal] obtained through health care settings may reflect broader access to affordable and/or free contraception made possible through programs such as Title X.''

Fifth, the Departments previously created the accommodation, in part, as a way to provide for payments of contraceptives and sterilization in a way that is ''seamless'' with the coverage that eligible employers provide to their plan participants and their beneficiaries. (80 FR 41318). As noted above, some commenters contended that seamlessness between contraceptive coverage and employer sponsored insurance is important and is a compelling governmental interest, while other commenters disagreed. Neither Congress, nor the Departments in other contexts, have concluded that seamlessness, as such, is a compelling interest in the federal government's delivery of contraceptive coverage. For example, the preventive services Mandate itself does not require contraceptive coverage and does not apply to grandfathered plans, thereby failing to guarantee seamless contraceptive coverage. The exemption for houses of worship and integrated auxiliaries, and the application of the accommodation to certain self-insured church plans, also represents a failure to achieve seamless contraceptive coverage. HHS's Title X program provides contraceptive coverage in a way that is not necessarily seamless with beneficiaries' employer sponsored insurance plans. After reviewing the public comments and reconsidering this issue, the Departments no longer believe that if a woman working for an objecting religious employer receives contraceptive access in ways that are not seamless to her employer sponsored insurance, a compelling government interest has nevertheless been undermined. Therefore the Departments conclude that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides employers' religious objections to the contraceptive Mandate.

Some commenters contended that obtaining contraceptive coverage from other sources could be more difficult or more expensive for women than obtaining it from their group health plan or health insurance plan. The Departments do not believe that such differences rise to the level of a compelling interest or make it inappropriate for us to issue the expanded exemptions set forth in these final rules. Instead, after considering this issue, the Departments conclude that the religious liberty interests that would be infringed if we do not offer the expanded exemptions are not overridden by the impact on those who will no longer obtain contraceptives through their employer sponsored coverage as a result. This is discussed in more detail in following section, II.D., Burdens on Third Parties.

D. Burdens on Third Parties

The Departments received a number of comments on the question of burdens that these rules might impose on third parties. Some commenters asserted that the expanded exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might not otherwise receive contraceptive coverage with no cost-sharing. These included commenters agreeing with the Departments' explanations in the Religious IFC, stating that unintended pregnancies were decreasing before the Mandate was implemented, and asserting that any benefit that third parties might receive in getting contraceptive coverage does not justify forcing religious persons to provide such products in violation of their beliefs. Other commenters disagreed, asserting that the expanded exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more unintended pregnancies,[22] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as those found in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as

[21] M.L. Kavanaugh et al., Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[22] Some commenters attempted to quantify the costs of unintended pregnancy, but failed to persuasively estimate the population of women that this exemption may affect.

prioritizing religious liberty of exempted entities over the religious liberty, conscience, or choices of women who would not receive contraceptive coverage where an exemption is used.

The Departments note that the exemptions in the Religious IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these final rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. HHS exercised discretion granted to HRSA by the Congress to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits. But Congress did not create a right to receive contraceptive coverage from other private citizens through PHS Act section 2713, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to benefit other private parties, does not prevent the government from relieving some or all of the burden of its Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Religious IFC and these rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third-party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae,* 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the Government refrain from requiring private citizens, in violation of their religious beliefs, to cover contraception for other citizens. *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 constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting religious objections to such governmental mandates, especially where, as here, the mandate is not an explicit statutory requirement.[23] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these final rules.

As the Department of Justice has observed, the fact that exemptions may relieve a religious adherent from conferring a benefit on a third party ''does not categorically render an exemption unavailable,'' and RFRA still applies.[24] The Departments conclusion on this matter is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants ''to confer benefits on third parties.'' *See Hobby Lobby,* 134 S. Ct. at 2781 n.37. Here, no law contains such a requirement, but the Mandate is derived from an administrative exercise of discretion that Congress charged HRSA and the Departments with exercising. Burdens that may affect third parties as a result of revisiting the exercise of agency discretion 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.*

When government relieves burdens on religious exercise, it does not violate the Establishment Clause; rather, ''it follows the best of our traditions.'' *Zorach* v. *Clauson,* 343 U.S. 306, 314 (1952). The Supreme Court's cases ''leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice.'' *Board of Educ. of Kiryas Joel Village Sch. Dist.* v. *Grumet,* 512 U.S. 687, 705 (1994). Rather, the Supreme Court ''has long recognized that the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause.'' *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* 483 U.S. 327, 334 (1987) (quoting *Hobbie* v. *Unemployment Appeals Comm'n of Fla.,* 480 U.S. 136, 144–45 (1987)). ''[T]here is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.'' *Cutter* v. *Wilkinson,* 544 U.S. 709, 713 (2005) (internal quotation omitted). Thus, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII's prohibition against discrimination in employment on the basis of religion, *see Amos,* 483 U.S. at 335–39; a state property tax exemption for religious organizations, *see Walz* v. *Tax Comm'n of City of New York,* 397 U.S. 664, 672–80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach,* 343 U.S. at 315.

Before 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under PHS

[23] *See, for example, 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.'').

[24] See Federal Law Protections for Religious Liberty, 82 FR at 49670.

Act section 2713 to be covered by grandfathered plans. Many States do not impose contraceptive coverage mandates, or they offer religious exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or State courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters said that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others said that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to states or local governments. We are not aware of instances where the various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage (other than through the Religious and Moral IFCs), have been determined to cause a cognizable injury to state or local governments. Some states that were opposed to the IFCs submitted comments objecting to the potential impacts on their programs resulting from the expanded exemptions, but they did not adequately demonstrate that such impacts would occur, and they did not explain whether, or to what extent, they were impacted by the other kinds of instances mentioned above in which no federal mandate of contraceptive coverage has applied to certain plans. The Departments find no legal prohibition on finalizing these rules based on the speculative suggestion of an impact on state or local governments, and we disagree with the suggestion that once we have exercised our discretion to deny exemptions—no matter how recently or incompletely—we cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, these expanded exemptions apply only to a small fraction of entities to which the Mandate would otherwise apply—those with qualifying religious objections. Public comments did not provide reliable data on how many entities would use these expanded religious exemptions, in which states women in such plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would have to cover. As mentioned above, at least one study, published by the Guttmacher Institute, concluded the Mandate has caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the expanded exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates.

In the discussion below concerning estimated economic impacts of these rules, the Departments explain there is not reliable data available to accurately estimate the number of women who may lose contraceptive coverage under these rules, and the Departments set forth various reasons why it is difficult to know how many entities will use these exemptions or how many women will be impacted by those decisions. Solely for the purposes of determining whether the rules have a significant economic impact under Executive Order 12,866, and in order to estimate the broadest possible impact so as to determine the applicability of the procedures set forth in that Executive Order, the Departments propose that the rules will affect no more than 126,400 women of childbearing age who use contraceptives covered by the Guidelines, and conclude the economic impact falls well below $100 million. As explained below, that estimate assumes that a certain percentage of employers which did not cover contraceptives before the ACA will use these exemptions based on sincerely held religious beliefs. The Departments do not actually know that such entities will do so, however, or that they operate based on sincerely held religious beliefs against contraceptive coverage. The Departments also explain that other exemptions unaffected by these rules may encompass many or most women potentially affected by the expanded exemptions. In other words, the houses of worship and integrated auxiliaries exemption, the accommodation's failure to require contraceptive coverage in certain self-insured church plans, the non-applicability of PHS Act section 2713 to grandfathered plans, and the permanent injunctive relief many religious litigants have received against section 2713(a)(4), may encompass a large percentage of women potentially affected by religious objections, and therefore many women in those plans may not be impacted by these rules at all. In addition, even if 126,400 women might be affected by these rules, that number constitutes less than 0.1% of all women in the United States.[25] This suggests that if these rules have any impact on state or local governments, it will be statistically de minimus. The Departments conclude that there is insufficient evidence of a potential negative impact of these rules on state and local governments to override the appropriateness of deciding to finalize these rules.

Some commenters contended that the expanded exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions

[25] U.S. Census Bureau, ''Quick Facts: Population Estimates, July 1, 2017'' (estimating 325,719,178 persons in the U.S., 50.8% of which are female), available at *https://www.census.gov/quickfacts/fact/table/US/PST045217.*

would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these final rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The expanded exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead they allow entities that have sincerely held religious objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

These commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.,* 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII ''does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women''). Second, these rules create no disparate impact. The women's preventive services mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inures to the specific benefit of women—men are denied any benefit from that section. Both before and after these final rules, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or male contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions are expanded to encompass religious objections. The previous regulations, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that few women of childbearing age in the country will be affected by these expanded exemptions.[26] In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters observed that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some objected to the suggestion in the Religious IFC that many forms of contraceptives are available for around $50 per month and other forms, though they bear a higher one-time cost, cost a similar amount over the duration of use. But some of those commenters cited sources maintaining that birth control pills can cost up to $600 per year (that is, $50 per month), and said that IUDs, which can last three to six years or more,[27] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters said that, for lower income women, contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately insured individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, pointing out that some government programs that provide family planning have income and eligibility thresholds, so that women earning certain amounts above those levels would need to pay full cost for contraceptives if they were no longer covered in their health plans.

The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules. In addition, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed regulation to amend the regulations governing its Title X family planning program. The proposed regulation would amend the definition of ''low income family''—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions (see 83 FR 25502). If that regulation is finalized as proposed, it could further reduce any potential effect of these final rules on women's access to contraceptives. That proposal also demonstrates that the government has other means available to it for increasing women's access to contraception. Some of those means are less restrictive of religious exercise than imposition of the contraceptive Mandate on employers with sincerely held religious objections to providing such coverage.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS ''shall not promulgate any regulation'' that ''creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,'' ''impedes timely access to health care services,'' ''interferes with communications regarding a full range of treatment options between the patient and the provider,'' ''restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,'' ''violates the principles of informed consent and the ethical standards of health care professionals,'' or ''limits the

[26] Below, the Departments estimate that no more than 126,400 women of childbearing age will be affected by the expanded exemptions. As noted above, this is less than 0.1% of the over 165 million women in the United States. The Departments previously estimated that, at most 120,000 women of childbearing age would be affected by the expanded exemptions. *See* Religious IFC, 82 FR 47,823–84.

[27] *See, for example,* Planned Parenthood, ''IUD,'' *https://www.plannedparenthood.org/learn/birth-control/iud.*

availability of health care treatment for the full duration of a patient's medical needs.'' 42 U.S.C. 18114. Such commenters urged, for example, that the Religious IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections. The Departments, which administer both ACA section 1554 and PHS Act section 2713, did not conclude that the exemptions or accommodations in those regulations violated section 1554. Moreover, the decision not to impose a governmental mandate is not the ''creation'' of a ''barrier,'' especially when that mandate requires private citizens to provide services to other private citizens. Nor, in any event, are the exemptions from the Mandate unreasonable. Section 1554 of the ACA does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 prohibit the Departments from providing exemptions for burdens on religious exercise, or, as is the case here, from refraining to impose the Mandate in cases where religious exercise would be burdened by it. In light of RFRA and the First Amendment, providing religious exemptions is a reasonable administrative response in the context of this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts. Religious exemptions from federal mandates in sensitive health contexts have existed in federal laws for decades, and President Obama referenced them when he issued Executive Order 13535 (March 24, 2010), declaring that, under the ACA, ''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.'' While the text of Executive Order 13535 does not require the expanded exemptions issued in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect religious beliefs.

In short, the Departments do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

Members of the public have widely divergent views on whether expanding the exemptions is good public policy. Some commenters said the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind expanding the exemptions and arguing that the exemptions would not interfere with the physician-patient relationship. For all the reasons explained at length in this preamble, the Departments have determined that these rules are good policy. Because of the importance of the religious liberty values being accommodated, the limited impact of these rules, and uncertainty about the impact of the Mandate overall according to some studies, the Departments do not believe these rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

E. Interim Final Rulemaking

The Departments received several comments about their decision to issue the Religious IFC as interim final rules with requests for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Religious IFC in that way, agreeing that the Departments had explicit statutory authority to do so, good cause under the Administrative Procedure Act (APA), or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe legal authority existed to issue the Religious IFC as interim final rules. 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. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Religious IFC, the Departments issued three interim final rules implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Religious IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Religious IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules are being issued after receiving and thoroughly considering public comments as requested in the Religious IFC. These final rules therefore comply with the APA's notice and comment requirements.

F. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause or are associated with an increased risk of depression,[28] venous thromboembolic

[28] Commenters cited Charlotte Wessel Skovlund et al., ''Association of Hormonal Contraception with Depression,'' 73 *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) (''Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression,

disease,[29] fatal pulmonary embolism,[30] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[31] hypertension,[32] HIV–1 acquisition and transmission,[33] and breast, cervical, and liver cancers.[34] Some commenters also observed that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that contraceptive access does not reduce unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 IOM Report's discussions of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality.[35] Commenters also said studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer,[36] and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[37] Some commenters said that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters said that, in the Religious IFC, the Departments made incorrect statements concerning scientific studies. For example, some commenters argued there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Religious IFC for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality Report No.: 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR at 47804, the 2013 Agency for Healthcare Research and Quality study, and others, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to take into account both of those studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[38] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or, more specifically, the part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some

suggesting depression as a potential adverse effect of hormonal contraceptive use.'').

[29] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception: Recent Advances and Controversies,'' 82 *Fertility and Sterility* S20, S26 (2004); V.A. Van Hylckama et al., ''The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,'' 339 *Brit. Med. J.* 339b2921 (2009); Y. Vinogradova et al., ''Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,'' 350 *Brit. Med. J.* 350h2135 (2015) (''Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.''); Ø. Lidegaard et al., ''Hormonal contraception and risk of venous thromboembolism: national follow-up study,'' 339 *Brit. Med. J.* b2890 (2009): M. de Bastos et al., ''Combined oral contraceptives: venous thrombosis,'' Cochrane Database Syst. Rev. (no. 3, 2014). CD010813. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J Havrilesky 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;* and Robert A. Hatcher et al., *Contraceptive Technology* 405–07 (Ardent Media 18th rev. ed. 2004).

[30] Commenters cited N.R. Poulter, ''Risk of Fatal Pulmonary Embolism with Oral Contraceptives,'' 355 *Lancet* 2088 (2000).

[31] Commenters cited Ø. Lidegaard et al., ''Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception,'' 366 *N. Eng. J. Med.* 2257, 2257 (2012) (risks ''increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg''); Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception''; M. Vessey et al., ''Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,'' 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, ''Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,'' 349 *Lancet* 1202, 1202–09(1997); K.M. Curtis et al., Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review, 73 Contraception 73179, 179–88 (2006); L.A. Gillum et al., ''Ischemic stroke risk with oral contraceptives: A meta analysis,'' 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[32] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology* 407, 445 (Ardent Media 18th rev. ed. 2004).

[33] Commenters cited Renee Heffron et al., ''Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study,'' 12 *Lancet Infectious Diseases 19, 24* (2012) (''Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men.''); and ''Hormonal Contraception Doubles HIV Risk, Study Suggests,'' *Science Daily* (Oct. 4, 2011), *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[34] Commenters cited ''Oral Contraceptives and Cancer Risk'' (Mar. 21, 2012, National Cancer Institute (reviewed Feb. 22, 2018), *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky 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;* S.N. Bhupathiraju et al., ''Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study,'' 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, ''The Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment'', World Health Organization (Sept. 2005), *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, ''Known and Probably Human Carcinogens,'' American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

[35] Citing, *e.g.,* Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. JAMA 2006;295:1809–23, and John Hopkins Bloomberg Public Health School of Health, Contraception Use Averts 272,000 Maternal Deaths Worldwide, *https://www.jhsph.edu/news/news-releases/2012/ahmed-contraception.html.*

[36] Citing, *e.g.,* Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. International Journal of Endocrinology and Metabolism, 11 (1), 41–47.

[37] Citing, *e.g.,* id., and American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women. (2015, January). Committee Opinion Number 615: Access to Contraception. As discussed below, to the extent that contraceptives are prescribed to treat existing health conditions, and not for preventive purposes, the Mandate would not be applicable.

[38] 82 FR at 47803–04.

commenters agreed with the quotation, in the Religious IFC, of FDA materials [39] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Religious IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Religious IFC that some persons believe those possible effects are ''abortifacient.''

The objection on this issue appears to be partially one of semantics. People disagree about whether to define ''conception'' or ''pregnancy'' to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items ''abortifacient''—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby,* 134 U.S. at 2765 (''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.'').

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere religious objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of a sincerely held religious belief under RFRA.[40] Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer expanded religious exemptions with respect to this Mandate.

The Departments also received comments about their discussion of the uncertain effects of the expanded exemptions on teen sexual activity. In this respect, the Departments stated, ''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). 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.' '' [41] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that denying expanded exemptions to the Mandate is not a narrowly tailored way to advance the Government's interests in reducing teen pregnancy, and suggesting there are means of doing so that are less restrictive of religious exercise.[42] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[43]

Many commenters opposing the Religious IFC misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, we note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments' conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including but not limited to reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline), and concluded ''that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.'' [44] One

[39] 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.*

[40] ''Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.'' *Hobby Lobby,* 134 S. Ct. at 2762–63. ''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.'' *Id.* at 2765–66.

[41] Citing J.S. Santelli & A.J. Melnikas, ''Teen fertility in transition: recent and historic trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and 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/addicted13.pdf. See also* K. Buckles & D. Hungerman, ''The Incidental Fertility Effects of School Condom Distribution Programs,'' *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* (''access to condoms in schools increases teen fertility by about 10 percent'' and increased sexually transmitted infections).

[42] *See* Helen Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 400–02 (2013) (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).

[43] *See, for example,* Lindberg L., Santelli J., ''Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,'' 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[44] Kearney MS and Levine PB, ''Investigating recent trends in the U.S. birth rate,'' 41 *J. Health*

study found that during the teen pregnancy decline between 2007–2012, teen sexual activity was also decreasing.[45] One study concluded that falling unemployment rates in the 1990s accounted for 85% of the decrease in rates of first births among 18–19 year-old African Americans.[46] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[47] One study concluded that an ''increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.'' [48] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[49] Some commenters also cited studies, which are not limited to the issue of teen pregnancy, that have found many women who have abortions report that they were using contraceptives when they became pregnant.[50]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of the public comments has reinforced the Departments' conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing religious exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments for implementing the ACA.

G. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promotes the health and equality of women, especially low income women and promotes female participation and equality in the workforce. Other commenters contended that there was insufficient evidence that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed the study quoted above, published and revised by the Guttmacher Institute in October 2017, concluding that through 2014 there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy, that there was no significant shift from less effective to more effective methods, and that it was ''unclear'' whether this Mandate impacted contraceptive use because there was no significant increase in the use of contraceptive methods the Mandate covered.[51] These commenters also noted that, in the 29 States where contraceptive coverage mandates have been imposed statewide,[52] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[53] Other commenters, however, disputed the significance of these state statistics, noting that of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the expanded exemptions in these rules might have on the Mandate more broadly. The state mandates apply to a very large number of plans and plan participants, notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups are, and have been, exempt from the federal Mandate prior to the Religious IFC. The exemptions as set forth in the Religious IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might

Econ. 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[45] *See, for example,* K. Ethier et al., ''Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,'' 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* (''Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall. . . .'').

[46] Colen CG, Geronimus AT, and Phipps MG, ''Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,'' 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[47] Atkins DN and Wilkins VM, ''Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,'' 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[48] E. Collins & B. Herchbein, ''The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,'' *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* (''[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women'').

[49] *See* D. Paton & L. Wright, ''The effect of spending cuts on teen pregnancy,'' 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* (''Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates'').

[50] Commenters cited, for example, Guttmacher Institute, ''Fact Sheet: Induced Abortion in the United States'' (Jan. 2018) (''Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant''), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

[51] Kavanaugh, 97 *Contraception* at 14–21.

[52] *See* Guttmacher Institute, ''Insurance Coverage of Contraceptives'' (June 11, 2018); Kaiser Family Foundation, ''State Requirements for Insurance Coverage of Contraceptives,'' Henry J Kaiser Family Foundation (Jan. 1, 2018), *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[53] *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.*

result from a broad contraceptive coverage mandate.

Some commenters expressed concern that providing exemptions to the Mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, PHS Act section 2713(a)(2) requires coverage of ''immunizations,'' and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting religious beliefs from certain health care mandates concerning issues such as sterilization, abortion and birth control.

Some commenters took issue with the conclusion set forth in the Religious IFC, which is similar to that asserted in the 2017 Guttmacher study, that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.'' They observed that more women have coverage of contraceptives and contraception counseling under the Mandate and that more contraceptives are provided without co-pays than before. Still other commenters argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [54] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also argued that studies show that decreases in unintended pregnancies are due to broader access of contraceptives. Finally, some commenters argued that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on our review, it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, we conclude that the Religious IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small group of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. We also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, are an appropriate exercise of the Departments' discretion.

Moreover, we conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules will provide tangible protections for religious liberty, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise. The Departments view the provision of those protections to preserve religious exercise in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for religious exercise set forth in the Religious IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

[54] Citing, for example, Adelle Simmons et al., ''The Affordable Care Act: Promoting Better Health for Women,'' Table 1, Assistant Secretary for Planning and Evaluation (June 14, 2016), *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

III. Description of the Text of the Regulations and Response to Additional Public Comments

Here, the Departments describe the regulatory text set forth prior to the Religious IFC, the regulations from that IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. As noted above, various members of the public provided comments that were supportive, or critical, of the Religious IFC overall, or of significant policies pertaining to those regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

A. Restatement of Statutory Requirements of PHS Act Section 2713(a) and (a)(4) (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified these restatements to more closely align them with the text of PHS Act section 2713(a) and (a)(4).

Previous versions of these rules had varied from the statutory language. PHS Act section 2713(a) and (a)(4) require group health plans and health insurance issuers offering coverage to provide coverage without cost sharing for ''such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines'' supported by HRSA. In comparison, the previous version of regulatory restatements of this language (as drawn from 45 CFR 147.130(a)(1)

and (a)(1)(iv)) stated the coverage must include ''evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by'' HRSA. The Religious IFC amended this language to state, parallel to the language in section 2713(a)(4), that the coverage must include ''such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by'' HRSA.

These rules adopt as final, without change, the provisions in the Religious IFC amending 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). In this way, the regulatory text better conforms to the statutory language. In paragraph (a)(1) of the final regulations, instead of saying ''must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements . . . with respect to those items and services:'', the regulation now tracks the statutory language by saying ''must provide coverage for and must not impose any cost-sharing requirements . . . for—''. By eliminating the language ''coverage for all of the following items and services,'' and ''with respect to those items and services,'' the Departments do not intend that coverage for specified items and services will not be required, but we simply intend to simplify the text of the regulation to track the statute and avoid duplicative language.

By specifying that paragraph (a)(1)(iv) concerning the women's preventive services Guidelines encompasses ''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,'' the regulatory text also better tracks the statutory language that the Guidelines are for ''such additional'' preventive services as HRSA may ''provide[ ] for'' and ''support[ ].'' This text also eliminates language, not found in the statute, that the Guidelines are ''evidence-informed'' and ''binding.'' Congress did not include the word ''binding'' in PHS Act section 2713, and did include the words ''evidence-based'' or ''evidence-informed'' in section 2713(a)(1) and (a)(3), but omitted such terms from section 2713(a)(4). In this way, the regulatory text better comports with the scope of the statutory text. This text of paragraph (a)(1)(iv) also acknowledges that the Departments have decided Guidelines issued under section 2713(a)(4) will not be provided for or supported to the extent they exceed the exemptions and accommodation set forth in 45 CFR 147.131 and 147.132. Previous versions of the regulation placed that limit in 45 CFR 147.130(a)(1), but did not reiterate it in § 147.130(a)(1)(iv). To clearly set forth the applicability of the exemptions and accommodation, the Departments adopt as final the Religious IFC language, which included the language ''subject to §§ 147.131 and 147.132'' in both § 147.130(a)(1) and § 147.130(a)(1)(iv). Because these final rules adopt as final the Religious IFC language which includes the exemptions and accommodation in both §§ 147.131 and 147.132, and not just in § 147.131 as under the previous rules, the Departments correspondingly included references to both sections in this part.

Some commenters supported restoring the statutory language from PHS Act section 2713(a) and (a)(4) in the regulatory restatements of that language. Other commenters opposed doing so, asserting that Guidelines issued pursuant to section 2713(a)(4) must be ''evidence-informed'' and ''binding.'' The Departments disagree with the position that, even though Congress omitted those terms from section 2713(a)(4), their regulatory restatement of the statutory requirement should include those terms. Instead, the Departments conclude that it is more appropriate for the regulatory restatements of section 2713(a)(4) to track the statutory language in this regard, namely, ''as provided for in comprehensive guidelines supported by [HRSA] for purposes of'' that paragraph.

B. Prefatory Language of Religious Exemptions (45 CFR 147.132(a)(1))

These final rules adopt as final, with changes based on comments as set forth below, the regulatory provision in the Religious IFC that moved the religious exemption from 45 CFR 147.131(a) to 45 CFR 147.132.

