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The Honorable Ronald B. Leighton

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON,

Plaintiff,

v.

DONALD TRUMP, in his official capacity as President of the United States of America; ERIC HARGAN, in his official capacity as Acting Secretary of the United States Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, in his official capacity as Secretary of the Department of Treasury; U.S. DEPARTMENT OF TREASURY; R. ALEXANDER ACOSTA, in his official capacity as United States Secretary of Labor; and UNITED STATES DEPARTMENT OF LABOR,

Defendants.

NO. 2:17-cv-01510 RBL

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. INTRODUCTION

1. This suit challenges new rules issued by the Trump Administration that illegally jeopardize women's health and economic success in order to promote certain religious and moral views. The Administration implemented its new rules without regard to required legal

procedures. The State of Washington brings this suit to protect the state and its female residents from the substantial harm the Administration's new rules inflict.

2. The Affordable Care Act requires most health plans and insurance providers to cover certain preventive health services at no added cost to American men and women. The initial version of the Act did not adequately cover medically necessary preventive care for women, such as contraceptive services and screening for gestational diabetes. But the Senate introduced the Women's Health Amendment, and as finally enacted in 2010 the Affordable Care Act required health plans and insurance providers to include women's preventive services at no out-of-pocket cost to women.

3. Contraceptive use among women is widespread, with over 99% of sexually active women using at least one method during their lifetime. Consequently, the Women's Health Amendment has been a dramatic success. By 2013, most women had no out-of-pocket costs for their contraception. One study estimated that roughly $1.4 billion dollars per year in out-of-pocket savings on the pill resulted from the Affordable Care Act's contraceptive mandate.

4. The economic implications for women also are dramatic. Research links women's access to contraception to increases in the pursuit of college and advanced professional degrees, and to career trajectories with higher pay and prestige. Access to reliable contraception has contributed to women's increased earning power and the narrowing of the gender gap in pay.

5. On October 6, 2017, the Trump Administration issued two new regulations that slashed the contraceptive coverage introduced by the Affordable Care Act. One new set of rules allows any employer, not just a church or religious order, that asserts a religious objection to contraception to exempt itself from the requirement and carve out contraception coverage from

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its workplace insurance plan. The second set of rules authorizes certain employers with moral but not religious objections to contraception to opt out of Congress's requirement. Further, the new regulations change the prior rules and now allow objecting employers to dictate whether their women employees can get contraception directly from the insurance provider or third party administrator, at no cost to the employer.

6. The Administrative Procedure Act (APA) requires the federal government to provide public notice and opportunity for comment before changing substantive rights and obligations springing from the Affordable Care Act. Disregarding this obligation, the Trump Administration has made the new rules effective immediately without notice and comment rulemaking. Even if the Administration had complied with required procedures, its action would be illegal. The new regulations violate the Equal Protection guarantee and the Establishment Clause in the United States Constitution, the requirements of the Affordable Care Act, and the non-discrimination provisions of the Affordable Care Act, the Civil Rights Act, and the Pregnancy Discrimination Act. Finally, because the new regulations are arbitrary and capricious and ignore abundant evidence of the importance of contraceptive coverage to women's health and economic opportunity, they violate the substantive requirements of the APA.

7. The new regulations apply to nonprofit and for-profit employers, as well as to private colleges or universities with religious or moral objections to contraception. As a result of the new regulations, choices about contraception coverage will be made by employers and private colleges and universities that issue student plans. For many women, their employers or universities will determine whether they have no-cost coverage for the full range of

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FDA-approved contraceptive methods. Their choice of contraception will once again be limited by their own financial means.

8. More than 2.4 million women in Washington are of child-bearing age. Up to 746,200 women of child-bearing age in Washington State face losing contraception coverage entirely as a result of the Administration's new regulations, and others face losing no-cost contraceptive coverage. Washington maintains state government-funded programs to ensure Washington women have access to contraception and the economic opportunities it creates. Washington residents denied no-cost contraceptive coverage as a result of the new rules will be forced to turn to these programs to obtain contraceptive care. To prevent this injury to Washingtonians and the state's finances, Washington brings this suit to declare illegal and enjoin the new regulations.

II. JURISDICTION AND VENUE

9. The Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 2201(a) and 2202. The United States' sovereign immunity is waived by 5 U.S.C. § 702.

10. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) and (e)(1) and 5 U.S.C. § 703. Defendants are the President and three U.S. departments and their respective department heads. The State of Washington is a resident of this judicial district and no real property is involved in this action.

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III. PARTIES

PLAINTIFF STATE OF WASHINGTON

11. The Plaintiff is the State of Washington. The Attorney General is the chief legal adviser to the State of Washington. The Attorney General's powers and duties include acting in federal court on matters of public concern.

12. The State brings this action to redress harms to its proprietary interests, its quasi-sovereign authority, and its interests as *parens patriae*.

13. The State has declared its interest in protecting its female residents' "fundamental right to choose or refuse birth control" through statute. Wash. Rev. Code § 9.02.100.

14. The State has a quasi-sovereign interest in protecting the health and well-being of its residents. "The States . . . perform many of the vital functions of modern government – punishing street crime, running public schools, and zoning property for development, to name but a few – even though the Constitution's text does not authorize any government to do so. Our cases refer to this general power of governing, possessed by the States but not by the Federal Government, as the 'police power.' " *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 535-36 (2012). Health care is one of the police powers of Washington State. Washington's interest extends to ensuring that its residents have access to a full complement of affordable reproductive health care services, including contraception, and can make personal, private decisions about their reproductive health and family planning.

15. The State relies on Defendants' compliance with the procedural and substantive requirements of the APA in order to obtain timely and accurate information about activities that may have significant adverse impacts on access to health care, including contraceptive coverage,

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and to meaningfully participate in an impartial and public decision–making process that is consistent with the Affordable Care Act's requirements of free contraceptive coverage. Washington has been injured by Defendants' failure to comply with the notice-and-comment procedures required by the APA, because its agencies have been denied the opportunity to comment and be heard, prior to the effective date of the IFRs, concerning the impact of the rules on the State and its residents.

16. The State also has an interest in avoiding greater costs to provide subsidized contraception and costs relating to unintended pregnancies.

17. The State and its residents will suffer significant and irreparable harm if women's access to affordable contraception through employer-based health insurance is diminished.

DEFENDANTS

18. Defendant Donald Trump is the President of the United States, and issued Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017),[1] which directed Defendants to issue the rules challenged in this lawsuit. He is sued in his official capacity.

19. Defendant U.S. Department of Health and Human Services (HHS) is a federal cabinet department responsible for implementing and enforcing material portions of the Affordable Care Act. HHS is a Department of the Executive Branch of the U.S. Government, and is an agency within the meaning of 5 U.S.C. § 551(1). HHS is one of the agencies that issued the rules challenged in this lawsuit.

[1] https://www.gpo.gov/fdsys/pkg/FR-2017-05-09/pdf/2017-09574.pdf.

20. Defendant Eric Hargan is Acting Secretary of HHS. He is sued in his official capacity.

21. Defendant U.S. Department of Labor (DOL) is a federal cabinet department responsible for implementing and enforcing material portions of the Affordable Care Act. DOL is a Department of the Executive Branch of the U.S. Government, and is an agency within the meaning of 5 U.S.C. § 551(1). DOL is one of the agencies that issued the rules challenged in this lawsuit.

22. Defendant R. Alexander Acosta is Secretary of DOL. He is sued in his official capacity.

23. Defendant U.S. Department of Treasury (Treasury) is a federal cabinet department responsible for implementing and enforcing material portions of the Affordable Care Act. The Treasury is a Department of the Executive Branch of the U.S. Government, and is an agency within the meaning of 5 U.S.C. § 551(1). Treasury is one of the agencies that issued the rules challenged in this lawsuit.

24. Defendant Steven T. Mnuchin is Secretary of Treasury. He is sued in his official capacity.

IV. ALLEGATIONS

A. Statutory and Regulatory Background

1. The Affordable Care Act and the Contraceptive Coverage Requirement

25. In 2010, Congress enacted the Patient Protection and Affordable Care Act (Pub. L. No. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152) (collectively the ACA). The ACA aims to increase the number of Americans

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covered by health insurance and decrease the cost of health care. *Ntn'l Fed'n of Indep. Bus.*, 567 U.S. 519 at 538.

26. The ACA, in its initial form, required non-grandfathered[2] group health plans and insurance providers to cover three categories of preventive health services at no added cost to the plan participant or beneficiary: "(1) evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force; (2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and (3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration." 42 U.S.C. § 300gg-13(a)(1)-(3). Prevention is a well-recognized, effective tool in improving health and well-being and has been shown to be cost-effective in addressing many conditions early.[3]

27. Recognizing that the initial draft left out preventive services that "many women's health advocates and medical professionals believe are critically important," Senator Barbara Mikulski introduced the Women's Health Amendment, which added to the ACA's minimum coverage requirements a new category of preventive services specific to women's health. 155 Cong. Rec. 28841 (2009). The Amendment's proponents noted that women pay significantly more than men for preventive care, and that such cost barriers operated to block

[2] Grandfathered health plan coverage is that which has existed continually prior to March 23, 2010 and has not undergone any of several specified changes since that time. 29 C.F.R. § 2590.715-1251 (2010). The percentage of workers covered by grandfathered plans has decreased over time. http://www.kff.org/report-section/ehbs-2017-section-13-grandfathered-health-plans/.

[3] Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps 16 (2011).

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many women from obtaining needed care at all. *See, e.g.*, 155 Cong. Rec. 29070 (statement of Sen. Feinstein) ("Women of childbearing age spend 68 percent more in out-of-pocket health care costs than men."); *id*. at 29302 (statement of Sen. Mikulski) ("copayments are [often] so high that [women] avoid getting [preventive and screening services] in the first place."). The sponsors noted that increasing access to contraceptive services would yield important public health gains. *See, e.g.*, 155 Cong. Rec. 29768 (statement of Sen. Durbin) ("This bill will expand health insurance coverage to the vast majority of the [17 million women of reproductive age in the United States who are uninsured] . . . . This expanded access will reduce unintended pregnancies.").

28. As altered by the passage of the Women's Health Amendment, the ACA requires new insurance plans to include coverage without cost sharing of "with respect to women, such additional preventive care and screenings not [otherwise required] as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph." 42 U.S.C. § 300gg-13(a)(4). Congress included this provision because "women have different health needs than men, and these needs often generate additional costs." 155 Cong. Rec. 29070 (2009) (statement of Sen. Feinstein).

29. The Health Resources and Services Administration (HRSA) is a part of HHS. HRSA developed guidelines required under 42 U.S.C. § 300gg-13(a)(4) after consultation with the Institute of Medicine (IOM). The IOM is an arm of the National Academy of Sciences, an organization established by Congress "for the explicit purpose of furnishing advice to the Government." *Public Citizen v. Dep't of Justice*, 491 U.S. 440, 460, n.11 (1989).

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30. The IOM convened a group of independent experts, including "specialists in disease prevention [and] women's health," which prepared a report evaluating the efficacy of a number of preventive services. *See* Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps 10 (2011) (IOM Report). The IOM defined preventive services as measures "shown to improve well-being, and/or decrease the likelihood or delay the onset of a targeted disease or condition." *Id*. at 3.

31. Based on the IOM's review of the evidence, it recommended a number of preventive services for women, such as screening for gestational diabetes for pregnant women, screening and counseling for domestic violence, and at least one well-woman preventive care visit a year. IOM Report at 8-12. Consistent with the findings of "[n]umerous health professional associations" and other organizations, the IOM experts also determined that preventive coverage for women should include the "full range" of FDA-approved contraceptive methods. IOM Report at 10, 102-10. FDA-approved contraceptive methods include oral contraceptive pills, rings, patches, diaphragms and cervical caps, injections, implants, emergency contraceptive drugs, intrauterine devices (IUDs), and sterilization.