In the previous regulations, the exemption stated, at § 147.131(a), that HRSA's Guidelines ''may establish an exemption'' for the health plan or coverage of a ''religious employer,'' defined as ''an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code.'' The Religious IFC moved the exemption to a new § 147.132, in which paragraph (a) discussed objecting entities, paragraph (b) discussed objecting individuals, paragraph (c) set forth a definition, and paragraph (d) discussed severability. The prefatory language to § 147.132(a)(1) stated that HRSA's Guidelines ''must not provide for or support the requirement of coverage or payments for contraceptive services'' for the health plan or coverage of an ''objecting organization,'' and thus that HRSA ''will exempt'' such an organization from the contraceptive coverage requirments of the Guidelines. The remainder of paragraph (a)(1), which is discussed in greater detail below, describes what entities are included as objecting organizations.

This language not only specifies that certain entities are ''exempt,'' but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) 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 certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are ''exempt'' by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as ''exempt,'' and in referring to the ''exemption'' encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth 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 regulations have worked by means of similar language. When sections § 147.132(a)(1) and (a)(1)(i) specify that ''[a] group health plan,'' ''health insurance coverage provided in connection with a group health plan,'' and ''health insurance coverage offered or arranged by an objecting organization'' are exempt ''to the extent'' of the objections ''as specified in paragraph (a)(2),'' that language exempts the group health plans of the sponsors that object, and 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) (and as referenced by 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 § 147.132(a)(1) and (a)(1)(i) would face no penalty as a result of omitting certain contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while the objection of a plan sponsor (or entity that arranges coverage under the plan, as applicable) removes penalties from that plan's issuer, it only does so for that plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.132(a)(1)(iii) is included below.

The exemptions in § 147.132(a)(1) apply ''to the extent'' of the objecting entities' sincerely held religious 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. Some commenters said it was unclear whether the plans of entities or individuals that religiously object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite religious objection against some but not all contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects, and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules, the Departments finalize the prefatory language of § 147.132(a) with the following change, so that the final rules state that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, ''to the extent of the objections specified below.''

The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying ''to the extent'' of the objection(s).

C. Scope of Religious Exemptions and Requirements for Exempt Entities (45 CFR 147.132)

In 45 CFR 147.132(a)(1)(i) through (iii) and (b), the Religious IFC expands the exemption to plans of additional entities and individuals not encompassed by the exemption set forth in the regulations prior to the Religious IFC. Specific entities to which the expanded exemptions apply are discussed below.

The exemptions contained in previous regulations, at § 147.131(a), did not require exempt entities to submit any particular self-certification or notice, either to the government or to their issuer or third party administrator, in order to obtain or qualify for the exemption. Similarly, under the expanded exemptions in § 147.132, the Religious IFC did not require exempt entities to comply with a self-certification process. We finalize that approach in this respect without change. Although exempt entities do not need to file notices or certifications of their exemption, and these 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 identifies what benefits are provided to participants and beneficiaries under the plan; 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.[55] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosure documents 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.

Some commenters supported the expanded exemption's approach which maintained the policy of the previous exemption in not requiring exempt entities to comply with a self-certification process. They suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to religious objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters, however, favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process. Some commenters asked that the government publish a list of entities that claim the exemption.

The Departments believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption. The Departments believe the approach under the previous exemption is appropriate for the expanded exemption. Adding a self-certification or notice to the exemption process would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices were to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries in plans that reduce or eliminate contraceptive benefits as a result of the exemption will know whether their health plan claims an exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these rules to continue to not require notices or self-certifications for using the exemption.

[55] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 102–3, & 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 and individual issuers).

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these rules. The expanded exemptions in these rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. The rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (Below, these rules discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that, where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed below, the Departments are including, in these final rules, language from the previous regulations protecting issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in and derived from the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators.

Regarding the Religious IFC's expansion of the exemption to other kinds of entities and individuals in general, commenters disagreed about the likely effects of the exemptions on the health coverage market. Some commenters said that expanding the exemptions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or offer only some contraceptives—to houses of worship and integrated auxiliaries; some commenters and litigants said that issuers were doing so. These cases where plans did not need to comply with the Mandate, and the Departments' previous accommodation process allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[56]

Concerning the prospect raised by commenters of different risk pools between men and women, PHS Act section 2713(a) itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage would be required. These rules do not require issuers to offer products that satisfy religiously objecting entities or individuals; they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to religious entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

D. Plan Sponsors in General (45 CFR 147.132(a)(1)(i) Prefatory Text)

With respect to employers and others that sponsor group health plans, in § 147.132(a)(1)(i), the Religious IFC provided exemptions for non-governmental plan sponsors 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. The Departments finalize the prefatory text of § 147.132(a)(1)(i) without change.

The expanded exemptions covered any kind of non-governmental employer plan sponsor with the requisite objections, stating the exemption encompassed ''[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.'' For the sake of clarity, the expanded exemptions also stated that ''[s]uch non-governmental plan sponsors include, but are not limited to, the following entities,'' followed by an illustrative, non-exhaustive list of non-governmental organizations whose objections qualify the plans they sponsor for an exemption. Each type of such entities, and comments specifically concerning them, are discussed below.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.132(a)(1)(i). Some commenters suggested that the expanded religious exemptions should include government entities. Others disagreed. The Departments are not aware of reasons why it would be appropriate or necessary to offer a religious exemption to governmental employer plan sponsors with respect to the contraceptive Mandate. We are unaware of government entities that would attempt to assert a religious exemption to the Mandate, and it is not clear to us that a governmental entity could do so. Accordingly, we conclude that it is appropriate for us to not further expand the religious exemption to include governmental entities in the religious plan-sponsor exemption.

Nevertheless, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and, thus, to provide

[56] *See also Real Alternatives* v. *Sec'y, Dep't of Health & Human Servs.,* 867 F.3d 338, 389 (3d Cir. 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)).

health 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 final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union, or a sponsor of a multiemployer plan) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization. Some commenters objected to extending the exemption to such entities, arguing that they could not have the same kind of religious objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite religious objection. The Departments conclude that it is appropriate, where the plan sponsor of a union, multiemployer, or similar plan adopts a religious objection using the same procedures that such a plan sponsor might use to make other decisions, that the expanded exemptions should respect that decision by providing an exemption from the Mandate.

E. Houses of Worship and Integrated Auxiliaries (45 CFR 147.132(a)(1)(i)(A))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only ''an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.'' Section 6033(a)(3)(A)(i) or (iii) of the Code encompasses ''churches, their integrated auxiliaries, and conventions or associations of churches,'' and ''the exclusively religious activities of any religious order.''

The Religious IFC expanded the exemption to include, in § 147.132(a)(1)(i)(A), plans sponsored by ''[a] church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.'' Most commenters did not oppose the exemptions continuing to include these entities, although some contended that the Departments have no authority to exempt any entity or plan from the Mandate, an objection to which the Departments respond above. Notably, this exemption exempts ''a religious order,'' and not merely ''the exclusively religious activities of any religious order.'' In addition, section 6033(a)(3)(A)(i) specifies that it covers churches, not merely ''the exclusively religious activities'' of a church. Some religious people might express their beliefs through a church, others might do so through a religious order, and still others might do so through religious bodies that take a different form, structure, or nomenclature based on a different cultural or historical tradition. *Cf. Hosanna-Tabor Evangelical Lutheran Church and School* v. *E.E.O.C.,* 565 U.S. 171, 198 (2012) (Alito and Kagan, JJ., concurring) (''The term 'minister' is commonly used by many Protestant denominations to refer to members of their clergy, but the term is rarely if ever used in this way by Catholics, Jews, Muslims, Hindus, or Buddhists.''). For the purposes of respecting the exercise of religious beliefs, which the expanded exemptions in these rules concern, the Departments find it appropriate that this part of the exemption encompasses religious orders and churches similarly, without limiting the scope of the protection to the exclusively religious activities of either kind of entity. Based on all these considerations, the Departments finalize § 147.132(a)(1)(i)(A) without change.

Moreover, the Departments also finalize the regulatory text to exempt plans ''established or maintained by'' a house of worship or integrated auxiliary on a plan, not employer, basis. Under previous regulations, the Departments stated that ''the availability of the exemption or accommodation [was to] be determined on *an employer by employer basis,* which the Departments . . . believe[d] best balance[d] the interests of religious employers and eligible organizations and those of employees and their dependents.'' (78 FR 39886 (emphasis added)). 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 covered by the 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].'' Upon further consideration, in the Religious IFC, the Departments changed their view on this issue and expanded the exemption for houses of worship and integrated auxiliaries. Under these rules, 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 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 requirement of being integrated auxiliaries. Under this interpretation, houses of worship would not be faced with the potential of having to include, in the plans that they have established and maintained, coverage for services to which they have a religious objection for employees of an affiliated employer participating in the plans.

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 to participate 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 regulation where with respect to self-insured church plans, hundreds of nonprofit religious entities participating in those plans were provided a mechanism by which their plan participants would not receive contraceptive coverage through the plan or third party administrator.[57]

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.

F. Nonprofit Organizations (45 CFR 147.132(a)(1)(i)(B))

The exemption under previous regulations did not encompass nonprofit religious organizations beyond one that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code. The Religious IFC expanded the exemption to include plans sponsored by any other

[57] See supra at II.A.3.

''nonprofit organization,'' § 147.132(a)(1)(i)(B), if it has the requisite religious objection under § 147.132(a)(2) (see § 147.132(a)(1)(i) introductory text). The Religious IFC also specified in § 147.132(a)(1)(i)(A), 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.'' (Hereinafter ''houses of worship and integrated auxiliaries.'') These rules finalize, without change, the text of § 147.132(a)(1)(i)(A) and (B).

The Departments received comments in support of, and in opposition to, this expansion. Some commenters supported the expansion of the exemptions beyond houses of worship and integrated auxiliaries to other nonprofit organizations with religious objections (referred to herein as ''religious nonprofit'' organizations, groups or employers). They said that religious belief and exercise in American law has not been limited to worship, that religious people engage in service and social engagement as part of their religious exercise, and, therefore, that the Departments should respect the religiosity of nonprofit groups even when they are not houses of worship and integrated auxiliaries. Some public commenters and litigants have indicated that various religious nonprofit groups possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Other commenters did not support the expansion of exemptions to nonprofit organizations. Some of them described churches as having a special status that should not be extended to religious nonprofit groups. Some others contended that women at nonprofit religious organizations may support or wish to use contraceptives and that if the exemptions are expanded, it would deprive all or most of the employees of various religious nonprofit organizations of contraceptive coverage.

After evaluating the comments, the Departments continue to believe that an expanded exemption is the appropriate administrative response to the substantial burdens on sincere religious beliefs imposed by the contraceptive Mandate, as well as to the litigation objecting to the same. We agree with the comments that religious exercise in this country has long been understood to encompass actions outside of houses of worship and their integrated auxiliaries. The Departments' previous assertion that the exemptions were intended to respect a certain sphere of church autonomy (80 FR 41325) is not, in itself, grounds to refuse to extend the exemptions to other nonprofit entities with religious objections. Respect for churches does not preclude respect for other religious entities. Among religious nonprofit organizations, the Departments no longer adhere to 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.'' (78 FR 39874.) It is not clear to the Departments that the percentage of women who work at churches that oppose contraception, but who support contraception, is lower than the percentage of woman who work at nonprofit religious organizations that oppose contraception on religious grounds, but who support contraception. In addition, public comments and litigation reflect that many nonprofit religious organizations publicly describe their religiosity. Government records and those groups' websites also often reflect those groups' religious character. If a person who desires contraceptive coverage works at a nonprofit religious organization, the Departments believe it is sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit religious organization that opposes contraceptive coverage to hire a person who the organization knows disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to 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.[58]

In addition, it is not at all clear to the Departments that expanding the exemptions would, as some commenters asserted, remove contraceptive coverage from employees of many large religious nonprofit organizations. Many large religious nonprofit employers, including but not limited to some Catholic hospitals, notified the Department under the last Administration that they had opted into the accommodation and expressed no objections to doing so. We also received public comments from organizations of similar nonprofit employers indicating that the accommodation satisfied their religious objections. These final rules leave the accommodation in place as an optional process. Thus, it is not clear to the Departments that all or most of such large nonprofit employers will choose to use the expanded exemption instead of the accommodation. If they continue to use the accommodation, their insurers or third party administrators would continue to be required to provide contraceptive coverage to the plan sponsors' employees through such accommodation.

Given the sincerely held religious beliefs of many nonprofit religious organizations, some commenters also contended that continuing to impose the contraceptive Mandate on certain nonprofit religious objectors might also undermine the Government's broader interests in ensuring health coverage by causing some entities to stop providing health coverage entirely.[59] Although the Departments do not know the extent to which that effect would result from not extending exemptions, we wish to avoid that potential obstacle to the general expansion of health coverage.

G. Closely Held For-Profit Entities (45 CFR 147.132(a)(1)(i)(C))

The previous regulations did not exempt plans sponsored by closely held for-profit entities; however, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(C), ''[a] closely held for-profit entity.'' These rules finalize § 147.132(a)(1)(i)(C) without change.

Some commenters supported including these entities in the exemption, saying owners of such entities exercise their religious beliefs through their businesses and should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise religion or should not have their religious opposition to contraceptive coverage protected by the exemption. Some said the entities should not be able to impose their beliefs about contraceptive coverage on their employees, and that doing so constitutes discrimination.

As set forth in the Religious IFC, the Departments believe it is appropriate to expand the exemptions to include closely held for-profit employers in

[58] 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).

[59] See, *e.g.,* 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.

order to protect the religious exercise of those entities and their owners. The ACA did not apply the preventive services mandate to the many grandfathered health plans among closely held as well as publicly traded for-profit entities, encompassing tens of millions of women. As explained below, we are not aware of evidence showing that the expanded exemptions finalized here will impact such a large number of women. And, in the Departments' view, the decision by Congress to not apply the preventive services mandate to grandfathered plans did not constitute improper discrimination or an imposition of beliefs. We also do not believe RFRA or the large number of other statutory exemptions Congress has provided for religious beliefs (including those exercised for profit) in certain health contexts such as sterilization, contraception, or abortion have been improper.

Including closely held for-profit entities in the exemption is also 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,* the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization, and rejected the previous Administration's argument to the contrary. 134 S. Ct. at 2768–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.[60]

H. For-Profit Entities That Are Not Closely Held (45 CFR 147.132(a)(1)(i)(D))

The previous regulations did not exempt for-profit entities that are not closely held. However, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(D), ''[a] for-profit entity that is not closely held.'' These rules finalize § 147.132(a)(1)(i)(D) without change.

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. Some commenters supported including such entities, including publicly traded businesses, in the scope of the exemption. Some of them said that publicly traded entities have historically taken various positions on important public concerns beyond merely (and exclusively) seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to exercise religious views against contraceptive coverage. They also said that other protections for religious beliefs in federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines ''persons,'' protected under RFRA, to include corporations at 1 U.S.C. 1. Other commenters opposed including publicly traded companies in the expanded exemptions. Some of these commenters stated that such companies could not exercise religious beliefs, and opposed the effects on women if they could. These commenters also objected that including such employers, along with closely held businesses, would extend the exemptions to all or virtually all employers.

The Departments conclude it is appropriate to include entities that are not closely held within the expanded exemptions for entities with religious objection. RFRA prohibits the federal government from ''substantially burden[ing] a person's exercise of religion . . . .'' unless it demonstrates that the application of the burden to the person'' is the least restrictive means to achieve a compelling governmental interest. 42 U.S.C. 2000bb–1(a) & (b). As commenters noted, the definition of ''person'' applicable in RFRA is found at 1 U.S.C. 1, which defines ''person'' as including ''corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.'' Accordingly, the Departments' decision to extend the religious exemption to publicly traded for profit corporations is supported by the text of RFRA. The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held religious beliefs, is a matter of well-established State law with respect to corporate decision-making,[61] and the Departments expect that application of such laws would cabin the scope of this exemption.

As to the impact of so extending the religious exemption, the Departments are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief. As noted above, before the ACA, a substantial majority of employers covered contraceptives. Some commenters opposed to including publicly traded entities in these exemptions noted that there did not appear to be any known religiously motivated objections to the Mandate from publicly traded for-profit corporations. These comments support our estimates that including publicly traded entities in the exemptions will have little, if any effect, on contraceptive coverage for women. We likewise agree with the Supreme Court's statement in *Hobby Lobby* that it is unlikely that many publicly traded companies will adopt religious objections to offering women contraceptive coverage. *See* 134 S. Ct. at 2774. Some commenters contended that, because many closely held for-profit businesses expressed religious objections to the Mandate, or took advantage of the accommodation, it is likely that many publicly traded businesses will do so. The Departments agree it is possible that publicly traded businesses may use the expanded exemption. But while scores of closely held for-profit businesses filed suit against the Mandate, no publicly traded entities did so, even though they were not authorized to seek the accommodation. Based on these data points, we believe the impact of the extension of the exemption to publicly traded for-profit organizations will not be significant. Below, based on limited data, but on years of receiving public comments and defending litigation brought by organizations challenging the Mandate on the basis of their religious objections, our best estimate of the anticipated effects of these rules is that no publicly traded employers will invoke the religious exemption.

In the Departments' view, such estimate does not lead to the conclusion that the religious exemption should not be extended to publicly traded corporations. The Departments are generally aware that, in a country as large as the U.S., comprised of a supermajority of religious persons,[62] some publicly traded entities might claim a religious character for their company, or 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.[63] Thus we consider

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

[61] 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 the organization is incorporated or organized.

[62] For example, in 2017, 74 percent of Americans said that religion is fairly important or very important in their lives, and 87 percent of Americans said they believe in God. Gallup, ''Religion,'' available at *https://news.gallup.com/poll/1690/religion.aspx.*

[63] *See, for example,* Kapitall, ''4 Publicly Traded Religious Companies if You're Looking to Invest in

it possible that a publicly traded company might have religious objections to contraceptive coverage. Moreover, as noted, there are many closely held for-profit corporations that do have religious objections to covering some or all contraceptives. The Departments do not want to preclude such a closely held corporation from having to decide between relinquishing the exemption or financing future growth by sales of stock, which would be the effect of denying it the exemption if it changes its status and became a publicly traded entity. The Departments also find it relevant that other federal conscience statutes, such as those applying to hospitals or insurance companies, do not exclude publicly traded businesses from protection.[64] As a result, the Departments continue to consider it appropriate not to exclude such entities from these expanded exemptions.

I. Other Non-Governmental Employers (45 CFR 147.132(a)(1)(i)(E))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. The Religious IFC included, in its list of exempt plan sponsors at § 147.132(a)(1)(i)(E), ''[a]ny other non-governmental employer.'' These rules finalize § 147.132(a)(1)(i)(E) without change.

Some commenters objected to extending the exemption to other nongovernmental employers, asserting that it is not clear such employers should be protected, nor that they can assert religious objections. The Departments, however, agree with other commenters that supported that provision of the Religious IFC. The Departments believe it is appropriate that any nongovernmental employer asserting the requisite religious objections should be protected from the Mandate in the same way as other plan sponsors. Such other employers could include, for example, association health plans.[65] The reasons discussed above for providing the exemption to various specific kinds of employers, and for their ability to assert sincerely held religious beliefs using ordinary mechanisms of corporate decision-making, generally apply to other nongovernmental employers as well, if they have sincerely held religious beliefs opposed to contraceptive coverage and otherwise meet the requirements of these rules. We agree with commenters who contend there is not a sufficient basis to exclude other nongovernmental employers from the exemption.

J. Plans Established or Maintained by Objecting Nonprofit Entities (45 CFR 147.132(a)(1)(ii))

Based on the expressed intent in the Religious IFC, as discussed above, to expand the exemption to encompass plans established or maintained by nonprofit organizations with religious objections, and on public comments received concerning those exemptions, these rules finalize new language in § 147.132(a)(1)(ii) to better clarify the scope and application of the exemptions.

The preamble to the Religious IFC contained several discussions about the Departments' intent to exempt plans established or maintained by certain religious organizations that have the requisite objection to contraceptive coverage, including instances in which the plans encompass multiple employers. For example, as noted above, the Departments intended that the exemption for houses of worship and integrated auxiliaries be interpreted to apply on a plan basis, instead of on an employer-by-employer basis. In addition, the Departments discussed at length the fact that, under the prior regulations, where an entity was enrolled in a self-insured church plan exempt from ERISA under ERISA section 3(33) and the accommodation in the previous regulations was used, that accommodation process provided no mechanism to impose, or enforce, the accommodation requirement of contraceptive coverage against a third party administrator of such a plan. As a result, the prior accommodation served, in effect, as an exemption from requirements of contraceptive coverage for all organizations and employers covered under a self-insured church plan.

In response to these discussions in the Religious IFC, some commenters, including some church plans, supported the apparent intent to exempt such plans on a plan basis, but suggested that additional clarification is needed in the text of the rule to effect this intent. They observed that some plans are established or maintained by religious nonprofit entities that might not be houses of worship or integrated auxiliaries, and that some employers that adopt or participate in such plans may not be the ''plan sponsors.'' They recommended, therefore, that the final rules specify that the exemption applies on a plan basis when plans are established or maintained by houses of worship, integrated auxiliaries, or religious nonprofits, so as to shield employers that adopt such plans from penalties for noncompliance with the Mandate.

The text of the prefatory language of § 147.132(a)(1), as set forth in the Religious IFC, declared that the Guidelines would not apply ''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.'' We intended this language to exempt a plan and/or coverage where the entity that established or maintained a plan was an objecting organization, and not just to look at the views or status of individual employers (or other entities) participating in such plan. The Departments agree with commenters who stated that additional clarity is needed and appropriate in these final rules, in order to ensure that such plans are exempt on a plan basis, and that employers joining or adopting those plans are exempt by virtue of the plan itself being exempt. Doing so will make the application of the expanded exemption clearer, and protect employers (and other entities) participating in such plans from penalties for noncompliance with the Mandate. Clearer language will better realize the intent to exempt plans and coverage ''established or maintained by an objecting organization,'' and make the operation of that exemption simpler by specifying that the exemption applies based on the objection of the entity that established or maintains the plan. Such language would also resolve the anomaly that, under the previous rules, only self-insured church plans (not insured church plans) under ERISA section 3(33) were, in effect, exempt—but only indirectly through the Departments' inability to impose, or enforce, the accommodation process against the third party administrators of such plans, instead of being specifically exempt in the rules.

We believe entities participating in plans established or maintained by an objecting organization usually share the views of those organizations. Multiple lawsuits were filed against the Departments by churches that established or maintained plans, or the church plans themselves, and they generally declared that the entities or individuals participating in their plans

Faith'' (Feb. 7, 2014), *http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665.*

[64] *See, for example,* 42 U.S.C. 300a–7, 42 U.S.C. 238n, Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d), Public Law 115–141, and *id.* at Div. E, Sec. 808.

[65] See 29 CFR 2510.3–5.

are usually required to share their religious affiliation or beliefs. In addition, because, as we have stated before, ''providing payments for contraceptive services is cost neutral for issuers'' (78 FR 39877), we do not believe this clarification would produce any financial incentive for entities that do not have religious objections to contraceptive coverage to enter into plans established or maintained by an organization that does have such objections.

Therefore, the Departments finalize the text of § 147.132(a)(1) of the Religious IFC with the following change: adding a provision that makes explicit this understanding, in a new paragraph at § 147.132(a)(1)(ii). This language now specifies that the exemptions encompassed by § 147.132(a)(1) include: ''[a] group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan[.]''

K. Institutions of Higher Education (45 CFR 147.132(a)(1)(iii))

The previous regulations did not exempt student health plans arranged by institutions of higher education, although it did, for purposes of the accommodation, treat plans arranged by institutions of higher education similar to the way in which the regulations treated plans of nonprofit religious employers. *See* 80 FR at 41347. The Religious IFC included in its list of exemptions, at § 147.132(a)(1)(ii), ''[a]n 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.'' These rules finalize this language with a change to clarify their application, as discussed below, and by redesignating the paragraph as § 147.132(a)(1)(iii).

These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.132(a)(1)(iii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held religious beliefs, 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 that is an employer.

Some commenters supported including, in the expanded exemptions, institutions of higher education that provide health coverage for students through student health plans but have religious objections to providing certain contraceptive coverage. They said that religious exemptions allow freedom for certain religious institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemptions would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result among those women.

In the Departments' view, the reasons for extending the exemptions to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. Only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities.[66] It is necessarily true that an even smaller number receive such coverage from religious schools, and from religious or other private schools that object to arranging contraceptive coverage. Religious institutions of higher education are private entities with religious missions. Various commenters asserted the importance, to many of those institutions, of being able to adhere to their religious tenets. Indeed, many students who attend such institutions do so because of the institutions' religious tenets. No student is required to attend such an institution. At a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans they arrange. Some students wish to receive contraceptive coverage from a health plan arranged by an institution of higher education. But other students wish to attend an institution of higher education that adheres to its religious mission about contraceptives in health insurance. And still other students favor contraception, but are willing to attend a religious university without forcing it to violate its beliefs about contraceptive coverage. Exempting religious institutions that object to contraceptive coverage still allows contraceptive coverage to be provided by institutions of higher education more broadly. The exemption simply makes it legal under federal law for institutions to adhere to religious beliefs that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, and makes it more possible for students to attend institutions of higher education that hold those views.