32. The IOM Report noted the disproportionate burden women carried for comprehensive health services and the adverse health consequences of excluding contraception from preventive care available to employees without cost sharing. IOM Report at 19 ("[W]omen are consistently more likely than men to report a wide range of cost-related barriers to receiving . . . medical tests and treatments and to filling prescriptions for themselves and their families."), 103-1-4, 107 (pregnancy may be contraindicated for women with certain medical conditions, for example, some congenital heart diseases, pulmonary hypertension, and Marfan

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syndrome, and contraceptives may be used to reduce the risk of endometrial cancer, among other serious medical conditions), 103 (women with unintended pregnancies are more likely to experience depression and anxiety, and their children face "increased odds of preterm birth and low birth weight"). The IOM also noted that nearly half of all pregnancies in the United States are unintended, and that unintended pregnancies can have adverse health consequences for both mothers and children. IOM Report at 102-103. In addition, the IOM observed, use of contraceptives leads to longer intervals between pregnancies, which "is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced." *Id*. at 103.

33. Consistent with the IOM's suggestions, HRSA adopted guidelines recommending access to "[a]ll [FDA-]approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity" as prescribed by a health care provider. HRSA, HHS, Women's Preventive Services Guidelines (August 2011), *available at* https://www.hrsa.gov/womens-guidelines/index.html (last visited September 29, 2017).

34. HHS, DOL, and the Treasury promulgated regulations requiring non-grandfathered group health plans to include coverage for, among other preventive services, the contraceptive services recommended in the HRSA Guidelines. 45 C.F.R. § 147.130(a)(1)(iv) (2013) (HHS); 29 C.F.R. § 2590.715-2713(a)(1)(iv) (2013) (Labor); 26 C.F.R. § 54.9815-2713(a)(1)(iv)(2013) (Treasury).

35. To address advancements in science and gaps identified in existing guidelines, including a greater emphasis on practice-based clinical considerations, HRSA awarded a

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five-year cooperative agreement in March 2016 to convene a coalition of clinician, academic, and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the IOM (now known as the National Academy of Medicine (NAM)).[4] The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative (WPSI). WPSI submitted its report "Recommendations for Preventive Services for Women" (hereinafter WPSI Report) to HHS in December 2016. WPSI Report at iii. As to contraception, WSPI recommended that adolescent and adult women have access to the "full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes." WPSI Report at 18.

36. HRSA updated its Women's Preventive Services Guidelines on December 20, 2016, taking into account the clinical recommendations from WPSI.[5] The Guidelines continue to recommend that "the full range of female-controlled" FDA-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care. https://www.hrsa.gov/womens-guidelines-2016/index.html.

2. Exemption for "Religious Employers"

37. While the Women's Health Amendment succeeded, a countermove which would have enabled any employer or insurance provider to deny coverage based on its asserted

[4] https://www.hrsa.gov/womens-guidelines-2016/index.html.
[5] https://www.hrsa.gov/womens-guidelines/index.html.

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"religious beliefs or moral convictions," the so-called "conscience amendment," was voted down by the Senate. 158 Cong. Rec. S539 (Feb. 9, 2012), S1162-S1173 (Mar. 1, 2012) (debate and vote). That amendment, as observed by Senator Mikulski, would have "pu[t] the personal opinion of employers and insurers over the practice of medicine." *Id*. at S1127 (Feb. 29, 2012).

38. Instead, implementing regulations authorized a much narrower exemption for religious employers (defined as "churches, their integrated auxiliaries, and conventions or associations of churches," and "the exclusively religious activities of any religious order" that are organized and operate as nonprofit entities. 45 C.F.R. § 147.131(a); 26 U.S.C. §§ 6033(a)(3)A)(i), (iii)) from the requirement to cover contraceptive services under the Guidelines. 45 C.F.R. § 147.131(a); 76 Fed. Reg. 46,621 (Aug. 3, 2011).

3. Accommodation for "Eligible Organizations"

39. Implementing regulations also provided an accommodation to certain "eligible organizations"—nonprofit or closely held for-profit entities[6] that object to providing coverage for some or all of the contraceptive items or services required to be covered under the Act. 45 C.F.R. § 147.131(b); 26 C.F.R. 54.9815-2713A(a). Such entities could opt out of providing contraceptive coverage by self-certifying to DOL or providing notice to the Secretary of HHS of their religious objections to coverage for all or a subset of contraceptive services. 45 C.F.R. § 147.131(b); 26 C.F.R. 54.9815-2713A(a).

[6] The regulations originally only provided an accommodation to nonprofit organizations. 78 Fed. Reg. 39,870, 39,872, 39,874-39,886 (July 2, 2013). However, the Supreme Court held in *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), that that the contraceptive coverage requirement substantially burdened the free exercise of a "closely-held" for-profit corporation's religion, and that since the government had not demonstrated that the same accommodation provided to non-profits could not be made available to closely-held for-profits, the Religious Freedom Restoration Act prohibited the government from imposing the requirement on closely-held corporations. 134 S. Ct. at 2785. Accordingly, the regulations were revised to make the accommodation from the contraception mandate available to closely-held corporations. 80 FR 41,323-41,324.

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40. When a group health insurance issuer receives notice that one of its clients has invoked the accommodation provision, the issuer must then exclude contraceptive coverage from the employer's plan and provide separate payments for contraceptive services for plan participants without imposing any cost-sharing requirements on the eligible organization, its insurance plan, or its employee beneficiaries. 45 C.F.R. § 147.131(c). In the case of self-insured organizations entitled to the accommodation, the third-party administrator of the organization must "provide or arrange payments for contraceptive services" for the organization's employees without imposing any cost-sharing requirements on the eligible organization, its insurance plan, or its employee beneficiaries. 26 C.F.R. § 54.9815-2713A(b). Thus, women employed by "eligible organizations" were still entitled under the ACA to coverage for FDA-approved contraception at no additional cost to themselves.

B. Executive Order 13798

41. On May 4, 2017, President Trump signed Executive Order 13798, entitled "Promoting Free Speech and Religious Liberty." This Executive Order is attached to this First Amended Complaint as Exhibit D. The Executive Order directs the Secretaries of Treasury, DOL, and HHS to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code." Under the express terms of the Executive Order, any amended regulations were required to comply with the ACA, as well as with federal non-discrimination laws and the Constitution.

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C. 2017 Interim Final Rules and 2017 Updated Guidelines

42. On October 6, 2017, relying in part on Executive Order 13798 as justification, HHS, DOL, and the Treasury issued two sets of Interim Final Rules with respect to preventive care services for women required to be covered under the ACA (collectively referred to as the IFRs).

43. Taken together, the IFRs greatly expand eligibility for a complete exemption to the ACA's requirement that employers ensure women have access to insurance coverage for contraception without cost. The new regulations expand the *entities* to which the exemption is available. Rather than applying just to churches and religious orders, the exemption now applies to *all* for-profit or nonprofit employers that assert an objection to contraception based on their religious beliefs. Women employees of these employers now can be required to pay for their contraception or, if they cannot, go without.

44. The IFRs also expand the *reason* the exemption may be claimed. The new regulations create an exemption for all employers, except those that are publicly traded, that have *moral* objections to contraception. These employers too can deny their women employees insurance coverage for contraception.

45. Furthermore, the IFRs significantly cut back the previous accommodation that allowed women who worked for religiously affiliated non-profits or closely held for-profit corporations to obtain contraception at no out-of-pocket cost. Most significantly, the accommodation is entirely voluntary to exempt employers; if an employer that qualifies for an exemption declines to seek the accommodation, it may ignore it. The new rules undercut the previous system whereby women employees of objecting employers nevertheless were entitled

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to obtain insurance coverage of contraception from the insurance carrier or third-party administrator, at no cost to their employer.

46. Further, the expanded exemption also applies to private institutions of higher education that issue student health plans, where they object to contraception for religious or moral reasons. These institutions may single out contraception, among all of their male and female students' health care needs, for denial of coverage. For these institutions, providing an accommodation that permits their female students to maintain insurance coverage for their contraception at no cost to the institution is entirely voluntary.[7]

47. The IFRs are not based upon sound scientific or empirical evidence. For example, the IFRs state that contraceptives are not effective in preventing unintended pregnancy. This is false and inconsistent with the weight of scientific and empirical evidence.

48. The first IFR issued by HHS, DOL, and the Treasury is entitled Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (hereinafter Religious IFR). 82 Fed Reg. 47,658 (Oct. 13, 2017)[8] As stated, the Religious IFR makes the religious exemption available to *any* objecting entity that claims to object to establishing, maintaining, providing, or arranging coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services based on its sincerely held religious beliefs.

49. The second IFR is entitled Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (hereinafter Moral IFR).

[7] State laws requiring fully-insured plans to provide access to contraceptive coverage have not been displaced by the new rules. *See infra* ¶ 69.

[8] The Religious IFR is are attached to this First Amended Complaint as Exhibit A.

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82 Fed. Reg. 47,838 (Oct. 13, 2017).[9] The Moral IFR creates a moral exemption from the requirement to cover contraceptive services available to any non-profit entity, for-profit entity with no publicly-traded ownership interests, institution of higher education, or issuer that so objects based on its "sincerely held moral convictions."

50. On October 6, 2017, HRSA also updated its "Women's Preventive Services Guidelines" (hereinafter 2017 Updated Guidelines) to provide that "[t]hese Guidelines do 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" as set forth in the Moral and Religious IFRs set forth above. HRSA, Women's Preventive Services Guidelines (October 2017), *available at* https://www.hrsa.gov/womens-guidelines/index.html (last visited October 6, 2017).[10] The Guidelines' support of the recommendation to provide coverage without cost sharing of "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity" is otherwise unaffected. *Id*.

51. The IFRs and 2017 Updated Guidelines vastly expand the exemption from the contraception coverage requirement previously available only to religious employers to include any "objecting organization," which is defined to include any other kind of entity other than a government employer. Under the IFRs and 2017 Updated Guidelines, any entity that "objects to establishing, maintaining, providing, offering, or arranging (as applicable) for coverage,

[9] The Moral IFR is attached to this First Amended Complaint as Exhibit B.
[10] The 2017 Updated Guidelines are attached to this First Amended Complaint as Exhibit C.

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payments, or a plan that provides coverage or payments for some or all contraceptive services" based on "religious beliefs," or any similar nonprofit or for-profit entity with no publically traded ownership interests based on "moral convictions" is completely exempt from the contraceptive mandate.

52. The IFRs and 2017 Updated Guidelines make the accommodation process-which provided a mechanism to ensure women still had access to contraceptive coverage at no cost to the employer—entirely optional for all objecting entities entitled to exemption.

53. The IFRs provide that "exempt entities will not be required to comply with a self-certification process." A company that wants to take advantage of the exemption need not certify that its owners have a religious or moral objection to contraception. It merely needs to drop or omit contraception coverage from its plan's terms and comply with other applicable law.

54. The IFRs and 2017 Updated Guidelines are substantive changes that were issued prior to the passing of any notice and comment period. The Departments cited statutory general rulemaking authority as the basis for foregoing notice and comment. Generic grants of rulemaking authority do not permit the denial of public participation required by the APA.

55. The Departments are not subject to any court order or statutory deadline requiring them to place the Interim Final Rules into effect without consideration of public comments on the changes they wrought.

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D. Injuries to the State and Its Residents

56. Washington has standing to bring this action because Defendants' IFRs and Updated 2017 Guidelines, if allowed to go into effect,[11] will cause immediate and substantial harm to the State's quasi-sovereign, proprietary and *parens patriae* interests.

1. Washington's Sovereign and *Parens Patriae* Interest in the Health and Well-Being of Its Residents

57. The State's quasi-sovereign interest in protecting the health and well-being of its residents includes ensuring that its residents have access to affordable contraception and can make personal, private decisions about their reproductive health and family planning unfettered by their employers. Indeed, the State's has declared its interest in protecting individuals' "fundamental right to choose or refuse birth control" through statute. Wash. Rev. Code § 9.02.100.

58. Eliminating the requirement for coverage of contraception services by employer-and higher education-sponsored health plans will also cause harm to Washington citizens, whom the State represents through its *parens patriae* authority.

59. Implementation of the IFRs and 2017 Updated HRSA Guidelines will affect the health and financial well-being of numerous women and families who reside in Washington.[12]

60. Pregnancy is a medical condition that poses risks to, and consequences for, a woman.

[11] The IFRs are currently subject to two preliminary injunctions prohibiting them from going into effect. *Commonwealth of Pennsylvania v. Trump, et. al*., No. 2:17-cv-04540-WB, Dkt. 59, at 8-17 (E.D. Pa. Dec. 15, 2017); *California, et. al. v. Hargan, et al*., Case No. 4:17-cv-05783 (N.D. Cal. Dec. 21, 2017).