In addition, under the previous exemption and accommodation, it was possible for self-insured church plans exempt from ERISA that have religious objection to certain contraceptives to avoid any requirement that either they or their third party administrators provide contraceptive coverage. As seen

[66] The American College Health Association estimates that, in 2014, student health insurance plans at colleges and universities covered ''more than two million college students nationwide.'' ''Do You Know Why Student Health Insurance Matters?'' available at *https://www.acha.org/documents/Networks/Coalitions/Why_SHIPs_Matter.pdf.* We assume for the purposes of this estimate that those plans covered 2,100,000 million students. Data from the Department of Education shows that in 2014, there were 20,207,000 students enrolled in degree-granting postsecondary institutions. National Center for Education Statistics, Table 105.20, ''Enrollment in elementary, secondary, and degree-granting postsecondary institutions, by level and control of institution, enrollment level, and attendance status and sex of student: Selected years, fall 1990 through fall 2026,'' available at *https://nces.ed.gov/programs/digest/d16/tables/dt16_105.20.asp?current=yes.*

in some public comments and litigation statements, some such self-insured church plans provide health coverage for students at institutions of higher education covered by those church plans. In order to avoid the situation where some student health plans sponsored by institutions with religious objections are effectively exempt from the contraceptive Mandate, and other student health plans sponsored by other institutions with similar religious objections are required to comply with the Mandate, the Departments consider it appropriate to extend the exemption, so that religious colleges and universities with objections to the Mandate would not be treated differently in this regard.

The Departments also note that the ACA does not require institutions of higher education to provide student health insurance coverage. As a result, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student health insurance plans, rather than comply with the Mandate or be subject to the accommodation.[67] Extending the exemption in these rules removes an obstacle to such entities deciding to offer student health insurance plans, thereby giving students another health insurance option.

As noted above, it is not clear that studies discussing various effects of birth control access clearly and specifically demonstrate a negative impact to students in higher education because of the expanded exemption in these final rules. The Departments consider these expanded exemptions to be an appropriate and permissible policy choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these expanded exemptions.

Finally, the Religious IFC specified that the plan sponsor exemption applied to ''non-governmental'' plan sponsors (§ 147.132(a)(1)(i)), including ''[a]ny other non-governmental employer'' (§ 147.132(a)(1)(i)(E)). Then, in § 147.132(a)(1)(ii), the rule specified that the institution of higher education exemption applicable to the arrangement of student health insurance coverage applied ''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.'' Consequently, the Religious IFC's expanded exemptions only applied to non-governmental institutions of higher education, including for student health insurance coverage, not to governmental institutions of higher education. Nevertheless, the term ''non-governmental,'' while appearing twice in § 147.132(a)(1)(i) concerning plan sponsors, was not repeated in in § 147.132(a)(1)(ii). To more clearly specify that this limitation was intended to apply to § 147.132(a)(1)(ii), we finalize this paragraph with a change by adding the phrase ''which is non-governmental'' after the phrase ''An institution of higher education as defined in 20 U.S.C. 1002''.

L. Health Insurance Issuers (45 CFR 147.132(a)(1)(iv))

The previous regulations did not exempt health insurance issuers. However, the Religious IFC included in its list of exemptions at § 147.132(a)(1)(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[.]'' These rules finalize this exemption with technical changes to clarify the language based on public comments, and redesignate the paragraph as § 147.132(a)(1)(iv).

The Religious IFC extends the exemption to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services. Under this exemption, 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 whose plans are otherwise exempt based on their objection. An exempt issuer can then offer an exempt health insurance product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, 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.

Under these rules, issuers that hold their own objections, based on sincerely held religious beliefs, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their religious beliefs, or on their moral convictions under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held moral convictions, that are exempt under those companion final rules, 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.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments provided a similar exemption for issuers in the context of moral objections, but we used slightly different operative language. There, in the second sentence, instead of saying ''the plan remains subject to any requirement to provide coverage for contraceptive services,'' the exemption stated, ''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.'' Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. Consequently, these rules finalize the issuer exemption paragraph from the Religious IFC with minor technical changes so that the final language will mirror language from the Moral IFC, stating that the exemption encompasses: ''[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)(iv) of this section, the group health plan established or maintained by the plan sponsor with

[67] See, *e.g.,* 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.

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[.]''

Some commenters supported including this exemption for issuers in these rules, both to protect the religious exercise of issuers, and so that in the future religious issuers that may wish to specifically serve religious plan sponsors would be free to organize. Other commenters objected to including an exemption for issuers. Some objected that issuers cannot exercise religious beliefs, while others objected that exempting issuers would threaten contraceptive coverage for women. Some commenters said that it was arbitrary and capricious for the Departments to provide an exemption for issuers if we do not know that issuers with qualifying religious objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, 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 or group insurance coverage. The issuer exemption therefore serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors and plans that independently qualify for an exemption, will remove a possible obstacle to religious issuers being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, 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), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers from being required to issue policies that cover contraception in violation of the issuers' sincerely held religious beliefs, and from being 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.

The Departments reject the proposition that issuers cannot exercise religious beliefs. First, since RFRA protects the religious exercise of corporations as persons, the religious exercise of health insurance issuers—which are generally organized as corporations—is protected by RFRA. In addition, many federal health care conscience laws and regulations specifically protect issuers or plans. 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 specifically protects, among other entities, provider-sponsored organizations, health maintenance organizations (HMOs), health insurance plans, and ''any other kind of health care facilit[ies], organization[s], or plan[s]'' as a ''health care entity'' from being required to pay for, or provide coverage of, abortions. *See for example,* Consolidated Appropriations Act of 2018, Public Law 115–141, Div. H, Sec. 507(d), 132 Stat. 348, 764 (Mar. 23, 2018).[68] 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. E, Sec. 808, 132 Stat. at 603. 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.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these 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 final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) 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, 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 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 decline to continue, contracts as third party administrators of such plans.

M. Description of the Religious Objection (45 CFR 147.132(a)(2))

The previous regulations did not specify what, if any, religious objection applied to its exemption; however, the Religious IFC set forth the scope of the religious objection of objecting entities in § 147.132(a)(2), as follows: ''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.'' These rules finalize this description with technical changes to clarify the scope of the objection as intended in the Religious IFC, and based on public comments.

Throughout the exemptions for objecting entities, the rules specify that they apply where the entities object as specified in § 147.132(a)(2) of the Religious IFC. That paragraph describes the religious objection by specifying that exemptions for objecting entities will apply to the extent that an entity described in paragraph (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.

[68] ACA section 1553 protects an identically defined group of ''health care entities,'' including provider-sponsored organizations, HMOs, health insurance plans, and ''any other kind of . . . plan,'' from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(a)(2), provided a similar description of the scope of the objection based on moral convictions rather than religious beliefs, but we used slightly different operative language. There, instead of saying the entity ''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,'' the paragraph stated the entity ''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.'' Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. The Religious IFC explained that the intent of the expanded exemptions was to encompass entities that objected to providing or arranging for contraceptive coverage in their plans, and to encompass entities that objected to the previous accommodation process, by which their issuers or third party administrators were required to provide contraceptive coverage or payments in connection with their plans. In other words, an entity would be exempt from the Mandate if it objected to complying with the Mandate, or if it objected to complying with the accommodation. The language in the Religious IFC encompassed both circumstances by encompassing an objection to providing ''coverage [or] payments'' for contraceptive services, and by encompassing an objection to ''a plan that provides'' coverage or payments for contraceptive services. But the language describing the objection set forth in the Moral IFC does so more clearly, and restructuring the sentence could make it clearer still. Questions by commenters about the scope of the description suggests that we should restructure the description, in a non-substantive way, to provide more clarity. The Departments do this by breaking some of the text out into subparagraphs, and rearranging clauses so that it is clearer which words they modify. The new structure specifies that it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) coverage or payments for contraceptive services, and it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) a plan, issuer, or third party administrator that provides contraceptive coverage. This more clearly encompasses objections to complying with either the Mandate or the accommodation. Consequently, these rules finalize the paragraph describing the religious objection in the Religious IFC with minor technical changes so that the final language will essentially mirror language from the Moral IFC. The introductory phrase of the religious objection set forth in paragraph (a)(2) is finalized to state the exemption ''will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable)''. The remainder of the paragraph is broken into two sub-paragraphs, regarding either ''coverage or payments for some or all contraceptive services,'' or ''a plan, issuer, or third party administrator that provides or arranges such coverage or payments.''

Some commenters observed that by allowing exempt groups to object to ''some or all'' contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators. The Departments have concluded, however, that, just as the exemption under the previous regulations allowed entities to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. Notably, even where an entity or individual qualifies for an exemption under these rules, these rules do not require the issuer or third party administrator to contract with that entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual variation of a plan. These rules simply remove the federal Mandate that, in some cases, could have led to penalties for an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying religious objection. Similarly, under the previous exemption, the plans of houses of worship and integrated auxiliaries were exempt from offering some or all contraceptives, but the previous regulations did not require issuers and third party administrators to contract with those exempt entities if they chose not to do so.

N. Individuals (45 CFR 147.132(b))

The previous regulations did not provide an exemption for objecting individuals. However, the Religious IFC expanded the exemptions to encompass objecting individuals (referred to here as the ''individual exemption''), at § 147.132(b). These rules finalize the individual exemption from the Religious IFC with changes, which reflect both non-substantial technical revisions, and changes based on public comments to more clearly express the intent of the Religious IFC.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Religious IFC described what may be offered to objecting individuals as ''a separate benefit package option, or a separate policy, certificate or contract of insurance,'' the Moral IFC said a willing issuer and plan sponsor may offer ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects'' under the individual exemption. Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of ''a separate group health plan,'' as set forth in the version found in § 147.133(b), because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual

exemption by making a technical change to the language to adopt the formulation, ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects'' under the individual exemption.

Some commenters supported the individual exemption as providing appropriate protections for the religious beliefs of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to contraceptive coverage but is willing (and, as applicable, the issuer is also willing) to provide coverage that is consistent with an individual's religious objections. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage. Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. As discussed in the Religious IFC, the individual exemption only operates in the case where the group health plan sponsor or group or individual market health insurance issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases.

In addition, Congress has provided several protections for individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. *See for example,* Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–141, 132 Stat. 348, 593–94 (Mar. 23, 2018). While some commenters proposed to construe this provision narrowly, 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 Div. E, Sec. 808, 132 Stat. at 603. A religious exemption for individuals would not be effective if the government simultaneously made it illegal for issuers and group health plans to provide individuals with policies that comply with the individual's 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 generally, 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.

By its terms, the individual exemption would also apply with respect to individuals in plans arranged by institutions of higher education, if the issuers offering those plans were willing to provide plans complying with the individuals' objections. Because federal law does not require institutions of higher education to arrange such plans, the institutions would not be required by these rules to arrange a plan compliant with an individual's objection if the institution did not wish to do so.

As an example, in one lawsuit 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 group health insurance policies 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 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), 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 final rules do not affect such other laws or terms.

Some individuals commented that they welcomed the individual exemption so that their religious beliefs were not forced to be in tension with their desire for health coverage. The Departments believe the individual exemption may help to meet the ACA'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.[69] At the same time, this individual exemption ''does not undermine the governmental interests furthered by the contraceptive

[69] See also, 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.''

coverage requirement,'' [70] 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.

Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives. Other commenters expressed concern that there might be multiple variations in the kinds of contraceptive coverage to which individuals object, and this might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the religious beliefs of an exempt individual. As discussed above, where the individual exemption applies, it only affects the coverage of an individual. If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons they can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Religious IFC implied this conclusion, by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, this was different than the language applicable to the exemptions under § 147.132(a), which specifies that the exemptions apply ''to the extent'' of the religious objections, so that, as discussed above, the exemptions include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b) with the following change, by adding the following sentence at the end of the paragraph: ''Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the individual with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held religious beliefs objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to this employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under a policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with clarifying changes to reflect the Departments' intent.

O. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations set forth an accommodation process at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, as an alternative method of compliance with the Mandate. Under the accommodation, if a religious nonprofit entity, or a religious closely held for-profit business, objected to coverage of some or all contraceptive services in its health plan, it could file a notice or fill out a form expressing this objection and describing its objection to its plan and issuer or third party administrator. Upon doing so, the plan would not cover some or all contraceptive services, and the issuer or third party administrator would be responsible for providing or arranging for persons covered by the plan to receive coverage or payments of those services (except in the case of self-insured church plans exempt from ERISA, in which case no such obligation was imposed on the third party administrator). The accommodation was set forth in regulations of each of the Departments. Based on each Department's regulatory authority, HHS regulations applied to insured group health plans, and DOL and Treasury regulations applied to both insured group health plans and self-insured group health plans.

The Religious IFC maintained the accommodation process. Nevertheless, by virtue of expanding the exemptions to encompass all entities that were eligible for the accommodation process under the previous regulations, in addition to other newly exempt entities, the Religious IFC rendered the accommodation process optional. Entities could choose not just between the Mandate and the accommodation, but between the Mandate, the exemption, and the accommodation. These rules finalize the optional accommodation process and its location in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, but the Departments do so with several changes based on public comments.

Many commenters supported keeping the accommodation as an optional process, including some commenters who otherwise supported creating the expanded exemptions. Some commenters opposed making the accommodation optional, but asked the Departments to return to the previous regulations in which entities that did not meet the narrower exemption could only choose between the accommodation process or direct compliance with the Mandate. Some commenters believed there should be no exemptions and no accommodation process.

The Departments continue to consider it appropriate to make the accommodation process optional for entities that are otherwise also eligible for the expanded exemptions—that is, to keep it in place as an option that exempt entities can choose. The accommodation provides contraceptive access, which is a result many opponents of the expanded exemptions said they desire. The accommodation involves some regulation of issuers and third party administrators, but the previous

[70] 78 FR 39874.

regulations had already put that regulatory structure in place. These rules for the most part merely keep it in place and maintain the way it operates. The Religious IFC adds some additional paperwork burdens as a result of the new interaction between the accommodation and the expanded exemptions; those are discussed below.

Above, the Departments discussed public comments concerning whether we should have merely expanded the accommodation rather than expanding the exemptions. The Religious IFC and these final rules expand the kinds of entities that may use the optional accommodation, by expanding the exemptions and allowing any exempt entities to opt to make use of the accommodation. Consequently, under these rules, objecting employers may make use of the exemption or may choose to utilize the optional accommodation process. If an eligible organization uses 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.

Some commenters asked that these final rules create an alternative payment mechanism to cover contraceptive services for third party administrators obligated to provide or arrange such coverage under the accommodation. These rules do not concern the payment mechanism, which is set forth in separate rules at 45 CFR 156.50. The Departments do not view an alternative payment mechanism as necessary. As discussed below, although the Departments do not know how many entities will use the accommodation, it is reasonably likely that some entities previously using it will continue to do so, while others will choose the expanded exemption, leading to an overall reduction in the use of the accommodation. The Departments have reason to believe that these final rules will not lead to a significant expansion of entities using the accommodation, since nearly all of the entities of which the Departments are aware that may be interested in doing so were already able to do so prior to the Religious IFC. Moreover, it is still the case under these rules that if an entity serving as a third party administrator does not wish to satisfy the obligations it would need to satisfy under an accommodation, it could choose not to contract with an entity that opts into the accommodation. This conflict is even less likely now that entities eligible for the accommodation are also eligible for the exemption. For these reasons, the Departments do not find it necessary to add an additional payment mechanism for the accommodation process.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these 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. Some commenters suggested HHS has not yet issued guidance on the revocation process, but CCIIO provided guidance concerning this process on November 30, 2017.[71] These rules supersede that guidance, and adopt or modify its specific guidelines as explained below. As a result, these rules delete references, set forth in the Religious IFC's accommodation regulations, to ''guidance issued by the Secretary of the Department of Health and Human Services.''

The guidance stated that an entity that was using the accommodation under the previous rules, or an entity that adopts the accommodation maintained by the IFCs, could revoke its use of the accommodation and use the exemption. This guideline applies under the final rules. This revocation process applies both prospectively to eligible organizations that 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 invoked the accommodation prior to the effective date of the Religious IFC 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.

The guidance stated that, when the accommodation is revoked by an entity using the exemption, the issuer of the eligible organization must provide participants and beneficiaries written notice of such revocation. These rules adopt that guideline. 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. The guidance further stated that the notice may be provided by the organization itself, its group health plan, or its third party administrator, as applicable. The guidance stated that, under the regulation at 45 CFR 147.200(b), ''[t]he notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section,'' and (a)(4) has detailed rules on when electronic notice is permitted. These guidelines still apply under the final rules. These rules adopt those guidelines.

The guidance further specified that the revocation of the accommodation would be effective notice on the first day of the first plan year that begins on or after 30 days after the date of the revocation, or alternatively, whether or not the objecting entity's group health plan or issuer listed the contraceptive benefit in its Summary of Benefits of Coverage (SBC), the group health plan or issuer could revoke the accommodation by giving at least 60-days prior notice pursuant to section 2715(d)(4) of the PHS Act (incorporated into ERISA and the Code)[72] and applicable regulations thereunder to revoke the accommodation. The guidance noted that, unlike the SBC notification process, which can effectuate a modification of benefits in the middle of a plan year, provided it is allowed by State law and the contract of the policy, the 30 day notification process under the guidance can only effectuate a benefit modification at the beginning of a plan year. This part of the guidance is adopted in part and changed in part by these final rules, as follows, based on public comments on the issue.

Some commenters asked that revocations only be permitted to occur on the first day of the next plan year, or no sooner than January 2019, to avoid burdens on plans and because some states do not allow for mid-year plan changes. The Departments believe that providing 60-days notice pursuant to section 2715(d)(4) of the PHS Act, where applicable, is a mechanism that already exists for making changes in health benefits covered by a group health plan during a plan year; that process already takes into consideration any applicable state laws. However, in response to public comments, these rules change the accommodation provisions from the Religious IFC to indicate that, as a transitional rule, providing 60-days notice for revoking an accommodation is only available, if applicable, to plans that are using the accommodation at the time of the

[71] *See* Randy Pate, ''Notice by Issuer or Third Party Administrator for Employer/Plan Sponsor of Revocation of the Accommodation for Certain Preventive Services,'' CMS (Nov. 30, 2017), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf.*

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

publication of these final rules. As a general rule, for plans that use the accommodation in future plan years, the Departments believe it is appropriate to allow revocation of an accommodation only on the first day of the next plan year. Based on the objections of various litigants and public commenters, we believe that some entities already using the accommodation may have been doing so only because previous regulations denied them an exemption. For them, access to the transitional 60-days notice procedure (if applicable) is appropriate in the period immediately following the finalization of these rules. In future plan years, however—plan years that begin after the effective date of these final rules—plans and entities that qualify as exempt under these rules will have been on notice that they qualify for an exemption or the accommodation. If they have opted to enter or remain in the accommodation in those future plan years, when they could have chosen the exemption, the Departments believe it is appropriate for them to wait until the first day of the following plan year to change to exempt status.[73]

This change is implemented in the following manner. In the Religious IFC, the accommodation provisions addressing revocation were found at 45 CFR 147.131(c)(4), 26 CFR 54.9815–2713AT(a)(5),[74] and 29 CFR 2590.715–2713A(a)(5).

The provisions in the Religious IFC (with technical variations among the HHS, Labor, and Treasury rules) state that a written notice of revocation must be provided ''as specified in guidance issued by the Secretary of the Department of Health and Human Services.'' On November 30, 2017, HHS issued the guidance regarding revocation. These final rules incorporate this guidance, with certain clarifications, and state that the revocation notice must be provided ''as specified herein.'' The final rule incorporates the two sets of directions for revoking the accommodation initially set forth in the interim guidance in the following manner. The first, designated as subparagprah (1) as a ''[t]ransitional rule,'' explains that if contraceptive coverage is being offered through the accommodation process on the date on which these final rules go into effect, 60-days notice may be provided to revoke the accommodation process, or they revocation may occur ''on the first day of the first plan year that begins on or after 30 days after the date of the revocation'' consistent with PHS Act section 2715(d)(4), 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), or 29 CFR 2590.715–2715(b). The second direction, set forth in subparagraph (ii), explains the ''[g]eneral rule'' that, in plan years beginning after the date on which these final rules go into effect, revocation of the accommodation 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.''

The Religious IFC states that if an accommodated entity objects to some, but not all, contraceptives, an issuer for an insured group health plan that covers contraceptives under the accommodation may, at the issuer's option, choose to provide coverage or payments for all contraceptive services, instead of just for the narrower set of contraceptive services to which the entities object. Some commenters supported this provision, saying that it allows flexibility for issuers that might otherwise face unintended burdens from providing coverage under the accommodation for entities that object to only some contraceptive items. The Departments have maintained this provision in these final rules. Note that this provision is consistent with the other assertions in the rules saying that an entity's objection applies ''to the extent'' of the entity's religious beliefs, because in this instance, under the accommodation, the plan participant or beneficiary still receives coverage or payments for all contraceptives, and this provision simply allows issuers more flexibility in choosing how to help provide that coverage.

Some commenters asked that the Departments retain the ''reliance'' provision, contained in the previous accommodation regulations, 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. The Departments omitted this provision from the Religious IFC, on the grounds that this provision was less necessary where any organization eligible for the optional accommodation is also exempt. Nevertheless, in order to respond to concerns in public comments, and to prevent any risk to issuers of a mistake or misrepresentation by an organization seeking the accommodation process, the Departments have finalized the Religious IFC with an additional change that restores this clause. The clause uses the same language that was in the regulations prior to the Religious IFC, and it is inserted at 45 CFR 147.131(f), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e). As a result, these rules renumber the subsequent paragraphs in each of those sections.

P. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under ''Contraceptive methods and counseling,'' ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' The previous regulations concerning the exemption and the accommodation used the terms contraceptive services and contraceptive coverage as catch-all terms to encompass all of those Guidelines' requirements. The 2016 update to the Guidelines are similarly worded. Under ''Contraception,'' they include the ''full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,'' ''instruction in fertility awareness-based methods,'' and ''[c]ontraceptive care'' to ''include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).'' [75]

To more explicitly state that the exemption encompasses any of the contraceptive or sterilization services, items, or information that have been required under the Guidelines, the Religious IFC included a definition at 45

[73] These final rules go into effect 60 days after they are published in the **Federal Register**. Some entities currently using the accommodation may have a plan year that begins less than 30 days after the effective date of these final rules. In such cases, they may be unable, after the effective date of these final rules, to provide a revocation notice 30 days prior to the start of their next plan year. However, these final rules will be published at least 60 days prior to the start of that plan year. Therefore, entities exempt under these final rules that have been subject to the accommodation on the date these final rules are published, that wish to revoke the accommodation, and whose next plan years start after these final rules go into effect, but less than 30 days thereafter, may submit their 30 day revocation notices after these final rules are published, before these final rules are in effect, so that they will have submitted the revocation at least 30 days before their next plan year starts. In such cases, even though the revocation notice will be submitted before these final rules are in effect, the actual revocation will not occur until after these final rules are in effect, and plan participants will have been provided with 30 days' notice of the revocation.

[74] The Department of the Treasury's rule addressing the accommodation is being finalized at 26 CFR 54.9815–2713A, superseding its temporary regulation at 26 CFR 54.9815–2713AT.

[75] *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713AT(e), and 29 CFR 2590.715–2713A(e). These rules finalize those definitions without change, but renumber them as 45 CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e), respectively.

Q. Severability

The Departments finalize without change (except for certain paragraph redesignations), the severability clauses in the interim final rules, namely, at paragraph (g) of 26 CFR 54.9815–2713A, the redesignated paragraph (g) of 29 CFR 2590.715–2713A, and 45 CFR 147.132(d).

R. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. 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) only applies to ''preventive'' care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to ''preventive'' services or care.[76] The requirement in the Guidelines concerning ''contraception'' specifies several times that it encompasses ''contraceptives,'' that is, medical products, methods, and services applied for ''contraceptive'' uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage, without cost-sharing, of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[77] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use, or for another use. Section 2713(a)(4), however, draws a distinction between preventive care and screenings and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of contraceptive methods or care unless such methods or care is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules also do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply to the extent the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that under section 2713(a)(4), exempt organizations must provide coverage for drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the expanded exemptions could take contraceptive coverage away from many or most women. Still others opposed expanding the exemptions and contended that accurately determining the number of women affected by the expanded exemptions is not possible.

After reviewing the public comments, the Departments agree with commenters who said that estimating the impact of these final rules is difficult based on the limited data available to us, and with commenters who agreed with the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women. The Departments do not find the estimates of large impacts submitted by some commenters more reliable than the estimates set forth in the Religious and Moral IFCs. Even certain commenters that ''strongly oppos[ed]'' the Religious IFC commented that merely ''thousands'' would be impacted, a number consistent with the Departments' estimate of the number of women who may be affected by the rule. The Departments' estimates of the impact of these final rules are discussed in more detail in the following section. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious IFC are still the best estimates available. Our estimates are discussed in more detail in the following section.

3. Interaction With State Laws

Some commenters asked the Departments to discuss the interaction between these final rules and state laws that either require contraceptive

[76] *Id.*

[77] 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 from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act 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 final rules, the Departments clarify here that the reference prior to the Religious IFC 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 for contraceptive use. 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 and the contraceptive Mandate.

coverage or provide religious exemptions from those and other requirements. Some commenters argued that providing expanded exemptions in these rules would negate state contraceptive requirements or narrower state religious exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage. The Department agrees that these rules concern only the applicability of the Federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state religious exemptions. If a plan is exempt under the Religious IFC and these rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the religious exemptions to declare that the Federal contraceptive Mandate will still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[78]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1). These rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with religious objections to cover contraceptives.