[12] The available data focus on the impact of the provision or denial of contraception on women. However, the State recognizes that the denial of coverage for reproductive health care also affects people who do not identify as women, including some gender non-conforming people and some transgender men.

61. According to the American College of Obstetricians and Gynecologists, "[a]ccess to contraception is a medical necessity for women during approximately 30 years of their lives."[13]

62. Virtually all (99%) sexually active women in the United States have used at least one contraceptive method at some point in their lifetime.

63. Contraception use reduces the occurrence of unintended pregnancy and abortion.

64. Contraceptive use also helps women and couples time and space their births, which helps to reduce the risk of poor birth outcomes, such as low birth weight, preterm birth, and small size for gestational age.

65. Without insurance coverage, contraception costs can exceed $1,000 a year.

66. Early research has also associated the contraception coverage requirement with a historic drop in the U.S. abortion rate that occurred in 2014.

67. A recent nonpartisan poll found that a majority of women would struggle to afford birth control if they had a co-pay.[14]

68. Contraception coverage also impacts women's educations, careers, and economic standing. "The ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives." *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 856 (1992). The availability of

[13] ACOG Statement on Supreme Court Remand of *Zubik v. Burwell* (May 16, 2016), *available at* https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Supreme-Court-Remand-of-Zubik-v-Burwell (last visited Oct. 9, 2017).

[14] https://www.scribd.com/document/342699692/PerryUndem-Gender-and-Birth-Control-Access-Report.

contraceptives has been associated with wage gains made by women since the advent of legal methods of birth control in the 1960s.

69. Some contraceptive methods also are used for noncontraceptive purposes, such as treatment for acne, menstrual pain, and endometriosis.

70. American women have saved approximately $1.4 billion per year on birth control pills alone since the ACA began requiring coverage of contraception benefits. Prior to enactment of the ACA, contraception accounted for between 30% and 44% of women's out-of-pocket expenses for health care costs. When the ACA required coverage for contraception, women's out-of-pocket costs declined 38% for birth control pills and 68% for IUDs.

71. Washington has a Contraceptive Parity Rule that requires health plans that offer coverage of prescription drugs or devices to provide equal coverage for prescription contraceptives. WAC 284-43-5150. This Rule, however, does not require contraception to be covered without cost-sharing, and it cannot be enforced against employer self-funded insurance plans, which are governed by ERISA.

72. Removing the requirement for employer-sponsored plans to cover the full range of FDA-approved prescribed contraception methods will increase overall health care costs for Washington residents and increase their risk of poorer health outcomes.

73. As a result of the IFRs, some Washington women will lose insurance coverage for preventive contraceptive care and their options for contraception coverage will be constrained by cost. Cost will become a barrier to some women's use of the contraceptive that is medically recommended to them.

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74. According to the most recent data from the U.S. Census Bureau, more than 2.4 million women of child-bearing age reside in Washington. Bureau of Labor Statistics data reveals that the total civilian workforce in Washington in 2016 was 3,639,000. Of those, approximately 1.7 million workers were women and approximately 1.3 million were of child-bearing age.

75. Women in Washington will lose no-cost contraceptive coverage through non-governmental insurance plans because some employers and institutions of higher education will take advantage of the new exemptions and opt out of covering some or all of the contraceptive care required under the ACA. They will also opt out of the accommodation process that allowed their employees or students to still obtain no-cost contraceptive coverage without cost to the employer or college.

76. The IFRs themselves concede that a substantial number of women will be impacted and that a substantial number of entities previously using the accommodation process will take advantage of the expanded exemptions. Based upon the Departments' own concessions in the IFRs, between 698 and 2,640 Washington women who are currently using contraception will lose comprehensive, employer-sponsored contraceptive coverage. The direct cost of providing replacement contraceptive coverage and care for these women will be between $407,632 and $1,541,953 per year.

77. Several nationally known experts in women's reproductive health, including University of Washington Assistant Professor for Obstetrics and Gynecology Katherine E. Debiec, M.D., University of California, San Francisco Professor of Obstetrics, Gynecology, and Reproductive Science Daniel Grossman, M.D., FACOG, and University of California, Davis

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Martin Luther King, Jr. Professor of Law Lisa Ikemoto have opined that the IFRs will cause immediate and irreversible harm by causing women to lose contraceptive care under their employer group health plans.

78. It is important for women to have access to all approved contraceptive methods, as different methods work for different individuals, and some women must try several different methods to find one that best meets their medical needs. Thus, some of these women who will no longer receive contraceptive coverage will not only face financial harm, but will also face medical harm. This harm will manifest itself in the disruption of these patients' medical treatment, whether by substituting a less effective but cheaper method of contraception or by being forced to stop using contraceptives altogether for financial reasons. Some of these women will face unintended pregnancy and other adverse medical consequences.

79. At least one employer doing business in Washington State that would have been subject to the contraceptive coverage and accommodation process prior to October 7, 2017 (absent an agreement with the Federal Government for a temporary reprieve from the requirement), has informed the State that it is taking the position that it is exempt from that requirement now. Dkt. 19-3; Dkt. 22-2. Another employer doing business in Washington State announced to its Washington employees on October 27, 2017 that as a result of "recent changes to the ACA rules" by the Federal Government, the "accommodation is no longer" available to its employees. These statements are indicative of positions likely held by other employers and colleges doing business in Washington State. Nationally, at least 60% of all covered employees

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are enrolled in employers' self-funded insurance plans. In Washington State in 2016, 57.4% of covered employees were enrolled in self-funded insurance plans.[15]

80. Based on the percentage of Washington employees in employer self-funded plans, up to 2,088,786 insureds—plus their spouses and dependents—could lose contraceptive coverage through their employer or university's self-funded insurance plans as a result of the IFRs and 2017 Updated Guidelines. Considering only women of child-bearing age in the civilian workforce, and not spouses or daughters of other insureds, the new rules will cause up to 746,200 women in Washington to lose access to contraception through self-funded employer and college-sponsored insurance plans.

81. Even women who will not lose contraceptive coverage entirely because of the State contraceptive coverage mandate (i.e. those women who receive insurance through fully-insured plans) will be harmed, because unlike the ACA, the State contraception mandate does not require women be provided contraceptive coverage at no cost.

82. Limiting women's no-cost access to the full-range of FDA-approved contraception methods will harm women and the State because some contraception methods work better for certain individuals than others, and some may not be appropriate at all for a woman and her specific health needs. Additionally, some methods of contraception are cost-prohibitive for some women.

[15] Agency for Healthcare Research and Quality. Percent of private-sector enrollees that are enrolled in self-insured plans at establishments that offer health insurance by firm size and State (Table 11.B.2.b.1), year 1996-2016: 2016 (July 2017), *available at* https://meps.ahrq.gov/data_stats/summ_tables/insr/state/series_2/2016/tiib2b1.pdf (last visited Jan. 2, 2018).

2. Companies Doing Business in Washington Will Utilize the IFRs' Expanded Exemptions

83. Many companies that employ Washingtonians will utilize the expanded exemptions in the IFRs.

84. Because the IFRs do not require companies to provide any additional notification or certification in order to utilize the exemptions, the State will not learn of every employer or institute of higher education that will take utilize the exemptions.

85. Cherry Creek Mortgage Company is registered to do business in Washington State. Cherry Creek has approximately eight office locations in Washington. It reported to the State Department of Labor and Industries that during the third quarter of 2017, it employed the equivalent of between 31 and 50 fulltime workers. On information and belief, these workers include loan officers and office clerical staff.

86. Cherry Creek objects to providing a health plan to its employees that covers certain FDA-approved contraceptive services.

87. Cherry Creek previously obtained an injunction against enforcement of the pre-2015 contraceptive coverage mandate based on the Supreme Court's decision in *Hobby Lobby*. *See Armstrong v. Burwell*, No. 1:13-cv-00563, 2014 WL 4317354 (D. Colo. 2014). The injunction makes clear that it does not address any future statutory or regulatory changes that would be enacted after its issuance. *Id*. Accordingly, the injunction does not apply to the post-2015 mandate regulations, which made the accommodation available to closely-held corporations like Cherry Creek.

88. Cherry Creek also claims to object on religious grounds to the accommodation process that was made available to it after the *Hobby Lobby* decision. Cherry Creek planned to

file another lawsuit challenging the accommodations under the Religious Freedom Restoration Act and various constitutional provisions unless the Federal Government would agree not to enforce the contraceptive coverage requirement or the requirements of the accommodations against Cherry Creek until after the Supreme Court decided *Zubik v. Burwell*, No. 14-1418, and the cases consolidated with it.

89. On December 9, 2015, the Federal Government agreed by letter not to take any action against Cherry Creek to enforce the contraceptive coverage requirement or the requirements of the accommodations until at least 60 days after the Supreme Court issued a decision in *Zubik v. Burwell*, No. 14-1418.

90. On May 16, 2016, the Supreme Court issued an opinion in *Zubik* that vacated and remanded the judgments below to the respective Courts of Appeals.

91. Prior to October 6, 2017, Cherry Creek would have been subject to enforcement under the contraceptive coverage and accommodation requirements of the ACA.

92. If the new and expanded exemptions created on October 6, 2017 are allowed to take effect, Cherry Creek will decline to provide coverage for some FDA-approved contraception, and will decline to participate in the accommodation process by which its employees would still be able to obtain no-cost contraception through the employer's insurance company or third party administrator. Accordingly, Cherry Creek employees, and their spouses and dependents, will be denied no-cost contraceptive coverage.

93. Electric Mirror, LLC, is a for-profit corporation headquartered in Washington, and employs approximately 400 workers.

94. Electric Mirror offers its employees a self-insured medical plan.

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95. Electric Mirror objects to providing health coverage for some of the FDA-approved contraceptive methods.

96. Electric Mirror objects to participating in the accommodation process by which its employees would still be able to access no-cost contraception through the third party administrator.

97. If the new and expanded exemptions created on October 6, 2017 are allowed to take effect, Electric Mirror will decline to provide coverage for some FDA-approved contraception, and will decline to participate in the accommodation process by which its employees would be able to obtain no-cost contraception through its third party administrator. Electric Mirror employees, and their spouses and dependents, will be denied no-cost contraceptive coverage.

98. Continuant, Inc., is a for-profit corporation headquartered in Washington State, and employs approximately 290 people across all of its locations.

99. Continuant offers it employees a health plan.

100. Continuant objects to providing health coverage for some of the FDA-approved contraceptive methods.

101. On information and belief, Continuant also objects to participating in the accommodation process by which its employees would still be able to access contraception through the insurance issuer or third party administrator.

102. If the new and expanded exemptions created on October 6, 2017 are allowed to take effect, Continuant will decline to provide coverage for some FDA-approved contraception, and will decline to participate in the accommodation process by which its employees would be

able to obtain no-cost contraception through its insurance issuer or third party administrator. Continuant employees, and their spouses and dependents, will be denied no-cost contraceptive coverage.

103. Conestoga Wood Specialties Corporation is a for-profit corporation that does business in Washington State.

104. Conestoga employees approximately 40 people in Washington State.

105. Conestoga previously filed a lawsuit against the federal government challenging the contraception coverage mandate.

106. Conestoga objects to providing health coverage for some of the FDA-approved contraceptive methods to its employees.

107. On information and belief, Conestoga also objects to participating in the accommodation process by which its employees would still be able to access contraception through the insurance issuer or third party administrator.

108. If the new and expanded exemptions created on October 6, 2017 are allowed to take effect, Conestoga will decline to provide coverage for some FDA-approved contraception, and will decline to participate in the accommodation process by which its employees would be able to obtain no-cost contraception through its insurance issuer or third party administrator. Conestoga employees, and their spouses and dependents, will be denied no-cost contraceptive coverage.

109. Hobby Lobby Stores, Inc. is a for-profit corporation that does business in Washington State.

110. Hobby Lobby operates approximately 9 stores in Washington State, and employs 32,000 employees nationwide. On information and belief, Hobby Lobby employees hundreds, if not thousands of employees in Washington State.

111. According to the Bureau of Labor Statistics, the annual mean wage for cashiers in Washington State in 2016 was $27,220.00.

112. Hobby Lobby previously filed a lawsuit against the federal government challenging the contraception coverage mandate.