IV. Economic Impact and Paperwork Burden

The Departments have examined the impacts of the Religious IFC and the 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 their anticipated effects, the Religious IFC and these 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 rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These final rules adopt as final and further change the amendments made by the Religious IFC, which amended the Departments' July 2015 final regulations. The Religious IFC and these 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 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 religious beliefs, and they revise the accommodation process to make it optional for eligible organizations. The expanded exemption applies to certain 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 has been taken, among other reasons discussed above, to provide for participation in the health insurance market by certain entities or individuals, by freeing them from penalties they could incur if they follow their sincerely held religious beliefs against contraceptive coverage.

2. Anticipated Effects

a. Removal of Burdens on Religious Exercise

Regarding entities and individuals that are extended an exemption by the Religious IFC and these final rules, without that exemption the Guidelines would require many of them 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

[78] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the Federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. Elsewhere in this preamble, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

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 final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections to, 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.

b. Notices When Revoking Accommodated Status

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption, a notice will need to be sent to enrollees (either by the objecting 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 the current 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 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 the 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 $302,036.

c. Impacts on Third Party Administrators and Issuers

The Departments estimate that these 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 new exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation to which they were not previously provided access. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations for serving the fewer number of entities that will now 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. While these rules make it legal for issuers to offer insurance coverage that omits contraceptives to exempt entities and individuals, these final rules do not require issuers to do so.

The Departments anticipate that the effect of these rules on adjustments made to the federally facilitated Exchange user fees under 45 CFR 156.50 will be that fewer overall adjustments will be made using the accommodation process, because there will be more entities who previously were reluctant users of the accommodation that will choose to operate under the newly expanded exemption than there will be entities not previously eligible to use the accommodation that will opt into it. The Departments' estimates of each number of those entities is set forth in more detail below.

d. Impacts on Persons Covered by Newly Exempt Plans

These final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. As discussed in the Religious IFC, the Departments did not have sufficient data on a variety of relevant factors to precisely estimate how many women would be impacted by the expanded exemptions or any related costs they may incur for contraceptive coverage or the results associated with any unintended pregnancies.

i. Unknown Factors Concerning Impact on Persons in Newly Exempt Plans

As referenced 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 have still provided coverage for 14 of the 18 FDA-approved 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.

ii. Public Comments Concerning Estimates in Religious IFC

In the public comments, some commenters agreed with the Departments' estimate that, at most, the economic impact would lead to a potential transfer cost, from employers (or other plan sponsors) to affected women, of $63.8 million. Some commenters said the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women.

These general comments do not, however, substantially assist us in

estimating how many women would be affected by these expanded exemptions specifically, or among them, how many unintended pregnancies would result, or how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the transfer costs the Departments estimate, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives. The Departments conclude, therefore, that our estimates of the anticipated effect in the Religious IFC are still the best estimates we have based on the limited data available to make those estimates. We do not believe that the higher estimates submitted by various public commenters sufficiently took into consideration, or analyzed, the various factors that suggest the small percentage of entities that will now use the expanded exemptions out of the large number of entities subject to the Mandate overall. Instead, the Departments agree with various public commenters providing comment and analysis that, for a variety of reasons, the best estimate of the impact of the expanded exemptions finalized in these rules is that most women receiving contraceptive coverage under the Mandate will not be affected. We agree with such commenters that the number of women covered by entities likely to make use of the expanded exemptions in these rules is likely to be very small in comparison to the overall number of women receiving contraceptive coverage as a result of the Mandate.

iii. Possible Sources of Information for Estimating Impact

The Departments have access to the following general sources of information that are relevant to this issue, but these sources do not provide a full picture of the impact of these final rules. First, the regulations prior to the Religious IFC already exempted certain houses of worship and their integrated auxiliaries and, as explained elsewhere, effectively did not apply contraceptive coverage requirements to various entities in self-insured church plans. The effect of those previous exemptions or limitations are not included as effects of these rules, which leave those impacts in place. Second, in the Departments' previous regulations creating or expanding exemptions and the accommodation process we concluded that no significant burden or costs would result. 76 FR 46625; 78 FR 39889. Third, some entities, including some for-profit entities, object to only some but not all contraceptives, and in some cases will cover 14 of 18 FDA-approved women's contraceptive and sterilization methods.[79] *See Hobby Lobby,* 134 S. Ct. at 2766. The effects of the expanded exemptions will be mitigated to that extent. No publicly traded for-profit entities sued challenging the Mandate, and the public comments did not reveal any that specifically would seek to use the expanded exemptions. Consequently, the Departments agree with the estimate from the Religious IFC that publicly traded companies would not likely make use of these expanded exemptions.

Fourth, HHS previously estimated that 209 entities would make use of the accommodation process. To arrive at this number, the Departments used, as a placeholder, the approximately 122 nonprofit entities that brought litigation challenging the accommodation process, and the approximately 87 closely held for-profit entities that filed suit challenging the Mandate in general. The Departments' records indicate, as noted in the Religious IFC, that approximately 63 entities affirmatively submitted notices to HHS to use the accommodation,[80] and approximately 60 plans took advantage of the contraceptive user fees adjustments, in the 2015 plan year, to obtain reimbursement for contraceptive service payments made for coverage of such services for women covered by self-insured plans that were accommodated. Overall, while recognizing the limited data available, the Departments assumed that, under an expanded exemption and accommodation, approximately 109 previously accommodated entities would use an expanded exemption, and about 100 would continue their accommodated status. We also estimated that another 9 entities would use the accommodation where the entities were not previously eligible to do so.

These sources of information were outlined in the Religious IFC. Some commenters agreed with the Departments' estimates based on those sources, and while others disagreed, the Departments conclude that commenters did not provide information that allows us to make better estimates.

iv. Estimates Based on Litigating Entities That May Use Expanded Exemptions

Based on these and other factors, the Departments considered two approaches in the Religious IFC to estimate the number of women affected among entities using the expanded exemptions. First, following the use in previous regulations of litigating entities to estimate the effect of the exemption and accommodation, the Departments attempted to estimate the number of women covered by plans of litigating entities that could be affected by expanded exemptions. Based on papers filed in litigation, and public sources, the Departments estimated in the Religious IFC that approximately 8,700 women of childbearing age could have their contraception costs affected by plans of litigating entities using these expanded exemptions. The Departments believe that number is lower based upon the receipt, by many of those litigating entities, of permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate, which have been entered by federal district courts since the issuance of the Religious IFC.[81] As a result, these final rules will not affect whether such entities will be subject to the contraceptive Mandate. Subtracting those entities from the total, the Departments estimate that the remaining litigating entities employ

[79] 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), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[80] 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. In addition, the Departments 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 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 the Departments were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage.

[81] *See, for example, Catholic Benefits Ass'n LCA* v. *Hargan,* No. 5:14–cv–00240–R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll.* v. *Burwell,* No. 5:13–cv–04100 (N.D. Iowa order filed June 12, 2018).

approximately 49,000 persons, male and female. The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent.[82] This amounts to approximately 29,000 employees covered under those plans. EBSA estimates that for each employee policyholder, there is approximately one dependent.[83] This amounts to approximately 58,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15 to 44—compose 20.2 percent of the general population.[84] Furthermore, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[85] Therefore, the Departments estimate that approximately 5,200 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that might be affected by these final rules. The Departments also estimate that, for the educational institutions that brought litigation challenges objecting to the Mandate as applied to student coverage that they arranged—where (1) the institutions were not exempt under the prior rule, (2) their student plans were not self-insured, and (3) they have not received permanent injunctions preventing the application of the previous regulations—such student plans likely covered approximately 2,600 students. Thus, the Departments estimate the female members of those plans is 2,600 women.[86] Assuming, as referenced above, that 43.6 percent of such women use contraception covered by the Guidelines, the Departments estimate that 1,150 of those women would be affected by these final rules.

Together, this leads the Departments to estimate that approximately 6,400 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted previously, 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 the Departments 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.

v. Estimates of Accommodated Entities That May Use Expanded Exemptions

In the Religious IFC, the Departments also examined data concerning user-fee reductions to estimate how many women might be affected by entities that are using the accommodation and would use the expanded exemptions under these final rules. Under the accommodation, HHS has received information from issuers that seek user fees adjustments under 45 CFR 156.50(d)(3)(ii), for providing contraceptive payments for self-insured plans that make use of the accommodation. HHS receives requests for fees adjustments both where Third Party Administrators (TPAs) for those self-insured accommodated plans are themselves issuers, and where the TPAs use separate issuers to provide the payments and those issuers seek fees adjustments. Where the issuers seeking adjustments are separate from the TPAs, the TPAs are asked to report the number of persons covered by those plans. Some users do not enter all the requested data, and not all the data for the 2017 plan year is complete. Nevertheless, HHS has reviewed the user fees adjustment data received for the 2017 plan year. HHS's best estimate from the data is that there were $38.4 million in contraception claims sought as the basis for user fees adjustments for plans, and that these claims were for plans covering approximately 1,823,000 plan participants and beneficiaries of all ages, male and female.

This number fluctuates from year to year. It is larger than the estimate used in the Religious IFC because, on closer examination of the data, this number better accounts for plans where TPAs were also issuers seeking user fees adjustments, in addition to plans where the TPA is separate from the issuer seeking user fees adjustments. The number of employers using the accommodation where user fees adjustments were sought cannot be determined from HHS data, because not all users are required to submit that information, and HHS does not necessarily receive information about fully insured plans using the accommodation. Therefore, the Departments still consider our previous estimate of 209 entities using the accommodation as the best estimate available.

As noted in the Religious IFC, 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 tens of thousands of persons each and are proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

The Departments continue 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.[87]

[82] See Kaiser Family Foundation and Health Research and Educational Trust, ''Employer Health Benefits: 2018 Annual Survey'' at 62, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[83] Employee Benefits Security Administration, ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using Data for the March 2016 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-2016.pdf.*

[84] 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.

[85] See *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states* (reporting that of 61,491,766 women aged 15–44, 26,809,5550 use women's contraceptive methods covered by the Guidelines).

[86] On average, the Departments expect that approximately half of those students (1,300) 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. The Departments 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, the Departments assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 2,6,00. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, the Departments assume they are. Therefore, for the purposes of this estimate, the Departments assume that the effect of these expanded exemptions on student plans of litigating entities includes 2,600 women.

[87] See, *e.g., 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

Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these 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.[88] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[89] (The Departments take no view on the status of these particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.) Nevertheless, considering all these factors, it generally 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 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, the Religious IFC and these final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

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).

[88] 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.).

[89] 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).

vi. Combined Estimates of Litigating and Accommodated Entities

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 final rules. In addition to the estimate of 6,400 women of childbearing age that use contraception covered by the Guidelines, who will be affected by use of the expanded exemption among litigating entities, the Departments calculate the following number of women who we estimate to be affected by accommodated entities using the expanded exemption. As noted above, approximately 1,823,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2017. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, the Departments 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, the Departments 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 in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans.[90] Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in plans using the accommodation under the previous regulations.

Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans. The data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems and other entities likely to continue using the accommodation constitute over 60 percent of plans using the accommodation, and encompass more than 90 percent of the persons covered in accommodated plans.[91] In other words, plans sponsored by such entities appear to be a majority of plans using the accommodation, and also have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. Moreover, as 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 final rules would not impact the contraceptive coverage their employees receive.

The Departments 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. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments 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, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons

[90] ''Health Insurance Coverage Bulletin'' Table 3A, page 14. Using Data for the March 2016 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-2016.pdf.*

[91] The data also reflects a religious university using the accommodation that has publicly affirmed the accommodation is consistent with its religious views, and two houses of worship that are using the accommodation despite already qualifying for the previous exemption. We assume for the purposes of this estimate these three entities will also continue using the accommodation instead of the expanded exemption.

previously covered in accommodated plans.

Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, women of childbearing age comprise 20.2 percent of the population, which means that approximately 147,000 women of childbearing age are covered in previously accommodated plans that the Departments estimate will use the expanded exemption. As noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that the Departments expect approximately 64,000 women that use contraception covered by the Guidelines will 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 6,400 women in plans of litigating entities that may be affected by these rules. In order to more broadly estimate the possible effects of these rules, the Departments assume there is no overlap between the two numbers, and therefore that these final rules would affect the contraceptive costs of approximately 70,500 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these final rules is approximately 0.1 percent of the 55.6 million women in private plans that HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated in 2015 received 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 previous accommodation process, the total amount of contraceptive claims sought for self-insured plans for the 2017 benefit year was $38.5 million.[92] These adjustments covered the cost of contraceptive coverage provided to women. As also discussed above, the Departments estimate that amount corresponded to plans covering 1,823,000 persons. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age, and of those, approximately 43.6 percent use women's contraceptive methods covered by the Guidelines. This amounts to approximately 161,000 women. Therefore, entities using contraceptive user fees adjustments received approximately $239 per year per woman of childbearing age that used contraception covered by the Guidelines and covered in their plans. But in the Religious IFC, we estimated that the average annual cost of contraception per woman per year is $584. As noted above, public commenters cited similar estimates of the annual cost of various contraceptive methods, if calculated for the life of the method's effectiveness. Therefore, to estimate the annual transfer effects of these final rules, the Departments will continue to use the estimate of $584 per woman per year. With an estimated impact of these final rules of 70,500 women per year, the financial transfer effects attributable to these final rules on those women would be approximately $41.2 million.

Some commenters suggested that the Departments' estimate of women affected among litigating entities was too low, but they did not support their proposed higher numbers with citations or specific data that could be verified as more reliable than the estimates in the Religious IFC. Their estimates appeared to be overinclusive, for example, by counting all litigating entities and not just those that may be affected by these rules because they are not in church plans, or by counting all plan participants and not just women of childbearing age that use contraception. Moreover, since the Religious IFC was issued, additional entities have received permanent injunctions against enforcement of any regulations implementing the contraceptive Mandate and so will not be affected by these final rules. Taking all of these factors into account, the Departments are not aware of a better method of estimating the number of women affected by these expanded exemptions.

vii. Alternate Estimates Based on Consideration of Pre-ACA Plans

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

In 2015, ASPE estimated that 55.6 million women aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[93] The Religious IFC used this estimate in this second analysis of the possible impact of the expanded exemptions in the interim final rules. ASPE has not issued an update to its report. Some commenters noted that a private organization published a fact sheet in 2017 claiming to make similar estimates based on more recent data, in which it estimated that 62.4 million aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[94] The primary difference between these numbers appears to be a change in the number of persons covered by grandfathered plans.

The methodology of both reports do not fully correspond to the number the Departments seek to estimate here for the purposes of *Executive Orders 12866 and 13563.* These final rules will not affect all women aged 15 to 64 who are covered by private insurance and have coverage of preventive services under the Affordable Care Act. This is partly because the Departments do not have evidence to suggest that most employers will have sincerely held religious objections to contraceptive coverage and will use the expanded exemptions. In addition, both reports include women covered by plans that are not likely affected by the expanded exemptions for other reasons. For example, even though the estimates in those reports do not include enrollees in public plans such as Medicare or Medicaid, they do include enrollees in plans obtained on the health insurance marketplaces, purchased in the individual market, obtained by self-employed persons, or offered by government employers. Women who purchase plans in the marketplaces, the individual market, or as self-employed persons are not required to use the exemptions in these rules. Government employers are also not affected by the exemptions in these rules.

In response to public comments citing the more recent report, the Departments offer the following estimates based on more recent data than used in the Religious IFC. Data from the U.S. Census Bureau indicates that 167.6 million individuals, male and female, under 65 years of age, were covered by

[92] The amount of user fees adjustments provided was higher than this, since an additional administrative amount was added to the amount of contraceptive costs claimed.

[93] 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.*

[94] The commenters cited the National Women's Law Center's Fact Sheet from September 2017, available at *https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf.*

employment-based insurance in 2017.[95] Of those, 50.1 percent were female, that is, 84 million.[96] The most recent Health Insurance Coverage Bulletin from EBSA states that, within employer-sponsored insurance, 76.5% are covered by private sector employers.[97] As noted above, these expanded exemptions do not apply to public sector employers. Assuming the same percentage applies to the Census data for 2017, 64.2 million women under 65 years of age were covered by private sector employment based insurance. EBSA's bulletin also states that, among those covered by private sector employer sponsored insurance, 5% receive health insurance coverage from a different primary source.[98] We assume for the purposes of this estimate that an exemption claimed by an employer under these rules need not affect contraceptive coverage of a person who receives health insurance coverage from a different primary source. Again assuming this percentage applies to the 2017 coverage year, we estimate that 61 million women under 65 years of age received primary health coverage from private sector, employment-based insurance. In conducting this analysis, the Departments also observed that for 3.8 percent of those covered by private sector employment sponsored insurance, the plan was purchased by a self-employed person, not by a third party employer. Self-employed persons who direct firms are not required to use the exemptions in these final rules, but if they do, they would not be losing contraceptive coverage that they want to have, since they would be using the exemption based on their sincerely held religious beliefs. If those persons have employees, the employees would be included in this estimate in the number of people who receive employer sponsored insurance from a third party. Assuming this percentage applies to the 2017 coverage year, we estimate that 58.7 million women under 65 years of age received primary health coverage from private sector insurance from a third party employer plan sponsor.

The Kaiser Family Foundation's Employer Health Benefits Annual Survey 2018 states that 16% of covered workers at all firms are enrolled in a plan grandfathered under the ACA (and thus not subject to the preventive services coverage requirements), but that only 14% of workers receiving coverage from state and local government employer plans are in grandfathered plans.[99] Using the data cited above in EBSA's bulletin concerning the number of persons covered in public and private sector employer sponsored insurance, this suggests 16.6% of persons covered by private sector employer sponsored plans are in grandfathered plans, and 83.4% in non-grandfathered plans.[100] Applying this percentage to the Census data, 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based, non-grandfathered plans. Census data indicates that among women under age 65, 46.7% are of childbearing age (aged 15 to 44).[101] Therefore, we estimate that 22.9 million women aged 15–44 received primary health insurance coverage from private sector, third party employment based, non-grandfathered insurance plans.

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.[102] The 6 percent may have included approximately 1.37 million of the women aged 15 to 44 primarily covered by employer-sponsored insurance plans in the private sector. And as noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore, the Departments estimate that 599,000 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.[103]

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for religious or other reasons. Despite the lack of information about their motives, the Departments 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, the Departments 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

[95] See U.S. Census Bureau Current Population Survey Table HI–01, ''Health Insurance Coverage in 2017: All Races,'' available at *https://www2.census.gov/programs-surveys/cps/tables/hi-01/2018/hi01_1.xls.*

[96] *Id.*

[97] Table 1A, page 5 (stating that in coverage year 2015, 177.5 million persons of all ages were covered by employer sponsored insurance, with 135.7 million of those being covered by private sector employers), available at *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[98] *Id.* at Table 1C, page 8 (168.7 million persons received health insurance coverage from employer sponsored insurance as their primary source, compared to 177.5 million persons covered by employer sponsored insurance overall).

[99] ''Employer Health Benefits: 2018 Annual Survey'' at 211, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[100] EBSA's bulletin shows 168.7 million persons with primary coverage from employer sponsored insurance, with 131.6 million in the private sector and 37.1 million in the public sector. 16% of 168.7 million is 26.9 million. 14% of 37.1 million is 5.2 million. 26.9 million − 5.2 million is 21.8 million, which is 16.6% of the 131.6 million persons with primary coverage from private sector employer sponsored insurance.

[101] U.S. Census Bureau, Table S0101 ''Age and Sex'' (available at *https://data.census.gov/cedsci/results/tables?q=S0101:%20AGE%20AND%20SEX&ps=table*currentPage@1*).

[102] 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.*

[103] 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 final 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 final rules.

laws [104] 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 the Departments are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while the Departments consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those reasons used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions, the Departments 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.[105] That means that only approximately 411,000 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, because these final rules build on previous regulations that already exempted houses of worship and integrated auxiliaries and, as explained above, effectively eliminated obligations to provide contraceptive coverage within objecting self-insured church plans, the Departments attempt to estimate the number of such employers whose employees would not be affected by these rules. In attempting to estimate the number of such employers, the Departments 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 United States,[106] 197 Catholic dioceses,[107] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[108] 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 the Departments use the number of schools as an 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 covering 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[109] Christian Brothers is a plan that covers Catholic organizations including Catholic churches and integrated auxiliaries, which are estimated above, but has also said in litigation that it covers about 500 additional entities that are not exempt as churches.[110] In total, therefore, without having certain data on the number of entities exempt under the previous rules, the Departments 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 regulations. The Departments 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, the Departments 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 women would be of childbearing age, and 32,100 may use contraceptives covered by the Guidelines.

Taking all of these factors into account, the Departments 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 regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines. But to estimate the likely actual transfer impact of these final rules, the Departments must estimate not just the number of such women covered by those entities, but how many of those entities would actually qualify for, and use, the expanded exemptions.

The Departments 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 final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments 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, the Departments 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 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. Consequently, as explained below, the Departments believe that the potential impact of these final rules falls substantially below the $100 million threshold for an economically significant major rule.

First, as mentioned, the Departments are not aware of information, or of data from public comments, 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, specifically, religious beliefs, as opposed to having done so for other reasons. It would seem reasonable to assume that many of those entities did not do so based on sincerely held religious beliefs. According to a 2016 poll, only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective).[111] In addition,

[104] 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.

[105] 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*.

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

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

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

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

[110] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[111] Pew Research Center, ''Where the Public Stands on Religious Liberty vs. Nondiscrimination''

various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage, such as 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. 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.[112] Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees and, 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.

It may not be the case that all entities that objected on religious grounds to contraceptive coverage before the ACA brought suit against the Mandate. However, it is worth noting that, while less than 100 for-profit entities challenged the Mandate in court (and an unknown number joined two newly formed associational organizations bringing suit on their behalf), there are more than 3 million for-profit private sector establishments in the United States that offer health insurance.[113] Six percent of those would be 185,000, and one third of that number would be 62,000. The Departments consider it unlikely that tens or hundreds of thousands of for-profit private sector establishments omitted contraceptive coverage pre-ACA specifically because of sincerely held religious beliefs, when, after six years of litigation and multiple public comment periods, the Departments are aware of less than 100 such entities. The Departments do not know how many additional nonprofit entities would use the expanded exemptions, but as noted above, under the rules predating the Religious IFC, tens of thousands were already exempt as churches or integrated auxiliaries, or were covered by self-insured church plans that are not penalized if no contraceptive coverage is offered.

Finally, among entities that omitted contraceptive coverage based on sincerely held conscientious objections as opposed to other reasons, it is likely that some, albeit a minority, did so based on moral objections that are non-religious, and therefore would not be compassed by the expanded exemptions in these final rules.[114] Among the general public, polls vary about religious beliefs, but one prominent poll shows that 13 percent of Americans say they do not believe in God or have no opinion on the question.[115] Therefore, the Departments estimate that, of the entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, a small fraction did so based on sincerely held non-religious moral convictions, and therefore would not be affected by the expanded exemption provided by these final rules for religious beliefs.

For the reasons stated above, the Departments believe it would be incorrect to assume that all or even most of the plans that did not cover contraceptives before the ACA did so on the basis of religious objections. Instead, without data available on the reasons those plans omitted contraceptive coverage before the ACA, we assume that no more than one third of those plans omitted contraceptive coverage based on sincerely held religious beliefs. Thus, of the estimated 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines, who received primary coverage from plans of private, non-publicly traded, third party employers that did not cover contraception pre-Affordable Care Act, and whose plans were neither exempt nor omitted from mandatory contraceptive coverage under the previous regulations, we estimate that no more than 126,400 women would be in plans that will use these expanded exemptions.

viii. Final Estimates of Persons Affected by Expanded Exemptions

Based on the estimate of an average annual expenditure on contraceptive products and services of $584 per user, the effect of the expanded exemptions on 126,400 women would give rise to approximately $73.8 million in potential transfer impact. It is possible, however, that premiums would adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As referenced elsewhere in this analysis, such women may make up approximately 8.8 percent of the covered population,[116] in which case the offset would also be approximately 8.8 percent, yielding a potential transfer of $67.3 million.

Thus, in their most expansive estimate, the Departments conclude that no more than approximately 126,400 women would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. The Departments estimate this financial transfer to be approximately $67.3 million. This falls substantially below the $100 million threshold for an economically significant and major rule.

As noted above, the Departments view this alternative estimate as being the highest possible bound of the transfer effects of these rules, but believe the number of establishments that will actually exempt their plans as the result of these rules will be far fewer than contemplated by this estimate. The Departments make these estimates only for the purposes of determining whether the rules are economically significant under Executive Orders 12866 and 13563.

After reviewing public comments, both those supporting and those disagreeing with these estimates and similar estimates from the Religious IFC, and because the Departments do not have sufficient data to precisely

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.*

[112] 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.

[113] Tables I.A.1 and I.A.2, Medical Expenditure Panel Survey, ''Private-Sector Data by Firm Size, Industry Group, Ownership, Age of Firm, and Other Characteristics: 2017,'' HHS Agency for Healthcare Research and Quality (indicating total number of for-profit incorporated, for-profit unincorporated, and non-profit establishments in the United States, and the percentage of each that offer health insurance), available at *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia1.htm* and *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia2.htm.* 2523.