113. Hobby Lobby objects to providing health coverage for some of the FDA-approved contraceptive methods to its employees.

114. On information and belief, Hobby Lobby also objects to participating in the accommodation process by which its employees would still be able to access contraception through the insurance issuer or third party administrator.

115. If the new and expanded exemptions created on October 6, 2017 are allowed to take effect, Hobby Lobby will decline to provide coverage for some FDA-approved contraception, and will decline to participate in the accommodation process by which its employees would be able to obtain no-cost contraception through its insurance issuer or third party administrator. Hobby Lobby employees, and their spouses and dependents, will be denied no-cost contraceptive coverage.

116. Franciscan Health System dba CHI-Franciscan is a non-profit health care system doing business in Washington State. Franciscan employs over 11,000 people in Washington State.

117. Franciscan previously utilized the accommodation process with respect to the contraceptive coverage mandate.

118. If the new and expanded exemptions created on October 6, 2017 are allowed to take effect, Franciscan could decline to provide coverage for some FDA-approved contraception, and could decline to participate in the accommodation process by which its employees would be able to obtain no-cost contraception through its insurance issuer or third party administrator.

119. Cummins-Allison Corporation is a corporation that does business in Washington State. On information and belief, Cummins-Allison employs between 11 and 20 people in Washington State.

120. Cummins-Allison previously utilized the accommodation process with respect to the contraceptive coverage mandate.

121. If the new and expanded exemptions created on October 6, 2017 are allowed to take effect, Cummins-Allison could decline to provide coverage for some FDA-approved contraception, and could decline to participate in the accommodation process by which its employees would be able to obtain no-cost contraception through its insurance issuer or third party administrator.

122. SEIU organizes over 13,000 workers employed by religiously-affiliated health care organizations in Washington State. Of those workers, approximately 679 (433 who are female) make between $11.00 and $16.00 an hour, 2719 (1751 who are female) make between $16.00 and $21.00 an hour, and 1977 (1311 who are female) make between $26.00 and $31.00 an hour.

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3. Washington's Financial Harm From Implementation of the IFRs

123. In addition to the impact on Washington residents, the implementation of 2017 Interim Final Rules and 2017 Updated Guidelines will increase the costs borne by the State as residents who lose coverage for contraception through their employer or college seek coverage through State-subsidized programs which provide subsidized contraceptive coverage, including Apple Health, Washington's Medicaid program. The Departments acknowledge that many women who lose coverage as a result of the IFRs will receive "free or subsidized care" through state programs. *See* Religious IFR 42–43.

124. Apple Health is administered by a Washington state agency, the Washington Health Care Authority, and is funded in significant part by the State of Washington.

125. Apple Health provides integrated health care services that promote health, wellbeing, and quality of life for almost 1.8 million Washington residents. As part of that mission, Apple Health provides coverage for reproductive health services including family planning and pregnancy related services for eligible Washington residents through a variety of programs. Family planning services include all FDA approved contraceptive methods and the clinical services necessary for clients to safely and effectively use their chosen contraceptive method.

126. Apple Health serves as a secondary-payor for thousands of people in Washington who have primary insurance through their employer or institution of higher education (or through their spouse's or parents' insurance). Eligibility for Apple Health is based on several factors, including income level and family size. Factors such as age and pregnancy status determine the applicable income eligibility requirements for different groups. For example, childless adults are

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generally eligible for Apple Health at up to 138% of the Federal Poverty Level, but pregnant women are generally eligible at up to 193%. Individuals up to age 18 are eligible up to 210% of the Federal Poverty Level. Individuals at up to 260% of the Federal Poverty Level may be qualified for family planning services through an Apple Health program.

127. Apple Health serves as a secondary payor for services not otherwise fully covered by employer or higher education sponsored health plans for those clients that have both primary health coverage and Apple Health coverage. In 2016, the Health Care Authority provided secondary Apple Health coverage for 120,328 clients who had primary health coverage from other sources, including employer-sponsored coverage and student coverage. Of the total Apple Health clients that have primary health coverage from sources other than Apple Health, 69,652 are women, 38,336 of which are ages 15-44.

128. Employers and colleges and universities in Washington that choose to no longer cover contraception for their employees and students pursuant to the IFRs will shift the cost of family planning services to the State for employees who already have, or who will seek and be qualified for, Apple Health coverage as secondary insurance through the Health Care Authority.

129. There are also certain programs administered by the Washington State Health Care Authority that provide specific services for specific populations. For example, women and men up to 260% of the Federal Poverty Level may be eligible to receive family planning services from a family planning services only program that is part of Apple Health.

130. In 2016, the Health Care Authority and its contracted Managed Care Organizations spent $32,506,774.07 for coverage of family planning services for Apple Health clients.

131. Over 38,000 women aged 15-44 in Washington with non-governmental health coverage, including employer-sponsored insurance and student coverage, are already Apple Health clients. Additional women are likely qualified but not yet enrolled, and some will enroll in Apple Health when they lose coverage for contraception from their non-governmental health plans. Some women who are denied contraceptive coverage through their employer or college because of the IFRs will seek it from Apple Health.

132. Some women who lose access to contraceptive coverage through employer and college or college sponsored insurance plans will be unable to afford their current form of contraception and have an unintended pregnancy. In 2016, the Health Care Authority paid on average $9,886 per delivery and $582 per induced abortion. Additionally, there are pregnancy services costs for pregnancy losses prior to 20 weeks gestation.

133. Women who reduce or stop working due to pregnancy will change the families' income, causing some families to become eligible for Medicaid. The change in family size due to pregnancy also will cause some families to become eligible for Medicaid. This will result in an increase in state expenditures related to pregnancy and future family planning services.

134. Washington also subsidizes family planning services through the Department of Health's Family Planning Program (Family Planning Program), which is funded by federal Title X and state funding. This program provides for a full range of family planning, sexual and reproductive health services, and it funds 13 agencies with 71 clinic sites throughout Washington that offer affordable contraceptive services, including birth control and long-acting reversible contraception. In 2016, health care providers funded through the Family Planning Program served 90,168 clients in over 125,316 clinic visits in Washington. In 2016, 31% of the clients

served at these family planning clinics were privately insured. 49% of clients were on Apple Health.

135. Washington's Department of Health provides reproductive health services to individuals with incomes that are less than 251% of the Federal Poverty Level on a sliding fee scale. Washington State provides $8.8 million of funding to the Family Planning Program per year. Some women who lose coverage for contraception from their employers will be forced to seek contraception from the Family Planning Program.

136. As over 38,000 women on Apple Health also have health coverage through their employer, college, or otherwise, and 80% of women receiving services from Family Planning Clinics also have insurance and/or are already on Apple Health, it is clear that some women will turn to these programs for subsidized contraceptive care when they are denied it from their primary insurance.

137. The loss of contraceptive coverage will also harm the State through its public employees benefits program. For example, some state employees have spouses or dependents who are covered by a non-governmental health plan. Some state employees will add their spouses or dependents onto their plan if those spouses or dependents lose contraceptive coverage through a non-governmental health plan. The State's employer health plan costs increase when spouses or dependents are added onto a state employee's health plan.

138. The reduction in employer- or college-based coverage of contraception for women of reproductive capacity will result in more unintended pregnancies in Washington, to the extent that women may be unable to afford their current form of contraception. A substantial portion of medical care associated with unintended pregnancies are publically-funded in

Washington State. Increased unintended pregnancies will cause Washington's Medicaid program to incur greater costs in covering prenatal care and delivery services for low-income women. Additionally, individuals who increase the size of their family may become Medicaid eligible and cause the Medicaid program to incur greater costs.

139. Washington's 2013 unintended pregnancy rate was 37%.

140. In 2010, the cost of Medicaid-financed prenatal care and delivery in Washington was $220 million, or $10,124 per birth. Fifty-one percent of these Medicaid-covered births resulted from unintended pregnancies. Limiting access to contraceptives will increase the number of unplanned births that are publicly funded in Washington, and the State's costs will increase for each additional birth.

141. In 2010, the cost of Medicaid-financed prenatal care and delivery in Washington was $220 million, or $10,124 per birth. Fifty-one percent of these Medicaid-covered births resulted from unintended pregnancies. Limiting access to contraceptives will increase the number of unplanned births that are publicly funded in Washington, and the State's costs will increase for each additional birth.

142. In 2016, pregnancy-related expenses in Washington, including payments by both the Department of Health and Medicaid, were $426,513,331.

V. CLAIMS FOR RELIEF

Count I
Violation of the Fifth Amendment—Equal Protection

143. The State realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this First Amended Complaint.

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144. The Due Process Clause of the Fifth Amendment to the United States Constitution requires equal protection of the laws.

145. The ACA mandates that non-grandfathered insurance plans provide coverage for preventive care for men and women. The IFRs and 2017 Updated Guidelines carve out an exemption specific to women's reproductive health care. As a result of Defendants' new regulations, generally only women, not men, may have coverage for reproductive health care denied based on their employer's religious or moral objection.

146. The IFRs and 2017 Updated Guidelines intentionally interfere with women's ability to access necessary preventive care which is necessary to their equal participation in education, the workforce, and other elements of economic opportunity in our country.

147. The IFRs and 2017 Updated Guidelines also perpetuate gender stereotypes.

148. The IFRs and corresponding exemption in the 2017 Updated Guidelines do not serve an important governmental objective sufficient to justify the gender-based discrimination.

149. By purporting to legally authorize employers, institutions of higher education, and other entities to deny only women the preventive health benefits that they need, the IFRs and the 2017 Updated HRSA Guidelines classify based on gender and therefore violate the Due Process Clause of the Fifth Amendment to the United States Constitution.

150. Absent permanent injunctive and declaratory relief with respect to the IFRs and 2017 Updated Guidelines, the State and its residents will continue to be harmed by Defendants' illegal actions.

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Count II
Violation of the First Amendment—Establishment Clause

151. The State realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs of this First Amended Complaint.

152. The Establishment Clause of the First Amendment prohibits the federal government from preferring one religion over another (or no religion), and requiring people to bear the burdens of religions to which they do not belong.

153. The Religious IFR and the corresponding portion of the 2017 Updated Guidelines are intended to and have the effect of advancing, imposing, and endorsing certain religious interests. For example, they permit a for-profit business to impose the costs of its owners' anti-contraception beliefs on employees (and their dependents). Based on the religious beliefs of an employer or institution of higher education, the Religious IFR denies women access to contraceptive coverage that the ACA would otherwise secure.

154. The Religious IFR allows employers to decide whether employees receive separate contraceptive coverage through the accommodation process, at no cost to the employers. Employers have no legitimate interest in injecting their religious beliefs into this independent method for providing contraceptive coverage.

155. Through their actions, including those described above, Defendants have violated the Establishment Clause of the First Amendment.

156. Absent permanent injunctive and declaratory relief with respect to the IFRs and 2017 Updated Guidelines, the State and its residents will continue to be harmed by Defendants' illegal actions.

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Count III
Violation of the Administrative Procedure Act
Procedural Violations

157. The State realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs.

158. The IFRs and 2017 Updated Guidelines have changed the substantive rights and obligations imposed by the ACA and prior implementing regulations on employers, issuers, and others.

159. The IFRs and 2017 Updated Guidelines constitute final agency action and are legislative rules within the meaning of the APA

160. The IFRs and 2017 Updated Guidelines purport to take effect immediately, without the required 30-day waiting period between publication and effective date, without good cause for doing so.

161. The IFRs and 2017 Updated Guidelines were adopted without observing the notice and comment procedures required by the APA, which include publishing the proposed rule, allowing an appropriate time for "interested persons [to have] an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." 5 U.S.C. §§553(b), (c).

162. The Defendants did not have good cause to forgo notice and comment rulemaking.

163. By Defendants' actions, the State was denied its opportunity to participate in the rulemaking process. While the State provided comments after the IFRs were already issued, this is insufficient to protect the State's interest to influence the rules before they became effective.

164. Therefore, Defendants have taken agency action not in observance with procedures required by law, and the State is entitled to relief pursuant to 5 U.S.C. §§ 553 and 706(2)(D).

165. Absent permanent injunctive and declaratory relief with respect to the IFRs and 2017 Updated Guidelines, the State and its residents will continue to be harmed by Defendants' illegal actions.