[114] Such objections may be encompassed by companion final rules published elsewhere in today's **Federal Register**. Those final rules, however, are narrower in scope than these final rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

[115] Gallup, ''Religion,'' available at *https://news.gallup.com/poll/1690/religion.aspx.*

[116] As cited above, women of childbearing age are 20.2 percent of woman aged 15–65, and 43.6 percent of women of childbearing age use contraceptives covered by the Guidelines.

estimate the amount by which these factors render our estimate too high, or too low, the Departments simply conclude that the financial transfer falls substantially below the $100 million threshold for an economically significant rule based on the calculations set forth above.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

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. The Religious IFC was an interim final rule with comment period, and in these final rules, the Departments adopt the Religious IFC as final with certain changes. These final rules are, thus, being issued after a notice and comment period.

The Departments also carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866 and do not expect that these final rules will have a significant economic effect on a substantial number of small entities. These final rules will not result in any additional costs to affected entities, and, in many cases, may 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—businesses and organizations that would otherwise be faced with the dilemma of complying with the Mandate (and violating their religious beliefs) or following their beliefs (and incurring potentially significant financial penalties for noncompliance)—the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was 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 (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. In the October 13, 2017 (82 FR 47792) interim final rules, we solicited public comment on each of these issues for the following sections of the rule containing information collection requirements (ICRs). A description of the information collection provisions implicated in these final rules is given in the following section with an estimate of the annual burden. The burden related to these ICRs received emergency review and approval under OMB control number 0938–1344. They have been resubmitted to OMB in conjunction with these final rules and are pending re-approval. The Departments sought public comments on PRA estimates set forth in the Religious IFC, and are not aware of significant comments submitted that suggest there is a better way to estimate these burdens.

1. Wage Data

Average labor costs (including 100 percent fringe benefits and overhead) used to estimate the costs are calculated using data available derived from the Bureau of Labor Statistics.[117]

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupational code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Executive Secretaries and Executive Administrative Assistants	43–6011	$27.84	$27.84	$55.68
Compensation and Benefits Manager	11–3111	61.01	61.01	122.02
Legal Counsel	23–1011	67.25	67.25	134.50
Senior Executive	11–1011	93.44	93.44	186.88
General and Operations Managers	11–1021	58.70	58.70	117.40

2. 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 these 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 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 (80 FR 41318).

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 final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party

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

administrator). As explained above, HHS assumes that, among the 209 entities the Departments 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 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.[118] 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, 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour, 5 minutes for legal counsel at a cost of $134.50 per hour, and 5 minutes by a senior executive at a cost of $186.88 per hour) 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 of approximately $74.96 for a total hour burden of approximately 7.5 hours and an associated equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so that 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 $0.50 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 $0.55. 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 $2.75 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so that each will account for $1.38 of the cost burden.

[118] 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.

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

As required by the July 2015 final regulations (80 FR 41318), 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 previously provided by HHS or substantially similar language.

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) and 15 minutes of management review (at $117.40 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an associated cost of approximately $85.03. The total burden for all 109 issuers or third party administrators will be 136 hours, with an associated cost of approximately $9,268. As DOL and HHS share jurisdiction, they are splitting the burden each will account for 68 burden hours with an associated cost of $4,634, with approximately 55 respondents.

The Departments estimate that approximately 2,180,000 plan participants and beneficiaries 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. We reach this estimate using calculations set forth above, in which we used 2017 data available to HHS for contraceptive user fees adjustments to estimate that approximately 2,907,000 plan participants and beneficiaries were covered by plans using the accommodation. We further estimated that the 100 entities that previously used the accommodation and will continue doing so will cover approximately 75 percent of the persons in all accommodated plans, based on HHS data concerning accommodated self-insured plans that indicates 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 noted 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. The Departments do not have specific data on which plans of which employer sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments 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, the Departments estimate that previously accommodated entities encompassed approximately 2,907,000 persons; the estimated 100 entities that previously used the accommodation and continue to use it will account for 75 percent of those persons (that is, approximately 2,180,000 persons); and the estimated 109 entities that previously used the accommodation and will now use their exempt status will account for 25 percent of those persons (that is, approximately 727,000 persons). It is not known how many persons will be covered in the plans of the 9 entities we estimate will newly use the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity as the 100 entities encompassing 2,180,000

persons, the Departments estimate that all 109 accommodated entities will encompass approximately 2,376,000 covered persons.

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.[119] For 109 entities, the total number of notices will be 1,190,613. 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.[120] Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require $0.50 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 $0.55. The total cost for sending approximately 551,254 notices by mail will be approximately $303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $151,595 of the cost burden.

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

An eligible organization that now wishes to take advantage of the expanded exemption 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 send the notification; the issuer or third party administrator can send the notice on behalf of the entity. For the purpose of calculating the 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 their use of the accommodation 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, 30 minutes for legal counsel at a cost of $134.50 per hour, 1 hour for clerical staff at a cost of $55.68 per hour). The burden per respondent will be 2 hours with an associated cost of approximately $182; for 109 entities, the total hour burden will be 218 hours with an associated 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 associated cost of approximately $9,899.

As discussed above, HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[121] As before, the Departments 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 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require $0.50 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 $0.55. The total cost for sending approximately 168,579 notices by mail is approximately $93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately $46,772.

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	0938–1344	*5	5	0.83	3.75	$89.95	$337	$339
Notice of Availability of Separate Payments for Contraceptive Services	0938–1344	*55	595,307	1.25	68.13	68.02	4,634	156,229
Notice of Revocation of Accommodation	0938–1344	*55	182,051	2.00	109	90.82	9,899	56,671
Total		*115	777,363		180.88		14,870	213,239

*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.

[119] ''Health Insurance Coverage Bulletin'' Table 4, page 21. Using Data for the March 2016 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-2016.pdf.*

[120] 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.

[121] In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the number of women in accommodated plans affected by these final rules overlap with the number of women in plans offered by litigating entities that will be affected by these final 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.

5. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

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.

The Religious final rules amended 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 revokes their accommodation; these final rules confirm as final the Religious IFC provisions on the accommodation process. DOL submitted the ICRs to OMB in order to obtain OMB approval under the PRA for the regulatory revision. In an effort to consolidate the number of information collection requests, DOL is combining the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150 and discontinuing OMB control number 1210–0152. 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 1,190,613 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 their use of the accommodation (in favor of the expanded exemption) and will therefore be required to cause the Notice of Revocation of Accommodation to be sent, with the issuer or third party administrator able to 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 364,102 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 [122] (combined with HHS total is 227).

Total Responses: 777,362 (combined with HHS total is 1,554,724).

Frequency of Response: On occasion.

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

Estimated Total Annual Burden Cost: $197,955 (combined with HHS total is $395,911).

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 freer and open healthcare market.'' These 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), the Departments have estimated the costs and cost savings attributable to these final rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[123] However, in order to avoid double-counting with the Religious IFC, which has already been tallied as an Executive Order 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

[122] 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.

[123] 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 (Dominic J. Mancini, ''Guidance Implementing Executive Order 13771, Titled ''Reducing Regulation and Controlling Regulatory Costs,'' Office of Mgmt. & Budget (Apr. 5, 2017), *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf*) 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 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.

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 million or more (adjusted annually for inflation) in any one year.'' In 2018, that threshold after adjustment for inflation is $150 million. For purposes of the Unfunded Mandates Reform Act, the Religious IFC and these 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 $150 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 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.

V. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code, and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

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; Pub. L. 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4); 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, 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); and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

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 Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 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.* Beginning at the time described in paragraph (b) of this section 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—

* * * * *

(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.

* * * * *

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

§ 54.9815–2713A 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 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 herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-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 (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(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) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be

incorrect, the issuer is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such 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 § 54.9815–2713(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.

§ 54.9815–2713T [Removed]

■ 4. Section 54.9815–2713T is removed.

§ 54.9815–2713AT [Removed]

■ 5. Section 54.9815–2713AT is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor adopts as final the interim final rules amending 29 CFR part 2590 published on October 13, 2017 (82 FR 47792) with the following changes:

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 2590.715–2713A is amended by:
■ a. Revising paragraph (a)(5);
■ b. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g); and
■ c. Adding new paragraph (e).

The revision and addition read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) * * *

(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 herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, 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 (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 8. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 9. Section 147.131 is amended by:
■ a. Revising paragraph (c)(4);
■ b. Redesignating paragraphs (f) and (g) as (g) and (h); and
■ c. Adding new paragraph (f).

The revision and addition read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

* * * * *

(c) * * *

(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 herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, 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 (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after January 14, 2019, if

contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(f) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

■ 10. Section 147.132 is amended by:
■ a. Revising paragraph (a)(1) introductory text;
■ b. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (iii) and (iv);
■ c. Adding new paragraph (a)(1)(ii);
■ d. Revising newly designated paragraph (a)(1)(iii);
■ e. Revising newly designated paragraph (a)(1)(iv); and
■ f. Revising paragraphs (a)(2) and (b).

The revisions and addition read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) * * *

(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, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, 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

(iv) 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 subparagraph (iv), 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, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(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 group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24512 Filed 11–7–18; 4:15 pm]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

EXHIBIT B

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9841]

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–F]

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: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, the interim final rules issued in the **Federal Register** on October 13, 2017 concerning moral exemptions and accommodations regarding coverage of certain preventive services. These rules finalize expanded exemptions to protect moral 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, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an optional ''accommodation'' 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 regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT:
Jeff Wu at (301) 492–4305 or *marketreform@cms.hhs.gov* for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).
Amber Rivers or Matthew Litton at (202) 693–8335 for Employee Benefits Security Administration (EBSA), Department of Labor (DOL).
William Fischer at (202) 317–5500 for Internal Revenue Service, Department of the Treasury.
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 DOL's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of these final rules is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47838), ''Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act'' (the Moral IFC). The rules are necessary to protect sincerely held moral objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their moral beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, which was created by HHS through guidance promulgated by the Health Resources and Services

Administration (HRSA), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules finalize references to these moral exemptions in the previously created accommodation process that permit entities with certain objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's guidelines. The changes to the rules being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Moral Exemptions

These rules finalize exemptions provided in the Moral IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held moral convictions opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's guidelines. As in the Moral IFC, the exemptions include plan sponsors that are nonprofit organization plan sponsors or for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The exemptions also continue to include institutions of higher education in their arrangement of student health insurance coverage; health insurance issuers (but only with respect to plans that are otherwise also exempt under the rules); and objecting individuals with respect to their own coverage, where their health insurance issuer and plan sponsor, as applicable, are willing to provide coverage complying with the individual's moral objection. After considering public comments, the Departments have decided not to extend the moral exemptions to non-federal governmental entities at this time, although individuals receiving employer-sponsored insurance from a governmental entity may use the individual exemption if the other terms of the individual exemption apply, including that their employer is willing to offer them a plan consistent with their moral objection.

In response to public comments, various changes are made to clarify the intended scope of the language in the Moral IFC's exemptions. The prefatory exemption language is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to specify that the exemption for institutions of higher education applies to non-governmental entities. The Departments also modified language describing the moral objection applicable to the exemptions, to specify that the entity objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable) either: Coverage or payments for some or all contraceptive services; or a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The clarification is made to ensure that the HRSA guidelines do not 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 group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. References to Moral Exemptions in Accommodation Regulations and in Regulatory Restatement of Statutory Language

These rules finalize without change the references to the moral exemptions that were inserted by the Moral IFC into the rules that regulatorily restate the statutory language from section 2713(a) and (a)(4) of the Public Health Service Act. Similarly, these rules finalize without change from the Moral IFC references to the moral exemptions that were inserted into the regulations governing the optional accommodation process. These references operationalize the effect of the moral exemptions rule, and they allow contraceptive services to be made available to women if any employers with non-religious moral objections to contraceptive coverage choose to use the optional accommodation process.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and Benefits	Costs
Finalizing insertion of references to moral exemptions into restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	These provisions, finalized without change, are for the purpose of inserting references to the moral exemptions into the regulatory restatement of section 2713(a) and (a)(4) of the Public Health Service Act, which already references the religious exemptions. This operationalizes the moral exemptions in each of the tri-agencies' rules. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.

Provision	Savings and Benefits	Costs
Finalized moral exemptions	The moral exemptions to the contraceptive coverage requirement are finalized with technical changes. Their purpose is to relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their moral beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage in violation of their sincerely held moral beliefs.	We estimate there will be only a small amount of costs for these exemptions, because they will primarily be used by organizations and individuals that do not want contraceptive coverage. To the extent some other employers will use the exemption where there will be transfer costs for women previously receiving contraceptive coverage who will no longer receive that coverage, we expect those costs to be minimal due to the small number of entities expected to use the exemptions with non-religious moral objections. We estimate the transfer costs will amount to $8,760.
Finalizing insertion of references to moral exemptions into optional accommodation regulations.	These provisions, finalized without change, will allow organizations with moral objections to contraceptive coverage on the basis of sincerely held moral convictions to use the accommodation as an optional process. These provisions will allow contraceptive coverage to be made available to women covered by plans of employers that object to contraceptive coverage but do not object to their issuers or third party administrators arranging for such coverage to be provided to persons covered by their plans.	We do not estimate any entities with non-religious moral objections to use the accommodation process at this time.

B. Background

Over many decades, Congress has protected conscientious objections including based on moral convictions in the context of health care and human services, and including health coverage, even as it has sought to promote access to health services.[1] In 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended PPACA. As amended by HCERA, PPACA is known as the Affordable Care Act (ACA).

The ACA reorganized, amended, and added 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. The ACA added 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), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter ''section 2713(a)(4)''), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, ''with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported'' by HRSA (the ''Guidelines'').

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same

[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, 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (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. E, 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. E, 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. K, 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] The references in this document to ''contraception,'' ''contraceptive,'' ''contraceptive coverage,'' or ''contraceptive services'' generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to ''Contraceptive Methods and Counseling'' as ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header ''Contraception,'' to: ''the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family

time period, the administering agencies—HHS, the Department of Labor, and the Department of the Treasury (collectively, ''the Departments'' [3])—exercised discretion to allow exemptions to those requirements by issuing rulemaking various times, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments crafted exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Public comments were submitted on various iterations of the regulations issued before 2017, and some of those comments supported expanding the exemptions to include those who oppose the contraceptive coverage 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.[5]

During the period when the Departments were publishing and modifying the regulations, organizations and individuals filed dozens of lawsuits challenging the contraceptive coverage requirement and regulations (hereinafter, the ''contraceptive Mandate,'' or 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. For-profit entities with religious objections 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.[6] Later, 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 May 16, 2016, the Supreme Court issued a per curiam decision, 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. *Zubik* v. *Burwell,* 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.*

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations stated that they believe some methods classified by the Food and Drug Administration (FDA) as contraceptives may have an abortifacient effect and, therefore, in their view, are morally equivalent to abortion to which they have a moral objection. Under regulations preceding October 2017, these organizations neither received an exemption from the Mandate nor qualified for the accommodation. For example, 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, 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 the assumption that such entities are relatively more likely than other nonprofits with religious objections to have employees that share their views against certain contraceptives), 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 violated their rights under RFRA by making it impossible for them to obtain health coverage 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*

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planning practices, and sterilization procedures,'' ''contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method),'' and ''instruction in fertility awareness-based methods, including the lactation amenorrhea method.'' *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[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] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, 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.*

[5] *See, for example,* Denise M. Burke, Re: file code CMS–9968–P, *Regulations.gov* (posted May 5, 2013), *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54142;* David Sater, Re: CMS–9931–NC: Request for Information, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54218;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

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

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, while 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 in *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* v. *Sec'y of HHS* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. 867 F.3d 338, 367 (3d Cir. 2017) (Jordan, J., dissenting).

The Departments most recently solicited public comments on these issues again in two interim final regulations with request for comments published in the **Federal Register** on October 13, 2017: The regulations (82 FR 47838) (the Moral IFC) that are being finalized with changes here, and the regulations (82 FR 47792) (the Religious IFC) published on the same day as the Moral IFC, which are being finalized with changes in the companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Moral IFC, the Departments explained several reasons why, after exercising our discretion to reevaluate the exemptions and accommodations for the contraceptive Mandate, we sought public comment on whether to protect moral convictions in the Moral IFC and these final rules. The Departments noted that we considered, among other things, Congress's history of providing protections for moral convictions regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; Executive Order 13798, ''Promoting Free Speech and Religious Liberty'' (May 4, 2017); previously submitted public comments; and the extensive litigation over the contraceptive Mandate. The Departments concluded that it was appropriate that HRSA take into account the moral convictions of certain employers, individuals and health insurance issuers where the coverage of contraceptive services is concerned. Comments were requested on the interim final regulations.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Moral IFC, with changes based on comments as indicated herein.[7]

II. Overview of the Final Rules and Public Comments

During the 60-day comment period for the Moral IFC, which closed on December 5, 2017, the Departments received over 54,000 public comment submissions, which are posted to *www.regulations.gov*.[8] Below, the Departments provide an overview of the final rules and address the issues raised in the comments we received.

A. Moral Exemptions and Accommodation in General

These rules expand exemptions to protect certain entities and individuals with moral convictions that oppose contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also make available to exempt organizations the accommodation process, which was previously established in response to some objections of religious organizations, as an optional process for exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[9]

1. The Departments' Authority To Mandate Coverage or Provide Exemptions

The Departments received conflicting comments on their legal authority to provide exemptions and accommodations to the Mandate. Some commenters agreed that the Departments are legally authorized to provide expanded exemptions and an accommodation for moral convictions, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing moral exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the religious exemptions that existed prior to the 2017 IFCs, but not to protect moral convictions.

The Departments conclude that we are legally authorized to provide the exemption and accommodation for moral convictions set forth in the Moral IFC and these final rules. These rules concern section 2713 of the PHS Act, as incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Where it applies, section 2713(a)(4) requires coverage without cost sharing for ''such additional'' women's preventive care and screenings ''as provided for'' and ''supported by'' guidelines developed by HHS acting through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a

[7] The Department of the Treasury and Internal Revenue Service published proposed and temporary regulations as part of the joint rulemaking of the Moral IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules in these final rules. The Department of the Treasury and Internal Revenue Service are finalizing their regulations.

[8] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2017-0133* and *https://www.regulations.gov/docketBrowser?rpp=25&so=ASC&sb=postedDate&po=100&D=IRS-2017-0015.* Some of those submissions included form letters or attachments that, while not separately tabulated at regulations.gov, together included comments from, or were signed by, possibly over a hundred thousand separate persons. The Departments reviewed all of the public comments and attachments.

[9] *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.

positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS to shape that development, as the administering agency of HRSA, and to all three agencies as the administering agencies of the statutes by which the Guidelines are enforced. *See* 26 U.S.C. 9833; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must ''provide for'' and ''support'' the application of Guidelines that it chooses to adopt. HRSA's authority to support ''comprehensive guidelines'' involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only ''as provided for in comprehensive guidelines supported by [HRSA].'' That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word ''as'' in the phrase ''as provided for,'' it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase ''as you like it.'' [10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See for example,* 42 U.S.C. 1395x (''The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.'') (emphasis added). Thus, the inclusion of ''as'' in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has discretion whether to support how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word ''as'' is missing from the other three provisions in section 2713(a) of the PHS Act. Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require ''evidence-based'' or ''evidence-informed'' coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The moral objections at issue here, like the religious objections prompting exemptions dating back to the inception of the Mandate in 2011, may, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive-coverage Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines ''exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women,'' and ''it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans.'' *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a mandate that contraceptives be covered or that they be covered without any exemptions or exceptions, lead the Departments to conclude that we are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The Departments' conclusions are consistent with our interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4) to grant broad discretion to decide the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments created an exemption to the contraceptive Mandate when that Mandate was announced in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to plan participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrator of self-insured church plans (see 80 FR 41323). Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. In doing so, the Departments have been acting contrary to commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or its incorporation into ERISA and the Code, and who contended instead that the Departments must enforce Guidelines on the broadest spectrum of group health plans as possible, even including churches (see, for example, 2012 final regulations at 77 FR 8726).

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (see for

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) (''[u]sed to indicate by comparison the way something happens or is done'').

example, 76 FR 46623). On the contrary, Congress carved out an exemption from section 2713 of the PHS Act (and from several other provisions) for grandfathered plans. In contrast, the grandfathering exemption is not applicable to many of the other provisions in Title I of the ACA—provisions previously referred to by the Departments as providing ''particularly significant protections.'' (75 FR 34540). Those provisions include (from the PHS Act) 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 dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), and requires them to provide rebates to policyholders if that medical loss ratio is not met. (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.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but 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).

Some commenters argue that Executive Order 13535's reference to implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions in the Guidelines. The Departments, however, believe that they are acting consistent with Executive Order 13535 by creating exemptions using HRSA's authority under section 2713(a)(4), and the Departments' administrative authority over the implementation of section 2713(a) of the PHS Act. Executive Order 13535, issued upon the signing of the ACA, specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect holders of religious beliefs or moral convictions from certain requirements in health care contexts. Although the text of Executive Order 13535 does not require the expanded exemptions confirmed in these final rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect conscience objections, based on religious beliefs or moral convictions regarding certain health matters, and are consistent with the intent that the ACA be implemented in accordance with the conscience protections set forth in those laws.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities instead of to individuals, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for sincerely held moral convictions in sensitive healthcare contexts.[12] Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held moral convictions to the extent the Departments otherwise impose a contraceptive Mandate. These exemptions do not prohibit any services, nor authorize employers to prohibit employees from obtaining any services. The exemptions in the Moral IFC and these final rules simply refrain from imposing a federal mandate that employers cover contraceptives in their health plans even if they have sincerely held moral convictions against doing so.

Some commenters stated that the Supreme Court ruled that the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but that exemptions beyond those are not. But the Supreme Court did not rule on the question whether the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate unless RFRA prohibits us from doing so.

The appropriateness of including exemptions to protect moral convictions is informed by Congress's long history of providing exemptions for moral convictions, especially in certain health care contexts.

2. Congress's History of Protecting Moral Convictions

The Department received numerous comments about its decision in the Moral IFC to exercise its discretion to provide moral exemptions to, and an accommodation under, the contraceptive Mandate. Some commenters agreed with the Departments' decision in the Moral IFC, arguing that it is appropriate to exercise the Departments' discretion to protect moral convictions in light of Congress's history of protecting moral convictions in various contexts, especially concerning health care. Other commenters disagreed, saying that existing conscience statutes protecting moral convictions do not require these exemptions and, therefore, the exemptions should not be offered. Some commenters stated that because Congress has provided conscience protections, but did not specifically provide them in section 2713(a)(4), conscience protections are inappropriate in the implementation of that section. Still other commenters went further, disagreeing with conscience protections regarding contraceptives, abortions, or health care in general.

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on the most recent statements of Congress, along with nearly 50 years of statutes and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health coverage. Most recently, Congress 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, 2018, Div. E, section 808, Public Law 115–141, 132 Stat. 348, 603 (Mar. 23, 2018); *see also*

[11] Kaiser Family Foundation & Health Research & Educational Trust, ''Employer Health Benefits, 2017 Annual Survey,'' Henry J Kaiser Family Foundation (Sept. 19, 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017*.

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

Consolidated Appropriations Act, 2017, Div. C, section 808, Public Law 115–31 (May 5, 2017). The Departments consider it significant that Congress's most recent statements on the prospect of Government-mandated contraceptive coverage specifically intend that a conscience clause be included to protect moral convictions.

The Departments also consider significant the many statutes listed above, in section I—Background footnote 1, that show Congress's consistent protection of moral convictions alongside religious beliefs in the federal regulation of health care. These include laws such as the Church Amendments (dating back to 1973), which we discuss at length below, to the 2018 Consolidated Appropriations Act discussed above. Notably among those laws, and in addition to the Church Amendments, 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–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''). Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their ''religious beliefs or moral convictions.'' Consolidated Appropriations Act, 2018, Public Law 115–141, Division E, section 726(c); *see also* Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.[13]

The Departments disagree with commenters that suggested we should not consider Congress's history of protecting moral objections in certain health care contexts due to Congress's failure to explicitly include exemptions in section 2713(a)(4) itself. The argument by these commenters proves too much, since Congress also did not specifically require contraceptive coverage in section 2713 of the PHS Act. This argument would also negate not just these expanded exemptions, but the previous exemptions provided for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting moral convictions in the context of certain federal health care requirements.

a. 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 because they had received federal funds. These sections of the U.S. 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, not just religious beliefs. 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). Although the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens facilitate its exercise. Indeed, *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 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 records 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

[13] The Departments also note that, in protecting those individual and institutional health care entities that object to certain abortion-related services and activities regardless of the basis for such objection, the Coats-Snowe Amendment, PHS Act section 245 (42 U.S.C. 238n), and the Weldon Amendment, Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141, protect those whose objection is based on moral conviction.

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. 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. 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] [14] 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. S5723

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R–MA) [15] 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 sections 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, as well as those who object to such services on the basis of religious beliefs. 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); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141.
- Protections for entities and individuals that object to providing or covering contraceptives. *See id.* at Div. E, Sec. 808; *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act); *id.* at Div. K, Title III.
- 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. 1396a(w)(3); 42 U.S.C. 14406; 42 U.S.C. 18113 (adopted as part of the ACA).

The Departments believe that the intent behind Congress's protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports the Departments' decision in the Moral IFC and these final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

b. Court Precedents Relevant to These Expanded Exemptions

As reflected in the legislative history of the first Church Amendments, the Supreme Court has long afforded protection to moral convictions alongside religious beliefs. Indeed, Senator Church cited *Doe* v. *Bolton,* 410 U.S. 179, as a parallel instance of conscience protection and 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 had decided just three 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.

[14] The Senator might have meant ''[forced] . . . against his will.''

[15] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

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.''

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 beliefs constitute an illegitimate ''separat[ion]'' of moral convictions, nor do the Departments 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's intent in the Church Amendments and in later federal statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

c. Conscience Protections in Other Federal and State Contexts

The tradition of protecting moral convictions in certain health contexts is not limited to laws passed by Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[16] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs 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.[17]

Forty-five states have health care conscience protections covering objections to abortion; several of these also cover sterilization or contraception.[18] 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; Consolidated Appropriations, 2018, Public Law 115–141, Div. H, section 507(d).

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 the Mandate in part because they consider some forms of FDA-approved contraceptives to be morally equivalent to abortion due to the possibility that such items may prevent the implantation of a human embryo after fertilization.[19] 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. Based on pleadings in the litigation, all of the litigants challenging the Mandate and asserting purely non-religious objections share this view. And as Congress has implicitly recognized in providing health care conscience protections pertaining to sterilization, contraception, and other health care services and practices, individuals or entities may have additional moral objections to contraception.[20]

d. Founding Principles

The Departments also look to guidance from, and draw support for the Moral IFC and these final rules 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. In supporting the protection of 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.'' Representative 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

[16] *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).

[17] *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'').

[18] 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,'' The Guttmacher Institute (June 1, 2017), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

[19] FDA, ''Birth Control,'' U.S. Food and Drug Administration (Mar. 6, 2018), *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm* (various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization, but ''may also work . . . by preventing attachment (implantation) to the womb (uterus)'' of a human embryo after fertilization).

[20] *See supra* note 1.

citizenship.'' [21] 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.'' [22] 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.'' [23]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context, and the Departments do not suggest that the specific protections offered in the Moral IFC and these final rules would be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These final rules do not address in any way how the Government would balance its interests with respect to other health services not encompassed by the contraceptive Mandate.[24] Instead, the Departments highlight this tradition of respect for conscience from the Nation's Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4), while protecting conscience in the exercise of moral convictions. The Departments believe that these final rules are consistent both with the American tradition of respect for conscience and with Congress's history of providing conscience protections in the kinds of health care matters involved in this Mandate.

e. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in these expanded exemptions and accommodation in these final 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 both religious beliefs and moral convictions. Moreover, President Trump's first Executive Order, E.O. 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.'' The exemption and accommodation adopted in these final rules relieves a regulatory burden imposed on entities with moral convictions opposed to providing certain contraceptive coverage and is therefore consistent with both Executive Orders.

f. Litigation Concerning the Mandate

The Departments have further taken into consideration the litigation surrounding the Mandate in exercising their discretion to adopt the exemption in these final rules. 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 affirmed a district court ruling that allows the previous regulations to be imposed in a way that affects the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives* v. *Sec'y, Dep't of Health & Human Servs.,* 867 F.3d 338 (3d Cir. 2017). The Departments' litigation of these cases has thus 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 adopted longstanding moral tenets opposed to certain FDA-approved contraceptives, and hire only employees who share this view. As a result, it is reasonable to conclude that employees of these organizations would not benefit from the Mandate. Thus, 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, as well as the legal 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 final rules. Although, as discussed below, the Departments 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, the Departments 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, the Departments consider it appropriate to issue the protections set forth in these 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 the Departments, too, believe that ''our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government'' in this situation. *See* 119 Congr. Rec. S5717–18.

The litigation concerning the Mandate has also underscored how important it is for the Government to tread carefully when engaging in regulation concerning sensitive health care areas. As demonstrated by the litigation, as well as the 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 certain contraceptive items may cause early abortions. Providing conscience protections advances the ACA'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

[21] Letter 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*).

[22] 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*).

[23] James Madison, ''Essay on Property'' (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

[24] 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.

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 sort of outcome is one the Departments wish to avoid. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) in a way that respects the moral convictions of Americans so that they are freer to engage in ''full participation in the economic life of the Nation.'' The exemptions in these final rules 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.

3. Whether Moral Exemptions Should Exist, and Whom They Should Cover

As noted above, the Department received comments expressing diverse views as to whether exemptions based on moral convictions should exist and, if so, whom they should cover.

Some commenters supported the expanded exemptions and accommodation in the Moral IFC, and the choice of entities and individuals to which they applied. They stated the expanded exemptions and accommodation would be an appropriate exercise of discretion and would be consistent with moral exemptions Congress has provided in many similar contexts. Similarly, commenters stated that the accommodation would be an inadequate means to resolve moral objections and that the expanded exemptions are needed. They contended that the accommodation process was objectionable because it was another method of complying with the Mandate, its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and the coverage for contraceptive services ''hijacked'' or flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to moral objections that organizations would not have with an expanded exemption. Commenters also stated that, with respect to non-profit organizations that have moral objections and only hire persons who agree with those objections, the Mandate serves no legitimate government interest because the mandated coverage is neither wanted nor used and, therefore, would yield no benefits—it would only suppress the existence of non-profit organizations holding those views.

Several other commenters stated that the exemptions were still too narrow. They asked that the exemptions set forth in these final rules be as broad as the exemptions set forth in the Religious IFC concerning sincerely held religious beliefs. Some of these commenters also asked that HHS withdraw its Mandate of contraceptive coverage from the Guidelines entirely. They contended that fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of a preventive health service; that contraceptives can pose medical risks for women; and that studies do not show that contraceptive programs reduce abortion rates or unintended pregnancies. Some commented that many women report that they sought an abortion because their contraception failed. Some other commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacient and, therefore, violate federal conscience protections such as the Weldon Amendment, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, § 507(d).

Other commenters contended that the exemptions in the Moral IFC were too broad. Some of these commenters expressed concern about the prospect of publicly traded for-profit entities also being afforded a moral exemption. One such commenter commented that allowing publicly traded for-profit entities a moral exemption could cause instability and confusion, as leadership changes at such a corporation may effectively change the corporation's eligibility for a moral exemption. Still others stated that the Departments should not exempt various kinds of entities such as businesses, issuers, or nonprofit entities, arguing that only individuals, not entities, can possess moral convictions. Some commenters were concerned that providing moral exemptions would contribute to population growth and related societal woes. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318), which did not encompass moral convictions. Other commenters stated that the Departments should not provide exemptions, but merely an accommodation process, to resolve moral objections to the Mandate.

Some commenters objected to providing any exemption or accommodation for moral objections at all. Some of these commenters contended that even the previous regulations allowing an exemption and accommodation were too broad and that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible. Other commenters did not go that far, but rejected the idea of exemptions or an accommodation based on moral convictions, contending that such exemptions or accommodation would contribute to population growth and related social woes. Some of these commenters also contended that the exemption in the Moral IFC would constitute an exemption covering every business and non-profit organization.

After considering these comments, and although the previous Administration declined to afford any exemption based on moral convictions, the Departments have concluded that it is appropriate to provide moral exemptions and access to the accommodation, as set forth in these final rules. Congress did not mandate contraceptive coverage, nor provide any explicit guidance about incorporating conscience exemptions into the Guidelines. But as noted above, it is a long-standing Congressional practice to provide consistent exemptions for both religious beliefs and moral convictions in many federal statutes in the health care context, and specifically concerning issues such as abortion, sterilization, and contraception. It is not clear to the Departments that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar exemptions. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases. The exemptions finalized in these final rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. As noted above, the Departments consider the exemptions in these final rules consistent with the intent of Executive Order 13535. The Departments also wish to avoid the stark disparity that may result from respecting religious objections to providing contraceptive coverage among certain entities and individuals, but not respecting parallel objections for moral convictions possessed by any entities and

individuals at all because those objections are not specifically religious.

In addition, the Departments note that 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.[25] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the ACA, nor a statement about what the Federal Government may do consistent with other limitations in federal law, such state practices can inform the Departments' view that it is appropriate to provide conscience protections when exercising agency discretion.

The Departments decline to use these final rules to remove the contraceptive Mandate altogether, such as by declaring that HHS acting through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). HRSA's Guidelines were not issued, ratified, or updated through the regulations that preceded the Moral IFC and these final rules. Those Guidelines were issued in separate processes in 2011 and 2016, directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The regulations preceding these final rules attempted only to restate the statutory language of section 2713 in regulatory form, and delineate what exemptions and accommodations would apply if HRSA listed contraceptives in its Guidelines. We decline to use these final rules to direct the separate process that HRSA uses to determine what specific services are listed in the Guidelines generally. Some commenters stated that if contraceptives are not removed from the Guidelines entirely, entities or individuals with moral objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in these rules include a broad range of entities and individuals of whom we have notice may object based on moral convictions. The Departments are not aware of specific employers or individuals whose moral convictions would still be violated by compliance with the Mandate after the issuance of the Moral IFC and these final rules.

Some commenters stated that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions. Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These final rules focus on what moral exemptions and accommodation shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacient.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content and process of developing and updating the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov.*

The Departments also conclude that it would be inadequate to merely attempt to amend or expand the accommodation process to account for moral objectors, instead of providing the exemptions. In the past, the Departments stated in our regulations and court briefs that the previous accommodation required contraceptive coverage in a way that is ''seamless'' with the coverage provided by the objecting employer. As a result, in significant respects, the accommodation process did not actually accommodate the objections of many entities, as indicated by many entities with religious objections. The Departments have attempted to identify an accommodation that would eliminate the religious plaintiffs' objections, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but stated in January 2017 that we were unable to develop such an approach at that time.[26] Just as the Departments continue to believe merely amending the accommodation process would not adequately address religious objections to compliance with the Mandate, we do not believe doing so would adequately address similar moral objections. Furthermore, the few litigants raising non-religious moral objections have been non-profit organizations that assert they only hire persons who share the employers' objection to contraceptive coverage. Consequently, the Departments conclude that the most appropriate approach to resolve these concerns is to provide the exemptions set forth in the Moral IFC and these final rules. These final rules also finalize the modifications to the accommodation process to make it available to entities with moral objections, without forcing such entities to choose between compliance with either the Mandate or the accommodation.

Some commenters expressed concern over the lack of a definition of ''moral convictions'' in the Moral IFC, arguing that, without a definition, any objection could be encompassed by the exemptions even if it is not based on moral convictions. The Departments did not adopt a regulatory definition of ''moral convictions'' in the Moral IFC, and have decided not to adopt such a definition in response to public comments at this time. Nevertheless, the Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in the Moral IFC and these final rules. Neither these final rules or the Moral IFC, nor the Church Amendments or other Federal health care conscience statutes, define ''moral convictions'' (nor do they define ''religious beliefs''). But in issuing these final rules, we adopt 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 in 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

[25] *See* ''Insurance Coverage of Contraceptives,'' The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

[26] *See* Departments of Labor, Health and Human Services, and the Treasury, FAQs About Affordable Care Act Implementation Part 36, (Jan. 9, 2017), *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* (''the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage'').

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.

While moral convictions are the sort of principles that, in the life of an individual, occupy a place parallel to religion, sincerely held moral convictions can also be adopted by corporate bodies, not merely by individuals. Senators Church and Nelson, while discussing the fact that opposition to abortion or sterilization on the basis of ''moral questions'' does not include capricious opposition to abortion for no reason at all, were specifically talking about opposition to abortion by corporate entities: A ''hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise.'' [27] Corporate bodies operate by the decision-making actions of individuals. Thus, if individuals act in the governance of a corporate body so as to adopt a position for that body of adopting moral convictions against coverage of contraceptives, such an entity can be considered to have an objection to contraceptive coverage on the basis of sincerely held moral convictions.

4. The Departments' Rebalancing of Government Interests

The Departments also received comments on their rebalancing of interests as expressed and referenced in the Moral IFC. Some public commenters agreed with the Departments' conclusion that our interest in ensuring contraceptive coverage does not preclude the Departments from offering exemptions and an accommodation for entities, plans, and individuals with a qualifying objection to contraceptive coverage based on moral convictions. Some public commenters pointed out that protecting moral convictions serves to respect not only the interests of certain persons to access contraceptives, but also the interests of other persons to participate in a health coverage market consistent with their moral convictions. Other commenters disagreed with this rebalancing, and contended that the interest of women in receiving contraceptive coverage without cost-sharing is so great that it overrides private interests to the contrary, such that the government should or must force private entities to provide this coverage to other private citizens.

The Departments agree with the commenters who stated that the governmental interest in requiring contraceptive coverage does not override the interest in protecting moral convictions and does not make these expanded exemptions inappropriate. For additional discussion of the Government's balance of interests as applicable to religious beliefs, see section II.C.2.b. of the companion final rules concerning religious exemptions published by the Departments contemporaneously with these final rules elsewhere in today's **Federal Register**. There, and in the Religious and Moral IFCs, the Departments acknowledged the reasons why the Departments have changed the policies and interpretations previously adopted with respect to the Mandate and the governmental interests underlying it. For parallel reasons, the Departments believe the Government's legitimate interests in providing for contraceptive coverage do not require the Departments to violate sincerely held moral convictions while implementing the Guidelines. The Departments likewise believe Congress did not set forth interests that require us to violate sincerely held moral convictions if we otherwise require contraceptive coverage in our discretionary implementation of the women's preventive services Guidelines under section 2713(a)(4).

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), added to the PHS Act in 2010. The Departments' expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after considering public comments on various sides of the issue, and reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant federal law, the Departments have determined that affording the exemptions to protect 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 invoke these exemptions and accommodation may be small, the Departments believe that it is important to provide such protection, given the long-standing recognition of such protections in law and regulation in the health care and health insurance contexts. The Moral IFC and these 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, including through such programs as Medicaid and Title X. The Departments also note that the exemptions created here, like the exemptions created by the previous Administration, do not burden third parties to a degree that counsels against providing the exemptions, as discussed below.

5. Burdens on Third Parties

The Department received a variety of comments about the effect that the exemptions and accommodation based on moral convictions would have on third parties. Some commenters stated that the exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might otherwise receive contraceptive coverage with no cost sharing. Other commenters disagreed, asserting that the exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more

[27] Nor was this recognition of the need to protect organizations that object to performance of certain health care procedures on the basis of moral conviction limited to the Church Amendments' legislative history. The first of the Church Amendments provides, in part, that the receipt of certain federal funds ''by any individual or entity does not authorize any court or any public official or other public authority to require— . . . (2) such entity to—(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.'' 42 U.S.C. 300a–7(b).

unintended pregnancies,[28] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as prioritizing conscientious objection of exempted entities over the conscience, choices, or religious liberty of women who would not receive contraceptive coverage where an exemption is used. Some commenters disagreed and said the exemptions do not violate laws and constitutional protections, nor do they inappropriately prioritize the conscience of exempted entities over those of third parties.

The Departments note that the exemptions in the Moral IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. Agency discretion was exercised to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties whom the government chooses not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: That the government has an obligation to force private parties to benefit those third parties, and that the third parties have a right to those benefits. Congress did not create a right to receive contraceptive coverage from other private citizens through section 2713 of the PHS Act, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to which they morally object, to benefit other private parties, does not prevent the government from relieving some or all of the burden of that Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Moral IFC and these final rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through the grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae,* 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the government refrain from requiring private citizens, in violation of their moral convictions, to cover contraception for other citizens. *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 constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting moral objections to such governmental mandates, especially where, as here, the Mandate is not an explicit statutory requirement.[29] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these rules.

Some commenters objected that the exemptions would violate the Establishment Clause of the First Amendment. The Moral IFC and these final rules create exemptions for moral convictions, not religious beliefs, and they do so for the same neutral purposes for which Congress has created similar exemptions for over four decades. Not only do these final rules not violate the Establishment Clause, but the Departments' decision to provide the exemptions and accommodation for moral convictions, instead of limiting the exemptions to identical objections based on religious beliefs, further demonstrates that neither the purpose nor the effect of these exemptions is to establish religion. The Establishment Clause does not force the Department to impose a contraceptive Mandate in violation of the moral convictions of entities and individuals protected by these rules.

American governmental bodies have, in many instances, refrained from requiring certain private parties to cover contraceptive services for other private parties. From 1789 through 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under section 2713 of the PHS Act to be covered by grandfathered plans. Many states do not impose contraceptive coverage mandates, or they offer religious, and in some cases moral, exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or state courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. The Departments are not aware of federal courts declaring that the exemptions, safe harbor, or accommodations gave rise to third party burdens that required the government to mandate contraceptive coverage by entities eligible for an exemption or accommodation. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including

[28] Some commenters attempted to quantify the costs of unintended pregnancy, but were unable to provide estimates with regard to the number of women that this exemption may affect.

[29] *See, for example, 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.'').

under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters stated that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others commenters stated that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. Until 2012, there was no federal mandate of contraceptive coverage across health insurance and health plans nationwide. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to state or local governments. The various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage, have not been deemed to cause a cognizable injury to state or local governments. The Departments find no legal prohibition on finalizing these final rules based on the allegation of an impact on state or local governments, and disagree with the suggestion that once having exercised our discretion to deny exemptions—no matter how recently or incompletely—the Departments cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, the exemptions at issue here are available only to a tiny fraction of entities to which the Mandate would otherwise apply—those with qualifying moral objections. Public comments did not provide reliable data on how many entities would use these expanded moral exemptions, in which states women in those plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would potentially have to cover. As noted below, at least one study [30] has concluded the Mandate caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates. In addition, the only entities that have brought suit based on their moral objections to the Mandate are non-profit entities that have said they only hire persons who share their objections and do not use the contraceptives to which their employers object, so it is unlikely that exemptions for those entities would have any impact on safety net programs. Below, we predict that a small number of additional nonprofit and closely held for-profit entities will use the exemptions based on moral convictions. In light of the limited evidence of third party or state and local government impact of these final rules, the Departments consider it an appropriate policy option to provide the exemptions.

Some commenters contended that the exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead, they allow entities that have sincerely held moral objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

Those commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these final rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not in its capacity as an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.,* 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII ''does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women''). Second, these rules create no disparate impact. The women's preventive service mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inure to the specific benefit of women—men are denied any benefit from section 2713(a)(4). Both before and after these rules are in effect, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions encompass moral objections. The previous rules, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship and integrated auxiliaries, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby's* holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women

[30] M.L. Kavanaugh et al., ''Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,'', 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters stated that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some commenters objected that the Moral IFC's estimate of a $584 yearly cost of contraceptives for women was too low. But some of those same commenters provided similar estimates, citing sources claiming that birth control pills can cost up to $600 per year, and stated that IUDs, which can last 3 to 6 years or more,[31] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters stated that, for lower income women, contraceptives and related education and counseling can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately covered individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member, and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, emphasizing that income and eligibility thresholds could prevent some women from receiving contraceptives through certain government programs if they were no longer covered in their group health plans or health insurance plans.

The Departments do not believe that such differences make it inappropriate to issue the expanded exemptions set forth in these rules. As explained more fully below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. Moreover, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed rule to amend the regulations governing its Title X family planning program. The proposed rule would amend the definition of ''low income family''—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions. (83 FR 25502). If that rule is finalized as proposed, it would further reduce any potential effect of these final rules on women's access to contraceptives.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS ''shall not promulgate any regulation'' that ''creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care,'' ''impedes timely access to health care services,'' ''interferes with communications regarding a full range of treatment options between the patient and the provider,'' ''restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions,'' ''violates the principles of informed consent and the ethical standards of health care professionals,'' or ''limits the availability of health care treatment for the full duration of a patient's medical needs.'' 42 U.S.C. 18114. Such commenters urged, for example, that the Moral IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554 of the ACA. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections; multiple courts considered those regulations; and while many ruled that entities did not need to provide contraceptive coverage, none ruled that the exemptions or accommodations in the regulations violated section 1554 of the ACA. Moreover, the decision not to impose a governmental mandate is not the creation of a ''barrier,'' especially when that mandate requires private citizens to provide services to other private citizens. This would turn the assumptions of the United States' system of government on its head. *See, for example,* U.S. Constitution, Ninth Amendment. Section 1554 of the ACA likewise does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 of the ACA prohibit the Departments from providing exemptions to relieve burdens on moral convictions, or as is the case here, from refraining to impose the Mandate in cases where moral convictions would be burdened by the Mandate. Moral exemptions from federal mandates in certain health contexts, including sterilization, contraception, or items believed to be abortifacient, have existed in federal laws for decades. Some of those laws were referenced by President Obama in signing Executive Order 13535. In light of that Executive Order and Congress's long history of providing exemptions for moral convictions in the health context, providing moral exemptions is a reasonable administrative response to this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts.

In short, we do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered, or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

In summary, members of the public have widely divergent views on whether the exemptions in the Moral IFC and these final rules are good public policy. Some commenters stated that the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind the exemption, and arguing that the exemption would not interfere with the physician-patient relationship. The Departments have determined that these final rules are an appropriate exercise of public policy discretion. Because of the importance of the moral convictions being accommodated, the limited impact of these final rules, and uncertainty about

[31] *See, for example,* ''IUD,'' Planned Parenthood, *https://www.plannedparenthood.org/learn/birth-control/iud.*

the impact of the Mandate overall according to some studies, the Departments do not believe these final rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

6. Interim Final Rulemaking

The Departments received several comments about the decision to issue the Moral IFC as interim final rules with request for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Moral IFC in that way, agreeing with the Departments that there was explicit statutory authority to do so, good cause under the APA, or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe authority existed to issue the Moral IFC as interim final rules. 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 that Act, and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Moral IFC, the Departments issued three interim final regulations implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Moral IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Moral IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules were issued after receiving and thoroughly considering public comments as requested in the Moral IFC. These final rules therefore comply with the APA's notice and comment requirements.

7. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause, or are associated with, an increased risk of depression,[32] venous thromboembolic disease,[33] fatal pulmonary embolism,[34] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[35] hypertension,[36] HIV–1 acquisition and transmission,[37] and breast, cervical, and liver cancers.[38] Some commenters also stated that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that it is not the case that contraceptive access reduces unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated

[32] Commenters cited Charlotte Wessel Skovlund, et al., ''Association of Hormonal Contraception with Depression,'' *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) (''Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use.'').

[33] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception: Recent Advances and Controversies,'' 82 *Fertility and Sterility* S26, S30 (2004); V.A. Van Hylckama et al., ''The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study,'' 339 *Brit. Med. J.* b2921 (2009); Y. Vinogradova et al., ''Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases,'' 350 *Brit. Med. J.* h2135 (2015) (''Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year.''); Ø. Lidegaard et al., ''Hormonal contraception and risk of venous thromboembolism: national follow-up study,'' 339 *Brit. Med. J.* b2890 (2009): M. de Bastos et al., ''Combined oral contraceptives: venous thrombosis,'' Cochrane Database Syst. Rev., Mar. 3, 2014. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J. Havrilesky 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;* and Robert A. Hatcher et al., *Contraceptive Technology,* 405–07 (Ardent Media 18th rev. ed. 2004).

[34] Commenters cited N.R. Poulter, ''Risk of Fatal Pulmonary Embolism with Oral Contraceptives,'' 355 *Lancet* 2088 (2000).

[35] Commenters cited Ø. Lidegaard et al., ''Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception, 366 *N. Engl. J. Med.* 2257, 2257 (2012) (risks ''increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg''); Practice Committee of the American Society for Reproductive Medicine, ''Hormonal Contraception''; M. Vessey et al., ''Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking,'' 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, ''Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study,'' 349 *Lancet* 1202, 1202–09 (1997); K.M. Curtis et al., ''Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review,'' 73 Contraception 179, 179–188 (2006); L.A. Gillum et al., ''Ischemic stroke risk with oral contraceptives: A meta analysis,'' 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology,* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[36] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology,* 407, 445 (Ardent Media 18th rev. ed. 2004).

[37] Commenters cited Renee Heffron et al., ''Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study,'' 12 *Lancet Infectious Diseases* 19, 24 (2012) (''Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men.''); and ''Hormonal Contraception Doubles HIV Risk, Study Suggests,'' *Science Daily* (Oct. 4, 2011), *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[38] Commenters cited ''Oral Contraceptives and Cancer Risk,'' National Cancer Institute (Mar. 21, 2012), *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky 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;* S. N. Bhupathiraju et al., ''Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study,'' 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, ''Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment,'' (Sept. 2005), available at *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, ''Known and Probably Human Carcinogens,'' American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 Report of the Institute of Medicine (IOM), ''Clinical Preventive Services for Women: Closing the Gaps,'' in its discussion of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality. Commenters also stated that studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer, and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[39] Some commenters stated that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters stated that, in the Moral IFC, the Departments relied on incorrect statements concerning scientific studies. For example, some commenters stated that there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Departments for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR 47804, the 2013 Agency for Healthcare Research and Quality study, and other sources, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to consider these studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[40] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some commenters agreed with the quotation, in the Moral IFC, of FDA materials [41] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Moral IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Moral IFC that some persons believe those possible effects are ''abortifacient.''

This objection on this issue appears to be partially one of semantics. People disagree about whether to define ''conception'' or ''pregnancy'' to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items ''abortifacient''—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby,* 134 U.S. at 2765 (''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.'').

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere moral objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of an objection based on sincerely held religious belief under RFRA.[42] Several litigants have separately raised non-religious moral objections to contraceptive coverage based on the same basic rationale. Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer moral exemptions with respect to this Mandate.

The Departments also received comments about their discussion, located in the Religious IFC but partly relied upon in the Moral IFC, concerning uncertainty about the effects the Mandate's expanded exemptions might have on teen sexual activity. In this respect, the Departments stated, ''With respect to teens, the Santelli and Melnikas study cited by IOM 2011

[39] To the extent that contraceptives are prescribed to treat health conditions, and not for preventive purposes, the Mandate would not be applicable.