Count IV
Violation of the Administrative Procedure Act
Arbitrary and Capricious Action

166. The State realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs.

167. The IFRs and 2017 Updated Guidelines reverse a prior agency decision without providing a reasoned explanation for this change in policy or for the disregarding of material facts that supported the agencies' prior position.

168. The IFRs and 2017 Updated Guidelines are not evidence-based or evidence-informed.

169. Defendants' explanation for their decision to exempt any entity with religious or moral objections runs counter to the evidence submitted during the belated comment period for these IFRs and the predecessor rules.

170. Thus, Defendants' issuance of the IFRs and 2017 Updated Guidelines was arbitrary and capricious within the meaning of 5 U.S.C. § 706(2)(A).

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171. Absent permanent injunctive and declaratory relief with respect to the IFRs and 2017 Updated Guidelines, the State and its residents will continue to be harmed by Defendants' illegal actions.

Count V
Violation of the Administrative Procedure Act
Agency Action Not in Accordance With Law, Contrary to Constitutional Rights, and In Excess of Statutory Jurisdiction
(First Amendment to the United States Constitution, Fifth Amendment to the United States Constitution, Civil Rights Act, Pregnancy Discrimination Act, and Affordable Care Act)

172. The State realleges and incorporates by reference the allegations set forth in each of the preceding paragraphs.

173. The APA requires that agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," "not in accordance with law" or "contrary to constitutional right" be held unlawful and set aside. 5 U.S.C. § 706(2).

174. The IFRs and 2017 Updated Guidelines, which allow employers to choose whether their employees will receive coverage for contraception, are not in accordance with and in excess of statutory authority set forth in the ACA, which require coverage for preventive services for women and do not provide an exception for religious or moral objections. 42 U.S.C. § 300gg-13(a)(4).

175. The expanded exemptions are not required by the Religious Freedom Restoration Act or any other provision of federal law.

176. The IFRs and 2017 Updated Guidelines are contrary to the constitutional protections afforded by the First and Fifth Amendments, as described above.

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177. The IFRs and 2017 Updated Guidelines are not accordance with the Civil Rights Act, as amended by the Pregnancy Discrimination Act, which prohibits discrimination based on sex or capacity to be pregnant. 42 U.S.C. 2000e *et seq*. (Title VII).

178. The IFRs and 2017 Updated Guidelines are not in accordance with provisions of the ACA that prohibits discrimination based on gender. 42 U.S.C. § 18116.

179. The IFRs and 2017 Updated Guidelines are not in accordance with provisions of the ACA that prohibit the promulgation of any regulation that "[c]reates any unreasonable barrier to the ability of individuals to obtain appropriate medical care," "[i]mpedes timely access to health care services," or "[l]imits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. § 18114.

180. Absent permanent injunctive and declaratory relief with respect to the IFRs and 2017 Updated Guidelines, the State and its residents will continue to be harmed by Defendants' illegal actions.

VI. PRAYER FOR RELIEF

Wherefore, the State of Washington prays that the Court:

a. Declare that the IFRs and 2017 Updated Guidelines' exemptions for religious and moral objections are unauthorized by and contrary to the Constitution and laws of the United States;

b. Declare that the IFRs and 2017 Updated Guidelines were not promulgated in conformance with the procedures required by the APA;

c. Declare that the IFRs and 2017 Updated Guidelines are arbitrary and capricious and short of statutory right;

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d. Issue Permanent Injunctions enjoining Defendants from implementing or enforcing the IFRs and the 2017 Updated Guidelines' expanded exemptions for religious and moral objections;

e. Award Washington its costs and reasonable attorney fees; and

f. Award such additional relief as the interests of justice may require.

DATED this 2nd day of January, 2018.

ROBERT W. FERGUSON
Attorney General

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DECLARATION OF SERVICE

I hereby certify that on January 2, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

Elizabeth L. Kade
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Attorney for Defendants

DATED this 2nd day of January, 2018, at Seattle, Washington.

/s/ Jeffrey T. Sprung
JEFFREY T. SPRUNG
Assistant Attorney General

First Amended Complaint Exhibit A

CMS-9940-IFC

This document is scheduled to be published in the Federal Register on 10/13/2017 and available online at https://federalregister.gov/d/2017-21851, and on FDsys.gov

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD-9827]

RIN 1545-BN92

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS-9940-IFC]

RIN 0938-AT20

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

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

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions. These interim final rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive

coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave the "accommodation" process in place as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

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

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

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

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

Comments, identified by "Preventive Services," may be submitted one of four ways (please choose only one of the ways listed)

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

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9940-IFC,

P.O. Box 8016,

Baltimore, MD 21244- 8016.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9940-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850

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

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

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

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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

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

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

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's 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:

I. Background

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

[1] See, for example, 42 U.S.C. 300a-7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their "religious beliefs or moral convictions"); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Pub. L. No. 115-31 (protecting any "health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion for any reason); Id. at Div. C, Title VIII, Sec. 808 (regarding

Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, "with respect to women, such additional preventive care and screenings … as provided for in comprehensive guidelines supported by" by HRSA (the "Guidelines"). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, "the

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

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

Departments"[3])—exercised the same discretion to allow exemptions to those requirements. Through rulemaking, including three interim final rules, the Departments allowed exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the "contraceptive Mandate," or the "Mandate") as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb-1. Much of that litigation continues to this day.

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

In light of these factors, the Departments issue these new interim final rules to better balance the Government's interest in ensuring coverage for contraceptive and sterilization

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

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

services in relation to the Government's interests, including as reflected throughout Federal law, to provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, "[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a-7, and the Weldon Amendment, section 508(d)(1) of 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."

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

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS Act requires coverage without cost sharing for "such additional" women's

preventive care and screenings "as provided for" and "supported by" guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

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

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act's reference to "comprehensive guidelines supported by HRSA for purposes of this paragraph" to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines "supported by HRSA for purposes of this paragraph," the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from "the other guidelines referenced in section 2713(a) of the PHS Act, which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients." Id. Guidelines developed as nonbinding recommendations for care implicate significantly different

legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4) of the PHS Act, the Departments have previously promulgated regulations defining the scope of permissible exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92)

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 of the PHS Act for grandfathered plans. In contrast, this exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include: section 2704 of the PHS Act, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708 of the PHS Act, which prohibits excessive waiting periods (as of January 1, 2014); section 2711 of the PHS Act, which relates to lifetime limits; section 2712 of the PHS Act, which prohibits rescission of health insurance coverage; section 2714 of the PHS Act, which extends dependent coverage until age 26; and section 2718 of the PHS Act, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not

subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2764 n.10 (2014).

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

B. The Regulations Concerning Women's Preventive Services

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

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, "Clinical Preventive Services for Women, Closing the Gaps"

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

(IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[6]

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

One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He argued that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by the United States Preventive Services Task Force (USPSTF), HRSA's Bright Futures Project, and the Advisory Committee on Immunization Practices (ACIP) leads to lower rates of disability or disease and increased rates of well-being. He further argued that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and that

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

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

"the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy." Dr. LoSasso also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] (IOM 2011 at 231–32). In its response to Dr. LoSasso, the other 15 committee members stated, in part, that "At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions."

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

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

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules. (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specify that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such

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

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

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

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

[9] The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011. (76 FR 46621).
[10] See, for example, Comments of the United States Conference of Catholic Bishops on Interim Final Rules on Preventive Services, File Code CMS-9992-IFC2 (Aug. 31, 2011).
[11] The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

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

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

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

The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer (1) have the inculcation of religious values as its purpose, (2) primarily employ persons who share its religious tenets, and (3) primarily serve persons who share its religious tenets.

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

and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries.

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

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

The July 2013 regulations also finalized an accommodation for eligible organizations. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible

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

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

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

[14] See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.
[15] "[P]roviding payments for contraceptive services is cost neutral for issuers." (78 FR 39877).

2713A, 29 CFR 2510.3-16, and 29 CFR 2590.715-2713A" and concluded, in unindented text, that "[t]his form is an instrument under which the plan is operated."

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

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others. Religious plaintiffs principally argued that the Mandate violated the Religious Freedom Restoration Act of 1993 (RFRA) by forcing them to provide coverage or payments for sterilization and contraceptive services, including what they viewed as early abortifacient items, contrary to their religious beliefs. Based on this claim, in July 2012 a Federal district court issued a preliminary injunction barring the Departments from enforcing the Mandate against a family-owned business. Newland v. Sebelius, 881 F. Supp. 2d. 1287 (D. Colo. 2012). Multiple other courts proceeded to issue similar injunctions against the Mandate, although a minority of courts ruled in the Departments' favor. Compare Tyndale House Publishers, Inc. v. Sebelius, 904 F. Supp. 2d 106 (D.D.C. 2012), and The Seneca Hardwood Lumber Company, Inc. v. Sebelius (sub nom Geneva Coll. v. Sebelius), 941 F. Supp. 2d 672 (W.D. Pa. 2013), with O'Brien v. U.S. Dep't of Health & Human Servs., 894 F. Supp. 2d 1149 (E.D. Mo. 2012).

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

On June 30, 2014, the Supreme Court ruled against the Departments and held that, under RFRA, the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[16] Burwell v. Hobby Lobby Stores, Inc. 134 S. Ct. 2751 (2014). The Court held that the "contraceptive mandate 'substantially burdens' the exercise of religion" as applied to employers that object to providing contraceptive coverage on religious grounds, and that the plaintiffs were therefore entitled to an exemption unless the Mandate was the least restrictive means of furthering a compelling governmental interest. Id. at 2775. The Court observed that, under the compelling interest test of RFRA, the Departments could not rely on interests "couched in very broad terms, such as promoting 'public health' and 'gender equality,' but rather, had to demonstrate that a compelling interest was served by refusing an exemption to the "particular claimant[s]" seeking

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

an exemption. Id. at 2779. Assuming without deciding that a compelling interest existed, the Court held that the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner. The Court observed that "[t]he most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections." Id. at 2780. The Court also observed that the Departments had "not provided any estimate of the average cost per employee of providing access to these contraceptives," nor "any statistics regarding the number of employees who might be affected because they work for corporations like Hobby Lobby, Conestoga, and Mardel". Id. at 2780–81. But the Court ultimately concluded that it "need not rely on the option of a new, government-funded program in order to conclude that the HHS regulations fail the least-restrictive means test" because "HHS itself ha[d] demonstrated that it ha[d] at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs." Id. at 2781-82. The Court explained that the "already established" accommodation process available to nonprofit organizations was a less-restrictive alternative that "serve[d] HHS's stated interests equally well," although the Court emphasized that its ruling did not decide whether the accommodation process "complie[d] with RFRA for purposes of all religious claims". Id. at 2788–82.

Meanwhile, another plaintiff obtained temporary relief from the Supreme Court in a case challenging the accommodation under RFRA. Wheaton College, a Christian liberal arts college in Illinois, objected that the accommodation was a compliance process that rendered it complicit in delivering payments for abortifacient contraceptive services to its employees. Wheaton College refused to execute the EBSA Form 700 required under the July 2013 final regulations. It

was denied a preliminary injunction in the Federal district and appellate courts, and sought an emergency injunction pending appeal from the Unites States Supreme Court on June 30, 2014. On July 3, 2014, the Supreme Court issued an interim order in favor of the College, stating that, "[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing [the Mandate] against the [plaintiff] . . . pending final disposition of appellate review." Wheaton College v. Burwell. 134 S. Ct. 2806, 2807 (2014). The order stated that Wheaton College did not need to use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for injunctive relief. Id.

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

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

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The preamble to the July 2015 final regulations stated that, through the accommodation, payments for contraceptives and sterilization would be provided in a way that is "seamless" with the coverage that eligible employers provide to their plan participants and beneficiaries. Id. at 41328. The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

When an eligible organization maintains an insured group health plan or student health plan and provides the alternative notice, the July 2015 final regulations provide that HHS will inform the health insurance issuer of its obligations to cover contraceptive services to which the eligible organization objects. Where an eligible organization maintains a self-insured plan under ERISA and provides the alternative notice, the regulations provide that DOL will work with HHS to send a separate notification to the self-insured plan's third party administrator(s). The regulations further provide that such notification is an instrument under which the plan is

operated for the purposes of section 3(16) of ERISA, and the instrument would designate the third party administrator as the entity obligated to provide or arrange for payments for contraceptives to which the eligible organization objects. The July 2015 final regulations continue to apply the amended notice requirement to eligible organizations that sponsor church plans exempt from ERISA pursuant to section 4(b)(2) of ERISA, but acknowledge that, with respect to the operation of the accommodation process, section 3(16) of ERISA does not provide a mechanism to impose an obligation to provide contraceptive coverage as a plan administrator on those eligible organizations' third party administrators. (80 FR 41323).