[40] 82 FR at 47803–04.

[41] FDA's guide ''Birth Control'' 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.*

[42] ''Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You.'' *Hobby Lobby,* 134 S. Ct. at 2762–63. ''The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point.'' *Id.* at 2765–66.

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). 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.' '' [43] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that limiting the exemptions to the Mandate to those that existed prior to the Religious and Moral IFCs is not tailored towards advancing the Government's interests in reducing teen pregnancy. Instead they suggested there are means of reducing teen pregnancy that are less burdensome on conscientious objections.[44] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[45]

Many commenters opposing the moral exemptions misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, the Departments note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general make it difficult to establish causation between exemptions to the contraceptive Mandate, and an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including, but not limited to, reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline). It concluded that ''that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny.'' [46] One study found that, during the teen pregnancy decline between 2007 through 2012, teen sexual activity was also decreasing.[47] One study concluded that falling unemployment rates in the 1990s accounted for 85 percent of the decrease in rates of first births among 18 to 19 year-old African Americans.[48] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[49] One study concluded that an ''increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy.'' [50] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[51] Some commenters also cited studies—which are not limited to the issue of teen pregnancy—that have found that many women who have abortions report that they were using contraceptives when they became pregnant.[52]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of public comments has reinforced the Departments' view that the uncertainty surrounding these weighty and important issues makes it appropriate to provide the moral exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing moral exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments to implement the ACA.

8. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promoted the health and equality of women, especially low income women, and promoted female participation and

[43] Citing J.S. Santelli & A.J. Melnikas, ''Teen fertility in transition: recent and historic trends in the United States,'' 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and 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/addicted13.pdf. See also* K. Buckles & D. Hungerman, ''The Incidental Fertility Effects of School Condom Distribution Programs,'' *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* (''access to condoms in schools increases teen fertility by about 10 percent'' and increased sexually transmitted infections).

[44] *See* Helen Alvaré, ''No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom,'' 58 *Vill. L. Rev.* 379, 400–02 (2013) (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).

[45] *See, e.g.,* Lindberg L., Santelli J., ''Understanding the Decline in Adolescent Fertility in the United States, 2007–2012,'' 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[46] Kearney MS and Levine PB, ''Investigating recent trends in the U.S. birth rate,'' 41 *J. Health Econ.* 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[47] *See, e.g.,* K. Ethier et al., ''Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015,'' 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* (''Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall . . . .'').

[48] Colen CG, Geronimus AT, and Phipps MG, ''Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States,'' 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[49] Atkins DN and Wilkins VM, ''Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates,'' 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[50] E. Collins & B. Herchbein, ''The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act,'' *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* (''[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women'').

[51] *See* D. Paton & L. Wright, ''The effect of spending cuts on teen pregnancy,'' 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* (''Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates'').

[52] Commenters cited, for example, Guttmacher Institute, ''Fact Sheet: Induced Abortion in the United States'' (Jan. 2018) (''Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant''), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

equality in the workforce. Other commenters contended there was insufficient evidence showing that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence to show that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed a study published and revised by the Guttmacher Institute in October 2017, concluding that ''[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy.'' [53] This timeframe includes the first two years of the contraceptive Mandate's implementation. Despite some changes in the use of various methods of contraceptives, the study concluded that, ''[f]or the most part, women are changing method type within the group of most or moderately effective methods and not shifting from less effective to more effective methods.'' Regarding the effect of this Mandate in particular, the authors concluded that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use.'' The authors observed that other ''[s]tudies have produced mixed evidence regarding the relationship between the implementation of the ACA and contraceptive use patterns.'' In explaining some possible reasons or no clear effect on contraceptive use, the authors suggested that ''existence of these safety net programs [publicly funded family planning centers and Medicaid] may have dampened any impact that the ACA could have had on contraceptive use,'' ''cost is not the only barrier to accessing a full range of method options,'' and ''access to affordable and/or free contraception made possible through programs such as Title X'' may have led to income not being associated with the use of most contraceptive methods.[54] In addition, commenters noted that in the 29 states where contraceptive coverage mandates have been imposed statewide,[55] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[56]

Other commenters, however, disputed the significance of these state statistics, noting that, of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the exemption in these rules might have on the Mandate more broadly. The state mandates of contraceptive coverage still apply to a very large number of plans and plan participants notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups were already exempt from the federal Mandate prior to the 2017 Religious and Moral IFCs. The exemptions as set forth in the Moral IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might result from the contraceptive Mandate here.

Some commenters took a view that appears to disagree with the assertion in the 2017 Guttmacher study, that ''[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA.'' These commenters instead observed that, under the Mandate, more women have coverage of contraceptives and contraception counseling and that more contraceptives are provided without co-pays than before. Still others argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [57] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also stated that studies show that decreases in unintended pregnancies are due to broader access to contraceptives. Finally, some commenters also stated that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on that review, it is not clear that merely offering the exemption in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from contraceptive access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, the Departments

[53] M.L. Kavanaugh et al., ''Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014,'' 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[54] Id.

[55] See Guttmacher Institute, ''Insurance Coverage of Contraceptives'' (June 11, 2018); ''State Requirements for Insurance Coverage of Contraceptives,'' Henry J. Kaiser Family Foundation (Jan. 1, 2018), *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[56] *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.*

[57] Citing, for example, Adelle Simmons et al., ''The Affordable Care Act: Promoting Better Health for Women,'' Table 1, ASPE (June 14, 2016), *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

conclude that the Moral IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small number of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. The Departments also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, an appropriate exercise of the Departments' discretion.

Moreover, the Departments conclude that the best way to balance the various policy interests at stake in the Moral IFC and these final rules is to provide the exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules provide tangible conscience protections for moral convictions, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a burden on their moral convictions. The Departments view the provision of those protections to preserve conscience in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for moral convictions set forth in the Moral IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

9. Other General Comments

Some commenters expressed the view that the exemptions afforded in the Moral IFC and herein violate the RFRA rights of women who might not receive contraceptive coverage as the result of these final rules, by allowing their employers to impose their moral convictions on them by removing contraceptive coverage through use of the exemption. Still other commenters stated that employer payment of insurance premiums is part of any employee's compensation package, the benefits of which employers should not be able to limit. In the Departments' view, the expanded exemptions in these final rules do not prohibit employers from providing contraceptive coverage. Instead, they lift a government burden that was imposed on some employers to provide contraceptive coverage to their employees in violation of those employers' moral convictions. The Departments do not believe RFRA requires, or has ever required, the federal government to force employers to provide contraceptive coverage. The federal government's decision to exempt some entities from a requirement to provide no-cost-sharing services to private citizens does not constitute a federal government-imposed burden on the latter under RFRA.

Some commenters asked the Departments to discuss the interaction between these rules and state laws that either require contraceptive coverage or provide exemptions from those and other requirements. Some commenters argue that providing the exemptions in these rules would negate state contraceptive requirements or narrower state exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage.

The Departments agree that these rules only concern the applicability of the federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state exemptions. If a plan is exempt under the Moral IFC and these final rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the moral exemption rules to declare whether the federal contraceptive Mandate would still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[58]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1).

These final rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with moral objections to cover contraceptives.

Finally, some commenters expressed concern that providing moral exemptions to the mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, section 2713(a)(2) of the PHS Act requires coverage of ''immunizations,'' and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting moral convictions from certain health care mandates concerning issues such as sterilization, abortion and birth control.

B. Text of the Final Rules

In this section, the Departments describe the regulations from the Moral IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. We also note the regulatory text as it existed prior to the Religious and Moral IFCs, as appropriate. The Departments consider the exemptions finalized here to be an appropriate and permissible policy

[58] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. In the preamble to the companion final rules concerning religious exemptions published elsewhere in today's **Federal Register**, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these exemptions.

As noted above, various members of the public provided comments that were supportive, or critical, of the regulations overall, or of significant policies pertaining to the regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

1. Restatement of Statutory Requirements of Section 2713(a) and (a)(4) of the PHS Act (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) and (a)(4) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified those restatements to more closely align them with the text of section 2713(a) and (a)(4) of the PHS Act. Those sections cross-reference the other sections of the Departments' rules that provide exemptions to the contraceptive Mandate. After the Religious IFC changed those sections, the Moral IFC inserted, within those cross-references, references to the new § 147.133, which contains the text of the moral exemptions. The insertions correspond to the cross-references to the religious exemptions added by the Religious IFC. The Departments finalize these parts of the Moral IFC without change.

2. Exemption for Objecting Entities Based on Moral Convictions (45 CFR 147.133(a))

The previous regulations contained no exemption concerning moral convictions, as distinct from religious beliefs. Instead, at 45 CFR 147.131(a), they offered an exemption for houses of worship and integrated auxiliaries. In the remaining part of § 147.131, the previous regulations described the accommodation process for organizations with religious objections. The Religious IFC moved the religious exemption to a new section 45 CFR 147.132, and expanded its scope. The Moral IFC created a new section 45 CFR 147.133, providing exemptions for moral convictions similar to, but not exactly the same as, the exemptions for religious beliefs set forth in § 147.132.

The prefatory language of § 147.133(a) not only specifies that certain entities are ''exempt,'' but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) 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 certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are ''exempt'' by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as ''exempt,'' and in referring to the ''exemption'' encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.133(a) applies to several distinct entities involved in the provision of coverage to an objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When § 147.133(a)(1) and (a)(1)(i) specify that ''[a] group health plan,'' ''health insurance coverage provided in connection with a group health plan,'' and ''health insurance coverage offered or arranged by an objecting organization'' are exempt ''to the extent'' of the objections ''as specified in paragraph (a)(2),'' that language exempts the group health plans of the sponsors that object, and 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) (and as referenced by the parallel provisions in 26 CFR 54.9815 through 2713(a)(1)(iv) and 29 CFR 2590.715 through 2713(a)(1)(v)), 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. However, while a plan sponsor's or arranger's objection removes penalties from that group health plan's issuer, it only does so with respect to that group health plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.133(a)(1)(iii) is included below.

The exemptions in § 147.133(a)(1) 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. Some commenters stated it was unclear whether the plans of entities or individuals that morally object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite moral objection to some, but not all, contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules the Departments finalize the prefatory language of § 147.133(a) so that the first sentence of that paragraph states that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, ''to the extent of the objections specified below.'' The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying ''to the extent'' of the objection(s).

The exemptions contained in previous regulations, at § 147.131(a), did not require an exempt entity to submit any particular self-certification or notice, either to the government or to the entity's issuer or third party administrator, in order to obtain or qualify for their exemption. Similarly, under the expanded exemptions in § 147.133, the Moral IFC did not require exempt entities to comply with a self-certification process. We finalize that approach without change. Although exempt entities do not need to file notices or certifications of their exemption, and these 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 identifies what benefits are provided to participants and beneficiaries under the plan; 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.[59] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, 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.

Some commenters supported this approach, while others did not. Those in favor suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use their exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process.

After considering the comments, the Departments continue to believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption, although there may have been thousands of houses of worship and integrated auxiliaries covered by the previous exemption and the Departments think it likely that only a small number of entities will use the moral exemption. Adding a self-certification or notice to the exemption would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices are to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement and accountability under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries will know whether their health plan claims a contraceptive Mandate exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these final rules to continue to not require notices or self-certifications for using the exemption.

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these final rules. The exemptions in these final rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. Final rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (In the companion rules concerning religious beliefs published elsewhere in today's **Federal Register**, the Departments discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed in the companion religious final rule published elsewhere in today's **Federal Register**, the Departments have added language from the previous regulations, in § 147.131(f), to protect issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in, and derived from, the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators. The Departments do not believe it necessary to do so in these final rules.

Commenters disagreed about the likely effects of the moral exemptions on the health coverage market. Some commenters stated that expanding the exemptions to encompass moral convictions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans, or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or only some contraceptives—to houses of worship and integrated auxiliaries, and some commenters and litigants said that issuers were doing so. These cases

[59] 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).

where plans did not need to comply with the Mandate, and the Departments' previous accommodation process which had the effect of allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[60]

Concerning the prospect raised by some commenters of different risk pools between men and women, section 2713(a) of the PHS Act itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage will be required. The Moral IFC and these final rules do not require issuers to offer health insurance products that satisfy morally objecting entities, they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to objecting entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

3. Exemption for Certain Plan Sponsors (45 CFR 147.133(a)(1)(i))

The exemption in § 147.133(a)(1)(i) of the Moral IFC covers a group health plan and health insurance coverage for non-governmental plan sponsors that object as specified in paragraph (a)(2), and that are either nonprofit organizations, or are for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The Departments finalize this paragraph without change, and discuss each part of the paragraph in turn.

a. Plan Sponsors in General (45 CFR 147.133(a)(1)(i) Prefatory Text)

Under the plan sponsor exemption in § 147.132(a)(1)(i), the prefatory text in that paragraph specifies that it encompasses group health plans, and health insurance coverage provided in connection with such group health plans, that are sponsored by certain kinds of entities, namely, nonprofit organizations or for-profit entities that have no publicly traded ownership interests.

Such plan sponsors, if they are otherwise nonprofit organizations or for-profit entities that have no publicly traded ownership interests, can include entities that are not employers (for example, a union, or a sponsor of a multiemployer plan), where the plan sponsor objects based on sincerely held moral convictions to coverage of contraceptives or sterilization. Plan sponsors encompassed by the exemption can also include employers, and consistent with the definition of ''employer'' in 29 CFR 2510.3–5, can include association health plans, where the plan sponsor is a nonprofit organization or a for-profit entity that has no publicly traded ownership interests.

Some commenters objected to extending the exemption to plan sponsors that are not single employers, arguing that they could not have the same kind of moral objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite moral objection. The Departments conclude that it is appropriate, where a plan sponsor of a multiemployer plan or multiple employer plan adopts a moral objection using the same procedures that such a plan sponsor might use to make other decisions, to respect that decision by providing an exemption from the Mandate.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.133(a)(1)(i), which instead limits the moral exemptions to ''non-governmental plan sponsors.'' As noted above, the Departments sought public comment on whether to extend the exemptions to non-federal governmental plan sponsors. Some commenters suggested that the moral exemptions should include government entities because other conscience laws can include government entities, such as when they oppose offering abortions. Others disagreed, contending that governmental entities should not or cannot object based on moral convictions, or that it would be unlawful for them to do so.

The Departments are sympathetic to the arguments of commenters that favor including government entities in the exemption for moral convictions. The protections outlined in the first paragraph of the Church Amendments for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Both the Weldon and Coats-Snowe Amendments also protect state and local government entities from providing, promoting, or paying for abortions in particular ways.[61] Congress has generally not limited protections for conscience based on the nature of an entity—even in the case of governmental entities.

At the same time, the Departments do not at this time have information suggesting that an exemption for governmental entities is needed or desired. The Departments have not been sued by any governmental entities raising objections to the Mandate based on non-religious moral convictions. Although the Departments sought public comment on the issue, the Departments received no public comments identifying governmental entities that need or desire such an exemption. Rather, the Departments are aware of governmental entities that, despite not possessing their own objections to contraceptive coverage, have acted to protect their employees who have conscientious objections to receiving contraceptive coverage in their employer-provided health insurance plans. *See Wieland* v. *U.S. Dep't of Health & Human Servs.,* 196 F. Supp. 1010, 1015–16 (E.D. Mo. 2016) (quoting Mo. Rev. Stat. 191.724). The individual exemption adopted in these rules will ensure the Mandate is not an obstacle to those efforts.

Thus, in light of the balance of public comments, the Departments decline to extend the moral convictions exemption to governmental entities. As is the case with the Departments' decision not to extend the moral exemption to publicly traded for-profit entities, this decision does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions

[60] *See also Real Alternatives,* 867 F.3d 338, 389 (3d Cir. 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)).

[61] Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), 132 Stat. at 764 (protecting any ''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); 42 U.S.C. 238n (protecting entities that object to abortion, including, but not limited to, any ''postgraduate physician training program'').

without categorically excluding governmental entities. The Departments remain open to the possibility of future rulemaking on this issue if the Departments become aware of a governmental entity seeking to be exempt from the contraceptive Mandate.

b. Nonprofit Organizations (45 CFR 147.133(a)(1)(i)(A))

As discussed above, some commenters opposed offering exemptions based on moral convictions to any plan sponsors, and/or objected to doing so for nonprofit organizations, on various grounds, including but not limited to arguments that the benefits of contraception access should override moral objections, entities cannot assert moral objections, and moral objections burden third parties. Other commenters supported the exemptions, generally defending the interest of nonprofit organizations not to be forced to violate their moral convictions, supporting the history of government protection of moral convictions in similar contexts, and disputing the claims of opponents of the exemptions.

The Departments are aware, through litigation, of only two non-religious nonprofit organizations with moral objections to the contraceptive Mandate. Many more nonprofit religious organizations have sued suggesting—as discussed below—that the effect of this exemption for non-religious nonprofit objections to the Mandate will be far less significant than commenters who oppose the exemption believe it will. The two non-religious nonprofit organizations that challenged the Mandate in court provide a good illustration of the reasons why the Department has decided to provide this exemption to nonprofit organizations. Both organizations have said in court they oppose certain contraceptives on non-religious moral grounds as being abortifacient and state that they only hire employees who share that view. Public comments and litigation reflect that many nonprofit organizations publicly describe their beliefs and convictions. Government records and many of those groups' websites also often reflect those groups' religious or moral character, as the case may be. If a person who desires contraceptive coverage works at a nonprofit organization, the Departments view it as sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit organization that opposes contraceptive coverage to hire a person who disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association 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.[62]

The Departments agree with commenters who support offering the exemption to nonprofit organizations and believe that doing so is an appropriate protection and is not likely to have a significant impact on women who want contraceptive coverage.

c. For-Profit Entities (45 CFR 147.133(a)(1)(i)(B))

With respect to for-profit organizations addressed in § 147.133(a)(1)(i)(B), in the Moral IFC, the Departments did not limit the exemption to nonprofit organizations, but also included some for-profit entities. Some commenters supported including for-profit entities in the exemption, saying owners of such entities exercise their moral convictions through their businesses, and that such owners should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise moral convictions or should not have their moral opposition to contraceptive coverage protected by the exemption. Some commenters stated that the entities should not be able to impose their beliefs about contraceptive coverage on their employees and that doing so constitutes discrimination.

The Departments agree with commenters who support including some for-profit entities in the exemption. 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 nonprofit organizations or for-profit entities. In addition, nearly half of the states either impose no contraceptive coverage requirement or offer ''an almost unlimited'' exemption encompassing both ''religious and secular organizations.'' [63] States also generally protect moral convictions in other health care conscience laws whether or not an entity operates as a nonprofit.[64]

Extending the exemption to certain for-profit entities is also 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,* the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization and rejected the Departments' argument to the contrary. 134 S. Ct. at 2768–75. The mechanisms by which a for-profit company makes decisions of conscience, or resolves disputes on those issues among their owners, are problems that ''state corporate law provides a ready means'' of solving. *Id.* at 2774–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby.*[65] Because all of those appear to be informed by religious beliefs, extending the exemption to entities with non-religious moral convictions would seem to have an even smaller impact on access to contraceptive coverage.

The Moral IFC only extended the exemption covering for-profit entities to those that are closely held, not to for-profit entities that are publicly traded, but asked for comment on whether publicly traded entities should be included in the moral exemption. In this way the Moral IFC differed from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in the Religious IFC, at § 147.132(a)(1), finalized in companion rules published elsewhere in today's **Federal Register**.

Some commenters supported including publicly traded entities in the moral exemption, contending that publicly traded entities have historically taken various positions on important public concerns beyond merely seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to establish and exercise moral convictions against contraceptive coverage. They observed that large publicly traded entities are exempt from the contraceptive Mandate by means of the grandfathering provision of the ACA, so

[62] 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).

[63] ''Insurance Coverage of Contraceptives,'' The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

[64] *See, e.g.,* ''Refusing to Provide Health Services,'' The Guttmacher Institute (June 1, 2018), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.*

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

that it is inappropriate to refuse to exempt publicly traded entities that actually have sincerely held moral convictions against compliance with the Mandate. They further argued that in some instances there are closely held companies that are as large as publicly traded companies of significant size. They also stated that other protections for moral convictions in certain federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines ''persons'' to include all forms of corporations, not just closely held corporations, at 1 U.S.C. 1. Additionally, some commenters were concerned that not providing a moral exemption for publicly traded for-profit entities but allowing a religious exemption for publicly traded for-profit entities (as was allowed in the Religious IFC, and as is allowed in the companion religious final rules published elsewhere in today's **Federal Register**), may raise Establishment Clause questions, may cause confusion to the public, and may make the exemptions more difficult for the Departments and enforcing agencies to administer. They stated that it is incongruous to include publicly traded entities in the exemption for religious beliefs, but exclude them from the exemption for moral convictions.

Other commenters opposed including publicly traded companies in these moral exemptions. Some stated that such companies could not exercise moral convictions and opposed the effects on women if they would. They also objected that including such companies, along with closely held businesses, would extend the exemptions to all or virtually all companies. Some commenters stated that many publicly traded companies would use a moral exemption if available to them, because many closely held for-profit businesses expressed religious objections to the Mandate, or availed themselves of the religious accommodation.

As is the case for non-federal governmental employers, the Departments are sympathetic to the arguments of commenters that favor including publicly traded entities in the exemption for moral convictions. In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without regard to their ownership status. 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; the protections of the Church Amendments do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, 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. Other federal conscience protections in the health sector apply in the same manner:

- The Coats-Snowe Amendment (42 U.S.C. 238n) provides certain protections for health care entities and postgraduate physician training programs that, among other things, choose not to perform, refer for, or provide training for, abortions.
- The Weldon Amendment [66] 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.
- The ACA 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. (42 U.S.C. 18113).[67]
- Social Security Act sections 1852(j)(3)(B) (Medicare) and 1932(b)(3)(B) (Medicaid), 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B), provide protections so that the statutes cannot be construed to require organizations that offer Medicare Advantage and Medicaid managed care plans in certain contexts to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds.
- Congress's most recent statement on 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, 2018, Public Law 115–141, Div. E, Sec. 808.

In all of these instances, Congress did not limit the protection for conscience based on the nature of the entity—and did not exclude publicly traded entities from protection.

At the same time, as stated in the Moral IFC, the Departments continue to lack significant information about whether there is a need to extend the expanded exemption to publicly traded entities. The Departments have been sued by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, as well as by closely held for-profit entities expressing religious objections, but not by any publicly traded entities. In addition, the Departments sought public comments on whether publicly traded entities might benefit from extending the moral exemption to them. No such entities were brought to the attention of the Department through the comment process. The Supreme Court concluded it is improbable that 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.'' *Hobby Lobby,* 134 S. Ct. at 2774. It would appear to be even less probable that publicly traded entities would adopt that view based on non-religious moral convictions.

In light of the balance of public comments, the Departments decline to extend the moral convictions exemption to publicly traded entities. Because the Departments are aware of so many closely-held for-profit entities with religious objections to contraceptive coverage, and of some nonprofit entities with non-religious moral objections to contraceptive coverage, the Departments believe it is reasonably possible that closely held for-profit entities with non-religious moral objections to contraceptive coverage might exist or come into being. The Departments have also concluded that it is reasonably possible, even if improbable, that publicly traded entities with religious objections to contraceptive coverage might exist or come into being. But the Departments conclude there is not a similar probability that publicly traded for-profit entities with non-religious moral objections to contraceptive

[66] See Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d) (Mar. 2018).

[67] The lack of the limitation in this provision may be particularly relevant since it was enacted in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—were promulgated.

coverage may exist and need to be included in these expanded exemptions. The decision to not extend the moral exemption to publicly traded for-profit entities in these rules does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions without categorically excluding publicly traded entities. The Departments remain open to the possibility of future rulemaking on this issue, if we become aware of the need to expand the exemptions to publicly traded corporations with non-religious moral objections to all (or a subset of) contraceptives.

In contrast, the Departments finalize, without change, the Moral IFC's extension of the exemptions in these rules to closely held for-profit entities with moral convictions opposed to offering coverage of some or all contraceptives. The Departments conclude that it is sufficiently likely that closely held for-profit entities exist or may come into being and may maintain moral objections to certain contraceptives, so as to support including them in these expanded exemptions. The Departments seek to remove an obstacle that might prevent individuals with moral objections from forming or maintaining such small or closely held businesses and providing health coverage to their employees in accordance with their moral convictions.

In defining what constitutes a closely held for-profit entity to which these exemptions extend, the Moral IFC used language derived from the July 2015 final regulations. Those regulations, in offering the accommodation (not an exemption) to religious (not moral) closely held for-profit entities, did so by attempting to positively define what constitutes a closely held entity, formulating a multi-factor, and partially open-ended, definition for that purpose. (80 FR 41313). 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. Instead of attempting to positively define closely held businesses in the Moral IFC, however, the Departments considered it much clearer, effective, and preferable to define the category negatively, by reference to one element of the previous definition: 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).

4. Institutions of Higher Education (45 CFR 147.133(a)(1)(ii))

The previous regulations did not exempt plans arranged by institutions of higher education, although they did include, in the accommodation, plans arranged by institutions of higher education similarly to the way in which the regulations provided the accommodation to plans of nonprofit religious employers. (See 80 FR 41347). The Moral IFC provided an exemption, in § 147.133(a)(1)(ii), encompassing institutions of higher education that arrange student health insurance coverage, and stating the exemption would operate in a manner comparable to the exemption for employers with respect to plans they sponsor. In these final rules, the Departments finalize § 147.133(a)(1)(ii) with one change.

These rules treat the health plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. The rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these 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) with objections to the Mandate based on sincerely held moral convictions, to their arrangement of student health insurance coverage, in a manner comparable to the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

Some commenters supported including, in the exemptions, institutions of higher education that provide health coverage for students through student health plans but have moral objections to providing certain contraceptive coverage. They stated that moral exemptions allow freedom for certain institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemption would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result.

In the Departments' view, the reasons for extending the exemption to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. The Departments are not aware of any institutions of higher education that arrange student health insurance coverage and object to the Mandate based on non-religious moral convictions. But because the Departments have been sued by several institutions of higher education that arrange student health insurance coverage and object to the Mandate based on religious beliefs and by several nonprofit organizations with moral objections, the Departments believe the existence of institutions of higher education with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible to justify including protections for such entities in these final rules.

The Departments conclude that this aspect of the exemption is likely to have a minimal impact on contraceptive coverage for women at institutions of higher education. As noted above, the Departments are not aware of any institutions of higher education that would currently qualify for the objection. In addition, only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities, as opposed to from other sources, and an even smaller number receive such coverage from schools objecting to contraceptive coverage. Exempting institutions of higher education that object to contraceptive coverage based on moral convictions does not affect student health insurance contraceptive coverage at the vast majority of institutions of higher education. The exemption simply makes it legal under federal law for institutions to adhere to moral convictions that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, because it makes it easier for students to attend institutions of higher education that hold those views, if the institutions exist or come into being and students choose to attend them. Moreover, because institutions of higher education have no legal obligation to sponsor student health insurance coverage, providing this moral exemption removes an obstacle to such institutions sponsoring student health insurance coverage, thus possibly encouraging

more widespread health insurance coverage.

As noted above, after seeking public comment on whether the final moral exemptions rules should be extended to include non-federal governmental entities, the Departments have concluded they should only include non-governmental entities. For the same reasons, the Departments are inserting a reference into § 147.133(a)(1)(ii) specifying that it includes an institution of higher education ''which is non-governmental.'' This language is parallel to the same limiting phrase used in the religious exemptions rule governing institutions of higher education, at § 147.132(a)(1)(ii). Thus, the first sentence of § 147.133(a)(1)(ii) is finalized to read: ''An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section.'' The remaining text of § 147.133(a)(1)(ii) is finalized without change.

5. Health Insurance Issuers (45 CFR 147.133(a)(1)(iii))

The Moral IFC extended 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. The issuer exemption only applied to the group health plan if the plan itself was also exempt under an exemption for the plan sponsor or individuals. In these final rules, the Departments finalize § 147.133(a)(1)(iii) without change.

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 contraceptive 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 whose plans are otherwise exempt based on that objection. An exempt issuer can then offer an exempt product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. 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 exempt issuer 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 these rules, issuers that hold their own objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their moral convictions, or if they are exempt based on their religious beliefs under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held religious beliefs, that are exempt under those companion final rules, 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.

Some commenters supported including this exemption for issuers in these rules, both to protect the moral convictions of issuers, and so that, in the future, issuers would be free to organize that may wish to specifically serve plan sponsors and individuals that object to contraception based on religious or moral reasons. Other commenters objected to including an exemption for issuers. Some commenters stated that issuers cannot exercise moral convictions, while others stated that exempting issuers would threaten contraceptive coverage for women. Some commenters stated that it was arbitrary and capricious for the Departments to provide an exemption for issuers if they do not know that issuers with qualifying moral objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, 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 or group insurance coverage.

The issuer exemption serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors, plans, and individuals that independently qualify for an exemption, will remove a possible obstacle to issuers with moral convictions being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held moral convictions will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers both from being 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.

The Departments reject the proposition that issuers cannot exercise moral convictions. 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 Medicare Advantage or Medicaid. The Weldon Amendment specifically protects, among other entities, HMOs, health insurance plans, and ''any other kind of health care facility[ies], organization[s] or plan[s]'' as a ''health care entity'' from being required to provide coverage of, or pay for, abortions. See, for example, Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d).[68] The most recently enacted Consolidated Appropriations Act declares that Congress supports a

[68] ACA section 1553 protects an identically defined group of ''health care entities,'' including provider-sponsored organizations, HMOs, health insurance plans, and ''any other kind of . . . plan,'' from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

''conscience clause'' to protect moral convictions concerning ''the provision of contraceptive coverage by health insurance plans.'' *See id.* at Div. E, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion Religious IFC and final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**.[69]

6. Description of the Moral Objection (45 CFR 147.133(a)(2))

The Moral IFC set forth the scope of the moral objection of objecting entities in § 147.133(a)(2), so that it applies to the extent an entity described in paragraph (a)(1), based on sincerely held moral convictions, objects to ''establishing, maintaining, providing, offering, or arranging'' either ''coverage or payments'' for contraceptives, or ''for a plan, issuer, or third party administrator that provides or arranges such coverage or payments.'' The Departments are finalizing this exemption with structural changes separating the second half of the sentence into separate subparagraphs, so as to more clearly specify, as set forth in the Moral IFC text, that the objection may pertain either to coverage or payments for contraceptives, or to a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

Some commenters observed that, by allowing exempt plan sponsors to object to ''some or all'' contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators.

The Departments have concluded, however, that just as the previous exemption rules allowed certain religious plan sponsors to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. These rules do not require any issuer or third party administrator to contract with an exempt entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual plan variation. These rules simply remove the federal Mandate, in some cases, where it could have led to penalties on an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying moral objection. That approach is consistent with the approach under the previous regulations, which did not require issuers and third party administrators to contract with exempt plans of houses of worship or integrated auxiliaries if they did not wish to do so.

The definition does not specify that the moral convictions that can support an exemption need to be non-religious moral convictions. We find it unnecessary to limit the definition in that way. Even though moral convictions need not be based on religious beliefs, religious beliefs can have a moral component. It is not always clear whether a moral conviction is based on religious tenets. As noted in *Welsh,* a moral conviction can be ''purely ethical or moral in source and content but that nevertheless . . . occupy in the life of that individual a place parallel to that filled by God [and] function as a religion in his life.'' 398 U.S at 340. One reason for providing exemptions for moral convictions is so that the government need not engage in the potentially difficult task of parsing which convictions are religious and which are not. If sincerely held moral convictions supporting an exemption are religious, they will be encompassed by the exemption for sincerely held religious beliefs. If the moral convictions are not also religious, or if their religious quality is unclear but they are ethical or moral, they can qualify as sincerely held moral convictions under these rules if the other requirements of these rules are met.

The Departments are not aware of any entities that qualify for an exemption under the religious exemptions finalized elsewhere in today's **Federal Register**, but not under the moral exemptions finalized here, such as publicly traded entities. If publicly traded entities object to the Mandate, it seems unlikely their objection is based on moral convictions and not religious beliefs, given that many more objections to the Mandate have been based on religious beliefs. Thus, the Departments find it unlikely that they would be faced with a situation where a publicly traded entity, for example, has an objection to the contraceptive Mandate, but it is not clear whether that objection is based on sincerely held religious beliefs or merely based on sincerely held moral convictions.

7. Individuals (45 CFR 147.133(b))

The previous regulations did not provide an exemption for objecting individuals. The Moral IFC provided such an exemption for objecting individuals (referred to here as the ''individual exemption''), using the following language at § 147.133(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.''

The Departments finalize this language, with changes in response to public comments in some of the text and in a new sentence at the end of the paragraph that clarify how the exemption applies.

Section 147.133(b) sets forth a special rule pertaining to individuals (referred to here as the ''individual exemption''). This rule exempts plans of certain individuals with moral objections to contraceptive coverage where the plan sponsor and, as applicable, issuer is willing to provide a plan compliant with the individuals' objections to such plan sponsors or individuals, as applicable.

Some commenters supported this exemption as providing appropriate protections for the moral convictions of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to coverage of contraceptives but is willing (and, as applicable, the issuer is also willing) to provide coverage consistent with an individual's moral objections. They commented that this exemption

[69] 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 employers. Because the issuer exemption operates more narrowly than the exemption for plan sponsors operates, in the ways described here (*i.e.,* the issuer exemption does not operate unless the plan sponsor or individual, as applicable, is also exempt), and exists in part to help preserve market options for objecting plan sponsors and individuals, the Departments consider it appropriate to not draw such a distinction among issuers.

would free individuals from having their moral convictions placed in tension with their desire for health coverage. They also contended that the individual exemption would not undermine any government interests behind the contraceptive Mandate, since the individuals would be choosing not to have the coverage. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage.

Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. The Departments note that this individual exemption only operates in the case where the issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases. But the Departments do not wish to pose an obstacle to the offering of such coverage.

The Departments note that their decision is consistent with the decision by Congress to provide protections in certain contexts for individuals who object to prescribing or providing contraceptives contrary to their moral convictions. *See, for example,* Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Mar. 23, 2018). While some commenters argued that such express protections are narrow, 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 Div. E, Sec. 808. A moral exemption for individuals would not be effective if the government did not, at the same time, permit issuers and group health plans to provide individuals with policies that comply with their 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 generally, or, as applicable, to any other individual policies the issuer offers. Thus, 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. 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). For parallel reasons, as the Departments stated in the Moral IFC (83 FR at 47853 through 47854), this individual exemption does not undermine the governmental interests furthered by the contraceptive coverage requirement, 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.

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 group health insurance policies without coverage for contraception based on employees' religious beliefs ''or 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 in these rules, employers sponsoring governmental plans would be free to honor the moral 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.

In the separate companion IFC to the Moral IFC—the Religious IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Moral IFC said a willing issuer and plan sponsor may offer ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects'' under the individual exemption, the Religious IFC described what may be offered to objecting individuals as ''a separate benefit package option, or a separate policy, certificate or contract of insurance.'' Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of ''a separate group health plan,'' because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual exemption by making a technical change to the language to adopt the formulation, ''a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects.''

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), 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 rules do not affect such other laws or terms.

The Departments received numerous comments about the administrative burden from the potential variations in moral convictions held by individuals. Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives, while others expressed concern that the variations in the kinds of contraceptive coverage to which individuals object might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the moral convictions of an exempt individual.

If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Moral IFC implied this conclusion by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, that language differed from the language applicable to the exemptions under § 147.133(a), which specifies that those exemptions apply ''to the extent'' of the moral objections, so that, as discussed above, they include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b), with the following change, by adding the following sentence at the end of the paragraph: ''Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held moral convictions objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to the employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under her policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to do so. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with changes, to read as follows: ''(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 group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

8. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations did not offer the accommodation process to entities with moral non-religious objections. The Religious IFC amended the accommodation regulations to offer it to all entities that are exempt on the basis of religious beliefs under § 147.132, as an optional process in which such entities could participate voluntarily. The Moral IFC did not change that accommodation process, but inserted references in it to the new section § 147.133, alongside the references to section § 147.132. These changes made entities eligible for the voluntary accommodation process if they are exempt on the basis of moral convictions. The references were inserted in 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A.

In these rules, the Departments finalize, without change, the Moral IFC's revisions of 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. The operation of the accommodation process, changes made in the Religious IFC, and public comments concerning the accommodation, are more fully described in the Religious IFC, and in the companion final rules concerning the religious exemptions and accommodation, published elsewhere in today's **Federal Register**. Those descriptions are incorporated here by reference to the extent they apply to these rules.

Many commenters supported extending the accommodation process to entities with objections based on moral convictions. Others objected to doing so, raising arguments parallel to their objections to creating exemptions for group health plan sponsors with moral convictions. For much the same reasons discussed above concerning why the Departments find it appropriate to exempt entities with moral objections to contraceptive coverage, the Departments find it appropriate to extend the optional accommodation process to these entities. The Departments observe that, to the extent such entities wish to use the process, it will not be an obstacle to contraceptive coverage, but will instead help deliver contraceptive coverage to women who receive health coverage from such entities while respecting the moral convictions of the entities. The Departments are not aware of entities with non-religious moral convictions against contraceptive coverage that also consider the accommodation acceptable and would opt into it, but we are aware of a small number of entities with non-religious moral objections to the Mandate. The Departments, therefore, continue to consider it appropriate to extend the optional accommodation to such entities in case any wish to use it. Below, albeit based on very limited data, the Departments estimate that a small number of entities with non-religious moral objections may use the accommodation process.

9. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under ''Contraceptive methods and counseling,'' ''[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.'' The previous regulations concerning the exemption and the accommodation used the terms ''contraceptive services'' and ''contraceptive coverage'' as catch-all terms to encompass all of those Guidelines requirements. The 2016 update to the Guidelines are similarly worded. Under ''Contraception,'' they include the ''full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration,'' ''instruction in fertility awareness-based methods,'' and ''[c]ontraceptive care'' to ''include contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method).'' [70]

To more explicitly state that the expanded exemptions encompass any of the contraceptive or sterilization services, items, procedures, or related patient education or information that have been required under the Guidelines, the Moral IFC included a definition of contraceptive services, benefits or coverage, at 45 CFR 147.133(c). These rules finalize that definition without change.

10. Severability

The Departments finalize, without change, the severability clause set forth at § 147.133(d).

C. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that moral objections to the Mandate should not be permitted in cases where contraceptive methods are used to treat such existing medical conditions and not for preventive purposes, even if those contraceptive methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to ''preventive'' care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to ''preventive'' services or care.[71] The requirement in the Guidelines concerning ''contraception'' specifies several times that it encompasses ''contraceptives,'' that is, medical products, methods, and services applied for ''contraceptive'' uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[72] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so that plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use. Section 2713(a)(4), however, draws a distinction between preventive and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of care unless it is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are

[70] ''Women's Preventive Services Guidelines,'' HRSA (last reviewed Oct. 2017), *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[71] *Id.*

[72] 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 from contraceptives relating to conditions other than pregnancy.'' 77 FR 8727 & n.7. This was not, however, an assertion that 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 final rules, the Departments clarify here that the 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 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 and the contraceptive Mandate.

prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply if the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that, under section 2713(a)(4), exempt organizations must provide coverage for drugs or items prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Moral IFC that the moral exemptions are likely to affect only a very small number of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the exemptions could take contraceptive coverage away from many or most women. Still others opposed establishing the exemptions, but contended that accurately determining the number of women affected by the exemptions is not possible. Public comments included various statements that these exemptions would impact coverage for a large number of women, while others stated they would affect only a very small number. But few, if any, public commenters provided data predicting a precise number of entities that would make use of the exemptions for moral convictions nor a precise number of employees that would potentially be affected.

After reviewing the public comments, the Departments do not find the suggestions of commenters who predicted a very large impact any more reliable than the estimates set forth in the Religious and Moral IFCs. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious and Moral IFCs are still the best estimates available. The Departments' estimates are discussed in more detail in the following section.

III. Economic Impact and Paperwork Burden

The Departments have examined the impacts of these 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, section1102(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 1 year), and an ''economically significant'' regulatory action is subject to review by OMB. As discussed below regarding their anticipated effects, the these 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 rules and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

The Religious IFC amended the Departments' July 2015 final regulations. The Moral IFC amended those regulations further, and added an additional rule at 45 CFR part 147.133. These final rules adopt as final, and further amend, the amendments made by the Moral IFC. The Departments do so in conjunction with the amendments made in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. These rules provide an exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4), section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, for certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process by making the accommodation applicable to organizations with such convictions as an option. The exemption applies 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 some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action has been taken to provide for participation in the health insurance market by certain entities or individuals in a manner free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to ensure the preventive services coverage requirement is implemented in a way consistent with longstanding federal conscience statutes, to prevent lawsuits of the kind that were filed against the Departments when the expanded exemption in these final rules was not offered, and for the other reasons discussed above.

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 final rules, we believe it to be small.

With respect to the exemption for nonprofit organizations with objections based on moral convictions, as noted

above, the Departments are aware of two small nonprofit 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 nature of certain contraceptives subject to coverage under the Mandate.[73] One of them has obtained a permanent injunction against any regulations implementing the contraceptive Mandate, and so will not be affected by these final rules. Based on comments submitted in response to rulemakings prior to the Moral and Religious IFCs, the Departments believe that at least one other similar entity exists.[74] However, the Departments do not know how many similar entities exist and are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities.

The Departments 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 the conclusion in previous regulations that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (See 76 FR 46625 and 78 FR 39889). The Departments 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 requiring that such entities actually oppose contraception in order to be exempt (in contrast, the exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to contraceptive coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, the Departments relied on the assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is appropriate with respect to the expanded exemption for nonprofit organizations with objections based on moral convictions. To the knowledge of the Departments, the vast majority of organizations objecting to the Mandate assert objections based on religious beliefs. The only nonprofit organizations of which they 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 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 the Departments' previous regulations that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[75] Although the Departments are unable to find sufficient data on this issue, we believe that there are far fewer nonprofit organizations opposed to contraceptive coverage on the basis of moral convictions than there are houses of worship or integrated auxiliaries with religious objections to such coverage. Based on the limited data available, the Departments 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 certain contraceptive coverage. Therefore, the Departments expect that the moral exemption for nonprofit entities will have a minimal effect of reducing contraceptive coverage with respect to employees who want such coverage.

These rules extend the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and make exempt entities with moral objections eligible to avail themselves of the accommodation. The Departments are not aware of any institutions of higher education with this kind of non-religious moral convictions. Moreover, the Departments believe the overall number of entities that would 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. Public comments did not reveal the existence of any institutions of higher education with such moral convictions. Therefore, for the purposes of estimating the anticipated effect of these final rules on contraceptive coverage of women who wish to receive such coverage, the Departments 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 other 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 reasons similar to those given above for why the exemptions and accommodations are extended to other entities.

The Departments believe that the exemption for issuers with objections based on moral convictions 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, or in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. The 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 moral exemption will also cover for-profit entities that do not have publicly traded ownership interests and that have non-religious moral objections to the Mandate, if such entities exist. Some commenters agreed that the impact of these final rules would be no more than the Departments estimated in the Moral IFC, and some commenters stated the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended

[73] 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.

[74] 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*.

[75] *Cf., for example,* Frank Newport, ''Americans, Including Catholics, Say Birth Control Is Morally OK,'' Gallup, (May 22, 2012), *http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx* (''Eighty-two percent of U.S. Catholics say birth control is morally acceptable'').

pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women. These general comments did not, however, substantially assist the Departments in estimating the number of women that would potentially be affected by these exemptions for moral convictions specifically, or among them, how many unintended pregnancies would result, how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the estimated transfer costs, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives.

Some of the comments opposing these exemptions assert that they will lead to a large number of entities dropping contraceptive coverage. The Departments disagree; they are aware of only two entities that hold non-religious moral convictions against contraceptive coverage. Both only hire employees that share their beliefs, and one will not be affected by these final rules because it is protected by an injunction from any regulations implementing the contraceptive Mandate. Commenters cited no other specific entities that might assert these moral convictions, and did not provide better data to estimate how many entities might exist. Likewise, the Departments find it unlikely that any of the vast majority of entities that covered contraceptives before this Mandate was announced in 2011 would terminate such coverage because of these exemptions based on moral convictions. The Departments also find it unlikely that a significant number of for-profit entities, whose plans include a significant number of women, omitted contraceptive coverage before the ACA on the basis of objections grounded in non-religious moral convictions, and would claim an exemption under these final rules. No such entities, or data concerning such entities, were identified by public commenters, nor are the Departments aware of any involved in litigation over the Mandate.

Numerous for-profit entities claiming religious objections 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—and both were nonprofit organizations. Among the general public, polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.[76] Among non-religious persons, only a very small percentage of the population 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.[77] Combined, this suggests that 0.2 percent of Americans at most[78] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. The Departments 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 convictions set forth in these final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, the Departments assume that some similar for-profit entities with non-religious moral objections exist. But the Departments 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 without publicly traded ownership interests and with sincere moral objections to the Mandate, the Departments expect that fewer than 10 entities, if any, will do so—so the Departments assume nine for-profit entities will use the exemption in these final rules.

The moral 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.[79] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known how many employees would be employed by the for-profit employers that might claim this exemption, but as discussed above these final rules do not include publicly traded companies, and both of the two nonprofit entities that challenged the Mandate based on moral objections included fewer than five policyholders in their group plans. Therefore, the Departments assume that the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For 9 entities, the total number of policyholders would be approximately 81. DOL estimates that for each policyholder, there is approximately one dependent.[80] This amounts to approximately 162 covered persons. Census data indicate that women of childbearing age, *i.e.,* women aged 15 to 44, comprise 20.2 percent of the general population.[81] 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.[82] Thus, the Departments estimate that approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules.[83] In the companion final

[76] Frank Newport, ''Most Americans Still Believe in God,'' Gallup (June 29, 2016), *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

[77] Pew Research Center, ''Where the Public Stands on Religious Liberty vs. Nondiscrimination,'' Pew Research Center, 26 (Sept. 28, 2016), *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[78] 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.

[79] ''Health Insurance Coverage Bulletin,'' Dept. of Labor (June 28, 2016), 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.

[80] ''Health Insurance Coverage Bulletin'' Dept. of Labor'' (June 28, 2016), 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.*

[81] 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.'' Women's Preventive Services Guidelines, HRSA (last reviewed Oct. 2017), *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, e.g.,* ''Contraceptive Use in the United States,'' The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[82] *See* ''Contraceptive Use in the United States,'' The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[83] The Departments 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

Continued

rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, in health plans that cover contraception, is $584. Consequently, the Departments estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded moral exemption in these final rules is approximately $8,760.

The Departments estimate that these 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 avail themselves of the accommodation, although the Departments 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. While these final rules make it legal for issuers to offer insurance coverage that omits contraceptives to/for exempt entities and individuals, these final rules do not require issuers to do so. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, the Departments do not anticipate that these final rules will result in any burden from such entities acting to revoke their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the exemptions finalized in these final rules. The Departments acknowledge uncertainty in the estimate and, therefore, conducted a second analysis using an alternative framework, which is set forth in the companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, with reference to the analysis conducted in the Religious IFC. Under either estimate, these final rules are not deemed to be economically significant.

The Departments 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.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) imposes certain requirements with respect to federal regulations 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 Moral IFC was a set of interim final rules with comment, and in these final rules, the Departments finalize the Moral IFC with certain changes based on public comments. The Moral IFC was exempt from the notice and comment requirements of 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 did not apply to the Moral IFC. These final rules are, however, issued after a notice and comment period.

The Departments carefully considered the likely impact of the rules on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these 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—businesses and organizations which would otherwise be faced with the dilemma of complying with the Mandate (and violating their moral convictions), or of following their moral convictions and incurring potentially significant financial penalties for noncompliance—the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was 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** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. 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.

The Departments estimate that these final rules will not result in additional burdens not accounted for as set forth in companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**. As discussed there, rules 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(e)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burden related to these information collection requirements (ICRs) received emergency review and approval under OMB Control Number 0938–1344. They have been resubmitted to OMB in conjunction with this final rule and are pending re-approval.

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.

As discussed above, however, the Departments assume that no entities with non-religious moral objections to the Mandate will use the accommodation. The Departments know that no such entities were eligible for it until now, so that no entity possesses an accommodated status that would need to be revoked. Therefore, the Departments believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1344, as described in the final rules concerning religious beliefs issued contemporaneously with these final rules.

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. In an effort to consolidate the number of information collections the Department is combining OMB control numbers 1210–0150 and 1210–0152 under OMB control number 1210–0150 and discontinuing OMB control number 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 final rules make entities with certain moral convictions eligible for the accommodation, the Department assumes (1) that no entities will use the accommodation rather than the exemption, and (2) entities using the moral exemption would not have to revoke an accommodation, because they previously were not eligible for it. Therefore, the Department believes these final rules do not involve additional burden not accounted for under OMB control number 1210–0150, which is published elsewhere in today's issue of the **Federal Register** in connection with the companion Religious Exemption and Accommodation Preventive Health Service final rule. The Department will publish a notice informing the public of OMB's action with respect to the Department's submission of the ICRs under OMB control number 1210–0150.

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 [Affordable Care] 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.'' The Moral IFC and these 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), the Departments have estimated the costs and cost savings attributable to these rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[84] However, in order to avoid double-counting with the Moral IFC, which has already been tallied as an E.O. 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) (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 million or more (adjusted annually for inflation) in any 1 year.'' In 2018, that threshold is approximately $150 million. For purposes of the Unfunded Mandates Reform Act, the Moral IFC and these 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 $150 million 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 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.

IV. Statutory Authority

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

[84] 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 these final rules' 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.

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 Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October, 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

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. * * *

§ 54.9815–2713 [Amended]

■ 2. Section 54.9815–2713, 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''.

§ 54.9815–2713A [Amended]

■ 3. Section 54.9815–2713A, as amended elsewhere in this issue of the **Federal Register**, is further 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) 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

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ For the reasons set forth in the preamble, the Department of Labor adopts, as final, the interim final rules amending 29 CFR part 2590, published October 13, 2017 (82 FR 47838), without change.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47838) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 147, as revised elsewhere in this issue of the **Federal Register**, continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 5. Section 147.133 is amended by revising paragraph (a)(1) introductory text, (a)(1)(ii), (a)(2), and (b) to read as follow:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) * * *

(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, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, 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

* * * * *

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(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 group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

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