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

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

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

After remand, as indicated by the Departments in court filings, some meetings were held between attorneys for the Government and for the plaintiffs in those cases. Separately, at various times after the Supreme Court's remand order, HHS and DOL sent letters to the issuers and third party administrators of certain plaintiffs in Zubik and other pending cases, directing the issuers and third party administrators to provide contraceptive coverage for participants in those

plaintiffs' group health plans under the accommodation. The Departments also issued a Request for Information (RFI) on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in Zubik and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016.

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

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

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

objecting eligible organizations while pursuing the Departments' policy goals. Thus, the litigation on remand from the Supreme Court remains unresolved.

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

On May 4, 2017, the President issued an "Executive Order Promoting Free Speech and Religious Liberty." Regarding "Conscience Protections with Respect to Preventive-Care Mandate," that order instructs "[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services [to] consider issuing amended regulations, consistent

with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code."

II. RFRA and Government Interests Underlying the Mandate

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

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

concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.

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

In addition to relying on the text of section 2713(a)(4) of the PHS Act and the Departments' discretion to promulgate rules to carry out the provisions of the PHS Act, the

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

Notable among the many statutes (listed in footnote 1 in Section I-Background) that include protections for religious beliefs are, not only the Church Amendments, but also protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. (42 U.S.C. 1395w-22(j)(3)(B); 42 U.S.C. 1396u-2(b)(3)). In addition, Congress has protected individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Pub. L. No. 115-31 (May 5, 2017). Congress likewise provided that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions". Id. at Division C, Title VIII, Sec. 808. In light of the fact that Congress did not require HRSA to include contraception in Guidelines issued under section 2713 of the PHS Act, we consider it significant, in support of the implementation of those Guidelines by the expanded exemption in these interim final rules, that Congress' most recent statement on the prospect of Government mandated contraceptive coverage was to express

the specific intent that a conscience clause be provided and that it should protect religious beliefs.

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

A. Elements of RFRA

1. Substantial Burden

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

The Departments have reevaluated our position on this question, however, in light of all the arguments made in various cases, public comments that have been submitted, and the

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

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

Consistent with our conclusion earlier this year after the remand of cases in Zubik and our reviewing of comments submitted in response to the 2016 RFI, the Departments believe there is not a way to satisfy all religious objections by amending the accommodation.

Accordingly, the Departments have decided it is necessary and appropriate to provide the expanded exemptions set forth herein.

2. Compelling Interest

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

RFRA requires the Government to respect religious beliefs under "the most demanding test known to constitutional law": where the Government imposes a substantial burden on religious exercise, it must demonstrate a compelling governmental interest and show that the law or requirement is the least restrictive means of furthering that interest. City of Boerne v. Flores, 521 U.S. 507, 534 (1997). For an interest to be compelling, its rank must be of the "highest order". Church of the Lukumi Babalu Aye, Inc. v. City of Hialeah, 508 U.S. 520, 546 (1993); see also Sherbert v. Verner, 374 U.S. 398, 406–09 (1963); Wisconsin v. Yoder, 406 U.S. 205, 221–29 (1972). In applying RFRA, the Supreme Court has "looked beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants." Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 431 (2006). To justify a substantial

burden on religious exercise under RFRA, the Government must show it has a compelling interest in applying the requirement to the "particular claimant[s] whose sincere exercise of religion is being substantially burdened." Id. at 430–31. Moreover, the Government must meet the "exceptionally demanding" least-restrictive-means standard. Hobby Lobby, 134 S. Ct. at 2780. Under that standard, the Government must establish that "it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting parties." Id.

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

First, Congress did not mandate that contraception be covered at all under the Affordable Care Act. Instead, Congress merely provided for coverage of "such additional preventive care and screenings" for women "provided for in comprehensive guidelines supported by [HRSA]." Congress, thus, left the identification of any additional required preventive services for women to administrative discretion. The fact that Congress granted the Departments the authority to promulgate all rules appropriate and necessary for the administration of the relevant provisions of the Code, ERISA, and the PHS Act, including by channeling the discretion Congress afforded to HRSA to decide whether to require contraceptive coverage, indicates that the Departments' judgment should carry particular weight in considering the relative importance of the Government's interest in applying the Mandate to the narrow population of entities exempted in these rules.

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

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

the fact that they are willing to provide coverage for various contraceptive methods significantly detracts from the government interest in requiring that they provide coverage for other contraceptive methods to which they object.

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

through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs to become administrators of those plans to provide such coverage, has led to significant incongruity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

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

Fifth, the Departments' previous assertion that the exemption for houses of worship was offered to respect a certain sphere of church autonomy (80 FR 41325) does not adequately explain some of the disparate results of the existing rules. And the desire to respect church

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

As the Supreme Court recently confirmed, a self-insured church plan exempt from ERISA through ERISA 3(33) can include a plan that is not actually established or maintained by a church or by a convention or association of churches, but is maintained by "an organization … the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches" (a so-called "principal-

purpose organization"). See Advocate Health Care Network v. Stapleton, 137 S. Ct. 1652, 1656-57 (U.S. June 5, 2017); ERISA 3(33)(C). While the Departments take no view on the status of these particular plans, the Departments acknowledge that the church plan exemption not only includes some non-houses-of-worship as organizations whose employees can be covered by the plan, but also, in certain circumstances, may include plans that are not themselves established and maintained by houses of worship. Yet, such entities and plans—if they file a self-certification or notice through the existing accommodation—are relieved of obligations under the contraceptive Mandate and their third party administrators are not subject to a requirement that they provide contraceptive coverage to their plan participants and beneficiaries.

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

Sixth, the Government's interest in ensuring contraceptive coverage for employees of particular objecting employers is undermined by the characteristics of many of those employers, especially nonprofit employers. The plaintiffs challenging the existing accommodation include, among other organizations, religious colleges and universities, and religious orders that provide health care or other charitable services. Based in part on our experience litigating against such organizations, the Departments now disagree with our previous assertion that "[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the

same objection."[18] (78 FR 39874.) Although empirical data was not required to reach our previous conclusion, we note that the conclusion was not supported by any specific data or other source, but instead was intended to be a reasonable assumption. Nevertheless, in the litigation and in numerous public comments submitted throughout the regulatory processes described above, many religious nonprofit organizations have indicated that they possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Some of the religious nonprofit groups challenging the accommodation claim that their employees are required to adhere to a statement of faith which includes the entities' views on certain contraceptive items.[19] The Departments recognize, of course, that not all of the plaintiffs challenging the accommodation require all of their employees (or covered students) to share their religious objections to contraceptives. At the same time, it has become apparent from public comments and from court filings in dozens of cases—encompassing hundreds of organizations—that many religious nonprofit organizations express their beliefs publicly and hold themselves out as organizations for whom their religious beliefs are vitally important. Employees of such organizations, even if not required to sign a statement of faith, often have access to, and knowledge of, the views of their employers on contraceptive coverage, whether through the organization's published mission statement or statement of beliefs, through employee benefits disclosures and other communications with employees and prospective employees, or through publicly filed lawsuits objecting to providing such coverage and attendant media coverage. In

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

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

many cases, the employees of religious organizations will have chosen to work for those organizations with an understanding—explicit or implicit—that they were being employed to advance the organization's goals and to be respectful of the organization's beliefs even if they do not share all of those beliefs. Religious nonprofit organizations that engage in expressive activity generally have a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[20]

Given the sincerely held religious beliefs of many religious organizations, imposing the contraceptive-coverage requirement on those that object based on such beliefs might undermine the Government's broader interests in ensuring health coverage by causing the entities to stop providing health coverage. For example, because the Affordable Care Act does not require institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or be subject to the accommodation with respect to such populations.[21]

Seventh, we now believe the administrative record on which the Mandate rests is insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. To begin, in support of the IOM's recommendations, which HRSA adopted, the IOM identified several studies showing a preventive services gap because

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

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

women require more preventive care than men. (IOM 2011 at 19–21). Those studies did not identify contraceptives or sterilization as composing a specific portion of that gap, and the IOM did not consider or establish in the report whether any cost associated with that gap remains after all other women's preventive services are covered without cost-sharing. Id. Even without knowing what the empirical data would show about that gap, the coverage of the other women's preventive services required under both the HRSA Guidelines and throughout section 2713(a) of the PHS Act—including annual well-woman visits and a variety of tests, screenings, and counseling services—serves at a minimum to diminish the cost gap identified by IOM for women whose employers decline to cover some or all contraceptives on religious grounds.[22]

Moreover, there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families. According to the Guttmacher Institute, government-subsidized family planning services are provided at 8,409 health centers overall.[23] The Title X program, for example, administered by the HHS Office of Population Affairs (OPA), provides a wide variety of voluntary family planning information and services for clients based on their ability to pay, through a network that includes nearly 4,000 family planning centers. http://www.hhs.gov/opa/title-x-family-planning/ Individuals with family incomes at or below the HHS poverty guideline (for 2017, $24,600 for a family of four in the 48 contiguous States and the District of Columbia) receive services at no charge unless a third party (governmental or private) is authorized or obligated to pay for these services.

[22] The Departments are not aware of any objectors to the contraceptive Mandate that are unwilling to cover any of the other preventive services without cost sharing as required by PHS Act section 2713.
[23] "Facts on Publicly Funded Contraceptive Services in the United States," March 2016.

Individuals with incomes in excess of 100 percent up to 250 percent of the poverty guideline are charged for services using a sliding fee scale based on family size and income. Unemancipated minors seeking confidential services are assessed fees based on their own income level rather than their family's income. The availability of such programs to serve the most at-risk women (as defined in the IOM report) diminishes the Government's interest in applying the Mandate to objecting employers. Many forms of contraception are available for around $50 per month, including long-acting methods such as the birth control shot and intrauterine devices (IUDs).[24] Other, more permanent forms of contraception like implantables bear a higher one-time cost, but when calculated over the duration of use, cost a similar amount.[25] Various State programs supplement the Federal programs referenced above, and 28 States have their own mandates of contraceptive coverage as a matter of State law. This existing inter-governmental structure for obtaining contraceptives significantly diminishes the Government's interest in applying the Mandate to employers over their sincerely held religious objections.

The record also does not reflect that the Mandate is tailored to the women most likely to experience unintended pregnancy, identified by the 2011 IOM report as "women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority". (IOM 2011 at 102). For example, with respect to religiously objecting organizations, the Mandate applies in employer-based group health plans and student insurance at private colleges and universities. It is not clear that applying the Mandate among those objecting entities is a narrowly tailored way to benefit the most at-risk

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

[25] Id.

population. The entities appear to encompass some such women, but also appear to omit many of them and to include a significantly larger cross-section of women as employees or plan participants. At the same time, the Mandate as applied to objecting employers appears to encompass a relatively small percentage of the number of women impacted by the Mandate overall, since most employers do not appear to have conscientious objections to the Mandate.[26] The Guttmacher Institute, on which the IOM relied, further reported that 89 percent of women who are at risk of unintended pregnancy and are living at 0 through 149 percent of the poverty line are already using contraceptives, as are 92 percent of those with incomes of 300 percent or more of the Federal poverty level.[27]

The rates of—and reasons for—unintended pregnancy are notoriously difficult to measure.[28] In particular, association and causality can be hard to disentangle, and the studies referred to by the 2011 IOM Report speak more to association than causality. For example, IOM 2011 references Boonstra, et al. (2006), as finding that, "as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended

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

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

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

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

Similarly, in a study involving over 8,000 women between 2012 and 2015, conducted to determine whether contraceptive coverage under the Mandate changed contraceptive use patterns, the Guttmacher Institute concluded that "[w]e observed no changes in contraceptive use patterns among sexually active women."[31] With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship).[32] Another study, which proposed an economic model for the decision to engage in sexual activity, stated that "[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run."[33] Regarding emergency contraception in particular, "[i]ncreased access to emergency

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[29] H. Boonstra, et al., "Abortion in Women's Lives" at 18, Guttmacher Inst. (2006).
[30] Citing John S. Santelli & Andrea J. Melnikas, "Teen Fertility in Transition: Recent and Historic Trends in the United States," 31 Ann. Rev. Pub. Health 371 (2010).
[31] Bearak, J.M. and Jones, R.K., "Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis," 27 Women's Health Issues 316 (Guttmacher Inst. May-June 2017), available at http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.
[32] 31 Ann. Rev. Pub. Health at 375–76.
[33] Peter Arcidiacono, et al., "Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?" (2005), available at http://public.econ.duke.edu/~psarcidi/teensex.pdf.

contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates."[34] In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent,[35] unintended pregnancy rates in the Unites States rose from 35.4 percent[36] to 49 percent."[37] The Departments note these and other studies[38] to observe the complexity and uncertainty in the relationship between contraceptive access, contraceptive use, and unintended pregnancy.

Contraception's association with positive health effects might also be partially offset by an association with negative health effects. In 2013 the National Institutes of Health indicated, in funding opportunity announcement for the development of new clinically useful female contraceptive products, that "hormonal contraceptives have the disadvantage of having many undesirable side effects[,] are associated with adverse events, and obese women are at higher risk

[34] G. Raymond et al., "Population effect of increased access to emergency contraceptive pills: a systematic review," 109 Obstet. Gynecol. 181 (2007).
[35] William D. Mosher & Jo Jones, U.S. Dep't of HHS, CDC, National Center for Health Statistics, "Use of Contraception in the United States: 1982–2008" at 5 fig. 1, 23 Vital and Health Statistics 29 (Aug. 2010), available at https://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.
[36] Helen M. Alvaré, "No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom," 58 Vill. L. Rev. 379, 404–05 & n.128 (2013), available at http://digitalcommons.law.villanova.edu/vlr/vol58/iss3/2 (quoting Christopher Tietze, "Unintended Pregnancies in the United States, 1970-1972," 11 Fam. Plan. Persp. 186, 186 n.* (1979) ("in 1972, 35.4 percent percent of all U.S. pregnancies were 'unwanted' or 'wanted later'")).
[37] Id. (citing Lawrence B. Finer & Stanley K. Henshaw, "Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001" 38 Persp. on Sexual Reprod. Health 90 (2006) ("In 2001, 49 percent of pregnancies in the United States were unintended")).
[38] See, for example, J.L Dueñas, et al., "Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997–2007," 83 Contraception 82 (2011) (as use of contraceptives increased from 49 percent to 80 percent, the elective abortion rate more than doubled); D. Paton, "The economics of family planning and underage conceptions," 21 J. Health Econ. 207 (2002) (data from the UK confirms an economic model which suggests improved family planning access for females under 16 increases underage sexual activity and has an ambiguous impact on underage conception rates); T. Raine et al., "Emergency contraception: advance provision in a young, high-risk clinic population," 96 Obstet. Gynecol. 1 (2000) (providing advance provision of emergency contraception at family planning clinics to women aged 16–24 was associated with the usage of less effective and less consistently used contraception by other methods); M. Belzer et al., "Advance supply of emergency contraception: a randomized trial in adolescent mothers," 18 J. Pediatr. Adolesc. Gynecol. 347 (2005) (advance provision of emergency contraception to mothers aged 13–20 was associated with increased unprotected sex at the 12-month follow up).

for serious complications such as deep venous thrombosis."[39] In addition, IOM 2011 stated that "[l]ong-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011)." (IOM 2011 at 107). However, after IOM 2011 made this statement, AHRQ (a component of HHS) completed its systematic evidence review.[40] Based on its review, AHRQ stated that: "[o]varian cancer incidence was significantly reduced in OC [oral contraceptive] users"; "[b]reast cancer incidence was slightly but significantly increased in OC users"; "[t]he risk of cervical cancer was significantly increased in women with persistent human papillomavirus infection who used OCs, but heterogeneity prevented a formal meta-analysis"; "[i]ncidences of both colorectal cancer [] and endometrial cancer [] were significantly reduced by OC use"; "[t]he risk of vascular events was increased in current OC users compared with nonusers, although the increase in myocardial infarction was not statistically significant"; "[t]he overall strength of evidence for ovarian cancer prevention was moderate to low"; and "[t]he simulation model predicted that the combined increase in risk of breast and cervical cancers and vascular events was likely to be equivalent to or greater than

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

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

the decreased risk in ovarian cancer."[41] Based on these findings, AHRQ concluded that "[t]here is insufficient evidence to recommend for or against the use of OCs solely for the primary prevention of ovarian cancer…. the harm/benefit ratio for ovarian cancer prevention alone is uncertain, particularly when the potential quality-of-life impact of breast cancer and vascular events are considered."[42]

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

Finally, evidence from studies that post-date the Mandate is not inconsistent with the observations the Departments make here. In 2016, HRSA awarded a 5-year cooperative agreement to the American College of Obstetricians and Gynecologists to develop recommendations for updated Women's Preventive Services Guidelines. The awardee formed an expert panel called the Women's Preventive Services Initiative that issued a report (the WPSI report).[44] After observing that "[p]rivate companies are increasingly challenging the contraception provisions in the Affordable Care Act," the WPSI report cited studies through 2013 stating that application of HRSA Guidelines had applied preventive services coverage to

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[41] Id.

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

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

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

55.6 million women and had led to a 70 percent decrease in out-of-pocket expenses for contraceptive services among commercially insured women. Id. at 57–58. The WPSI report relied on a 2015 report of the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), "The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans," which estimated that persons who have private insurance coverage of preventive services without cost sharing includes 55.6 million women.[45]

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

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

[46] In addition, as in IOM 2011, the WPSI report bases its evidentiary conclusions relating to contraceptive coverage, use, unintended pregnancy, and health benefits, on conclusions that the phenomena are "associated" with the intended outcomes, without showing there is a causal relationship. For example, the WPSI report states that "[c]ontraceptive counseling in primary care may increase the uptake of hormonal methods and [long-acting reversible contraceptives], although data on structured counseling in specialized reproductive health settings demonstrated no such effect." Id. at 63. The WPSI report also acknowledges that a large-scale study evaluating the effects of providing no-cost contraception had "no randomization or control group." Id. at 63.
The WPSI report also identifies the at-risk population as young, low-income, and/or minority women: "[u]nintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities." Id. at 58. The WPSI report acknowledges that many in this population are already served by Title X programs, which provide family planning services to "approximately 1 million teens each year." Id. at 58. The WPSI report observes that between 2008 and 2011—before the contraceptive coverage requirement

mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[47]

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

During public comment periods, some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions. The IOM similarly stated that "the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain." IOM 2011 at 107. Consequently, some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes. Section 2713(a)(4) of the PHS Act does not, however, apply to non-preventive care provided solely for treatment of an existing condition. It applies only to "such additional preventive care and screenings . . . as provided for" by HRSA (Section 2713(a)(4) of the PHS Act). HRSA's Guidelines implementing this section state repeatedly that they apply to "preventive" services or care, and with respect to the coverage of contraception specifically, they declare that the methods covered are "contraceptive" methods as a "Type of Preventive Service," and that they are to be covered only

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was implemented—unintended pregnancy decreased to the lowest rate in 30 years. Id. at 58. The WPSI report does not address how to balance contraceptive coverage interests with religious objections, nor does it specify the extent to which applying the Mandate among commercially insured at objecting entities serves to deliver contraceptive coverage to women most at risk of unintended pregnancy.

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

"[a]s prescribed" by a physician or other health care provider. https://www.hrsa.gov/womensguidelines/ The contraceptive coverage requirement in the Guidelines also only applies for "women with reproductive capacity." https://www.hrsa.gov/womensguidelines/; (80 FR 40318). Therefore, the Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that the FDA has approved for contraceptive use is prescribed in whole or in part for such use. The Guidelines and section 2713(a)(4) of the PHS Act do not require coverage of such drugs where they are prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[48] As discussed above, the last Administration decided to exempt houses of worship and their integrated auxiliaries from the Mandate, and to relieve hundreds of religious nonprofit organizations of their obligations under the Mandate and not further require contraceptive coverage to their employees. In several of the lawsuits challenging the Mandate, some religious plaintiffs stated that they do not object and are willing to cover drugs prescribed for the treatment of an existing condition and not for contraceptive purposes—even if those drugs are also approved by the FDA for contraceptive uses. Therefore, the Departments conclude that the fact that some drugs that are approved for preventive

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

contraceptive purposes can also be used for exclusively non-preventive purposes to treat existing conditions is not a sufficient reason to refrain from expanding the exemption to the Mandate.

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

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

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

B. Discretion to Provide Religious Exemptions

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

Now, however, the Departments have reassessed the relevant interests and determined that, even if exemptions are not required by RFRA, they would exercise their discretion to address the substantial burden identified in Hobby Lobby by expanding the exemptions from the Mandate instead of revising accommodations previously offered. In the Departments' view, a broader exemption is a more direct, effective means of satisfying all bona fide religious objectors. This view is informed by the fact that the Departments' previous attempt to develop an appropriate accommodation did not satisfy all objectors. That previous accommodation

consumed Departmental resources not only through the regulatory process, but in persistent litigation and negotiations. Offering exemptions as described in these interim final rules is a more workable way to respond to the substantial burden identified in Hobby Lobby and bring years of litigation concerning the Mandate to a close.

C. General Scope of Expanded Religious Exemptions

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

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

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

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

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

Although the Departments previously took the position that allowing individual religious exemptions would undermine the workability of the insurance system, the Departments now agree with those district courts that have concluded that an exemption that allows—but does not require—issuers and employers to omit contraceptives from coverage provided to objecting individuals does not undermine any compelling interest. See Wieland, 196 F. Supp. 3d at 1019–20; March for Life, 128 F. Supp. 3d at 132. The individual exemption will only apply where the

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

employer and issuer (or, in the individual market, the issuer) are willing to offer a policy accommodating the objecting individual. As a result, the Departments consider it likely that where an individual exemption is invoked, it will impose no burdens on the insurance market because such burdens may be factored into the willingness of an employer or issuer to offer such coverage. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our lack of authority to enforce the accommodation with respect to self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[51] Furthermore, granting exemptions to individuals who do not wish to receive contraceptive coverage where the plan and, as applicable, issuer and plan sponsor are willing, does not undermine the Government's interest in ensuring the provision of such coverage to other individuals who wish to receive it. Nor do such exemptions undermine the operation of the many other programs subsidizing contraception. Rather, such exemptions serve the Government's interest in accommodating religious exercise. Accordingly, as further explained below, the Departments have provided an exemption to address the concerns of objecting individuals.

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

D. Effects on Third Parties of Exemptions

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

That conclusion is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants "to confer benefits on third parties." Hobby Lobby, 134 S. Ct. at 2781 n.37. The burdens imposed on such third parties may be relevant to the RFRA analysis, but they cannot be dispositive. "Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an

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

opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants).” Id. Where, as here, contraceptives are readily accessible and, for many low income persons, are available at reduced cost or for free through various governmental programs, and contraceptive coverage may be available through State sources or family plans obtained through non-objecting employers, the Departments have determined that the expanded exemptions rather than accommodations are the appropriate response to the substantial burden that the Mandate has placed upon the religious exercise of many religious employers.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including prior interim final rules), public comments, and litigation throughout the Federal court system. The interim final rules seek to resolve this matter and the long-running litigation with respect to religious objections by extending the exemption under the HRSA Guidelines to encompass entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage, and by making the accommodation process optional for eligible organizations.

The Departments acknowledge that the foregoing analysis represents a change from the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlie the Mandate. These changes in policy are within the Departments’ authority. As the Supreme Court has acknowledged, “[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change.” Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2125 (2016). This “reasoned analysis” requirement does not demand that an agency “demonstrate to a court’s satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new

policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates". United Student Aid Funds, Inc. v. King, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009)); also, see New Edge Network, Inc. v. FCC, 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").

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

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

These interim final rules modify the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815-2713(a)(1) introductory text and

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

(a)(1)(iv), 29 CFR 2590.715-2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) introductory text and (a)(1)(iv), so that they conform to the statutory text of section 2713 of the PHS Act.

B. Prefatory Language of the Exemption in 45 CFR 147.132

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

C. General Scope of Exemption for Objecting Entities

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

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

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

disclose that change to plan participants.[54] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

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

D. Exemption of Employers and Institutions of Higher Education

The scope of the exemption is expanded for non-governmental plan sponsors and certain entities that arrange health coverage under these interim final rules. The Departments have

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

consistently taken the position that section 2713(a)(4) of the PHS Act grants HRSA authority to issue Guidelines that provide for and support exemptions from a contraceptive coverage requirement. Since the beginning of rulemaking concerning the Mandate, HRSA and the Departments have repeatedly exercised their discretion to create and modify various exemptions within the Guidelines.[55]

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

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

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

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

1. Plan Sponsors Generally

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

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

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

informative as to the viability of broad protections for religious liberty. In this case, such practice supports the Departments' decision to expand the federal exemption, bringing the Federal Government's practice into greater alignment with the practices of the majority of the States.

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

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

Under these interim final rules, however, the Departments intend that, when this regulation text exempts a plan "established or maintained by" a house of worship or integrated auxiliary, such exemption will no longer "be determined on an employer by employer basis," but

will be determined on a plan basis—that is, by whether the plan is a "plan established or maintained by" a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these interim final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the threshold of being integrated auxiliaries. Moreover, under this interpretation, houses of worship would not be faced with the potential prospect of services to which they have a religious objection being covered for employees of an associated employer participating in a plan they have established and maintain.

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

(E.D.N.Y. 2013). Therefore the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

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

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

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

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

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

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. The Departments implicitly recognized the difficulty of providing an affirmative definition of closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely "substantially similar" to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was

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

permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. The exemptions in these interim final rules do not need to address this difficulty because they include both for-profit entities that are closely held and for-profit entities that are not closely held.[59] The mechanisms for determining whether a company has adopted and holds such principles or views is a matter of well-established State law with respect to corporate decision-making,[60] and the Departments expect that application of such laws would cabin the scope of this exemption.

In including entities in the exemption that are not closely held, these interim final rules provide for the possibility that some publicly traded entities may use the exemption. Even though the Supreme Court did not extend its holding in Hobby Lobby to publicly traded corporations (the matter could be resolved without deciding that question), the Court did instruct that RFRA applies to corporations because they are "persons" as that term is defined in 1 U.S.C. 1. Given that the definition under 1 U.S.C. 1 applies to any corporation, the Departments consider it appropriate to extend the exemption set forth in these interim final rules to for-profit corporations whether or not they are closely held. The Departments are generally aware that in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of

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

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

religiously devout persons so as to set forth such a religious character.[61] The fact that such a company is religious does not mean that it will have an objection to contraceptive coverage, and there are many fewer publicly traded companies than there are closely held ones. But our experience with closely held companies is that some, albeit a small minority, do have religious objections to contraceptive coverage. Thus we consider it possible, though very unlikely, that a religious publicly traded company might have objections to contraceptive coverage. At the same time, we are not aware of any publicly traded entities that challenged the Mandate specifically either publicly or in court. The Departments agree with the Supreme Court that it is improbable that many publicly traded companies with numerous "unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs" and thereby qualify for the exemption. (134 S. Ct. at 2774)

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

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

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

separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

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

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

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

E. Exemption for Issuers

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

The Departments are not currently aware of health insurance issuers that possess their own religious objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, 42 U.S.C. 1395w-22(j)(3)(B) and 1396u-2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations are protected from being required to provide coverage or pay for abortions. See, for example, Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, Div. H, Title V, Sec. 507(d). Congress also declared this year that "it is the intent of Congress" to include a "conscience clause" which provides exceptions for religious beliefs if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans." See Id. at Div. C, Title VIII, Sec. 808. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.132(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. As set forth in these interim final rules, the only plan sponsors, or in the case of individual insurance

coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection. Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under 42 CFR 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include coverage for some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt. Issuers that hold religious objections should identify to plan sponsors the lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

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

based on sincerely held religious beliefs will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4) of the PHS Act or related provisions for their failure to provide contraceptive coverage.

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

protections for third party administrators that may have religious beliefs implicated by the Mandate.

F. Scope of Objections Needed for the Objecting Entity Exemption

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

G. Individual Exemption

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

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

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

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

H. Optional Accommodation

Despite expanding the scope of the exemption, these rules also keep the accommodation process, but revise it so as to make it optional. In this way, objecting employers are no longer required to choose between direct compliance or compliance through the accommodation. These rules maintain the location of the accommodation process in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815-2713A, and 29 CFR 2590.715-2713A. These rules, by virtue of expanding the plan sponsor exemption beyond houses of worship and integrated auxiliaries that were previously exempt, and beyond religious nonprofit groups that were previously accommodated, and by defining eligible organizations for the accommodation with reference to those covered by the exemption, likewise expand the kinds of entities that may use the optional accommodation. This includes plan sponsors with sincerely held religious beliefs for the reasons described above. Consequently, under these interim final rules, objecting employers may make use of the exemption, or may choose to pursue the optional accommodation process. If an eligible organization pursues the optional accommodation process through the EBSA Form 700

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

[63] 78 FR 39874.

or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

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

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these interim final rules and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. This revocation process applies both prospectively to eligible organizations who decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that were included in the accommodation prior to the effective date of these interim final rules either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. If contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the 1st day of the 1st plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of

notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act,[64] if applicable, to revoke its use of the accommodation process.

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

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

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

J. Conclusion

The Departments believe that the Guidelines and the exemptions expanded herein will advance the limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for religious exemptions

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

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

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

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

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

Section 553(b) of the Administrative Procedure Act (APA) requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior to finalization of regulatory requirements – except when an agency, for good cause, finds that

notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to continue to update the Guidelines.

Dozens of lawsuits over the Mandate have been pending for nearly 5 years. The Supreme Court remanded several of those cases more than a year ago, stating that on remand "[w]e anticipate that the Courts of Appeals will allow the parties sufficient time to resolve any outstanding issues between them". Zubik, 136 S. Ct. at 1560. During that time, Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days. Those status reports have informed the courts that the parties were in discussions, and about the RFI issued in late 2016 and its subsequent comment process and the FAQ the Departments issued indicating that we could not find a way at that time to amend the accommodation process so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. Since then, several courts have issued orders setting more pressing deadlines. For example, on March 10, 2017, the United States Court of Appeals for the Seventh

Circuit ordered that, by May 1, 2017, "the court expects to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions. In the event no agreement is reported on or before May 1, 2017, the court will plan to schedule oral argument on the merits of the case on short notice after that date". The Departments submitted a status report but were unable to set forth their specific position because this interim final rule was not yet on public display. Instead, the Departments informed the Court that we "are now considering whether further administrative action would be appropriate". In response, the court extended the deadline to June 1, 2017, again declaring the court expected "to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions". The Departments were again unable to set forth their position in that status report, but were able to state that the "Departments of Health and Human Services, Labor, and the Treasury are engaged in rulemaking to reconsider the regulations at issue here," citing https://www.reginfo.gov/public/do/eoDetails?rrid=127381.

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

The Departments have also been subject to temporary injunctions protecting many religious nonprofit organizations from being subject to the accommodation process against their wishes, while many other organizations are fully exempt, have permanent court orders blocking

the contraceptive coverage requirement, or are not subject to section 2713 of the PHS Act and its enforcement due to Congress' limited application of that requirement. Good cause exists to change the Departments' previous rules to direct HRSA to bring its Guidelines in accord with the legal realities and remove the threat of a future violation of religious beliefs, including where such violations are contrary to Federal law.

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

These interim final rules provide a specific policy resolution that courts have been waiting to receive from the Departments for more than a year. If the Departments were to publish a notice of proposed rulemaking instead of these interim final rules, many more months

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

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

with the prompt availability of contraceptive coverage and delay the implementation of the alternative opt-out for religious objectors". Id. at 277.

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

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

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

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

VI. Economic Impact and Paperwork Burden

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

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

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

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

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

of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

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

2. Anticipated Effects

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

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

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

The Departments estimate that these interim final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their newly exempt status. In contrast, the Departments expect that a much smaller

number (which we assume to be 9) will make use of the accommodation that were not provided access to it previously. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations on issuers and third party administrators serving the fewer number of entities that will newly opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation.

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

- how many entities will make use of their newly exempt status.
- how many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in Hobby Lobby, several objecting entities still provide coverage for 14 of the 18 women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- how many women will be covered by plans of entities using their newly exempt status.

- which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- the degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- the degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- the degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- the extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

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

First, the prior rules already exempted certain houses of worship and their integrated auxiliaries. Further, as discussed above, the prior accommodation process allows hundreds of additional religious nonprofit organizations in self-insured church plans that are exempt from

ERISA to file a self-certification or notice that relieves not only themselves but, in effect, their third party administrators of any obligation to provide contraceptive coverage or payments. Although in the latter case, third party administrators are legally permitted to provide the coverage, several self-insured church plans themselves have expressed an objection in litigation to allowing such contraceptive coverage to be provided, and according to information received during litigation, it appears that such contraceptive coverage has not been provided. In addition, a significant portion of the lawsuits challenging the Mandate were brought by a single firm representing Catholic dioceses and related entities covered by their diocese-sponsored plans. In that litigation, the Departments took the position that, where those diocese-sponsored plans are self-insured, those plans are likely church plans exempt from ERISA.[65] For the purposes of considering whether the expanded exemption in these rules affects the persons covered by such diocese-sponsored plans, the Departments continue to assume that such plans are similar to other objecting entities using self-insured church plans with respect to their third party administrators being unlikely to provide contraceptive coverage to plan participants and beneficiaries under the previous rule. Therefore the Departments estimate that these interim final rules have no significant effect on the contraceptive coverage of women covered by plans of houses of worship and their integrated auxiliaries, entities using a self-insured church plan, or church dioceses sponsoring self-insured plans.

It is possible that an even greater number of litigating or accommodated plans might have made use of self-insured church plan status under the previous accommodation. Notably, one of

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

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

Second, when the Departments previously created the exemption, expanded its application, and provided an accommodation (which, as mentioned, can lift obligations on self-insured church plans for hundreds of nonprofit organizations), we concluded that no significant burden or costs would result at all. (76 FR 46625; 78 FR 39889.) We reached this conclusion despite the impact, just described, whereby the previous rule apparently lead to women not receiving contraceptive coverage through hundreds of nonprofit entities using self-insured church plans. We also reached this conclusion without counting any significant burden or cost to some women covered in the plans of houses of worship or integrated auxiliaries that might want contraceptive coverage. This conclusion was based in part on the assertion, set forth in previous regulations, that employees of houses of worship and integrated auxiliaries likely share their employers' opposition to contraception. Many other religious nonprofit entities, however, both adopt and implement religious principles with similar fervency. For the reasons discussed above, the Departments no longer believe we can distinguish many of the women covered in the plans of religious nonprofit entities from the women covered in the plans of houses of worship

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

and integrated auxiliaries regarding which the Departments assumed share their employers' objection to contraception, nor from women covered in the plans of religious entities using self-insured church plans regarding which we chose not to calculate any anticipated effect even though we conceded we were not requiring their third party administrators to provide contraceptive coverage. In the estimates and assumptions below, we include the potential effect of these interim rules on women covered by such entities, in order to capture all of the anticipated effects of these rules.

Third, these interim final rules extend the exemption to for-profit entities. Among the for-profit employers that filed suit challenging the Mandate, the one with the most employees was Hobby Lobby.[67] As noted above, and like some similar entities, the plaintiffs in Hobby Lobby were willing to provide coverage with no cost sharing of various contraceptive services: 14 of 18 FDA-approved women's contraceptive and sterilization methods.[68] (134 S. Ct. at 2766.) The effect of expanding the exemption to for-profit entities is therefore mitigated to the extent many of the persons covered by such entities' plans may receive coverage for at least some contraceptive services. No publicly traded for-profit entities have filed lawsuits challenging the Mandate. The Departments agree with the Supreme Court's expectation in this regard: "it

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

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

seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable". Hobby Lobby, 134 S. Ct. at 2774. Therefore, although publicly traded entities could make use of exempt status under these interim final rules, the Departments do not expect that very many will do so, as compared to the 87 religious closely held for-profit entities that brought litigation challenging the Mandate (some of which might be content with the accommodation).

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

After issuing those rules, the Departments have not received complete data on the number of entities actually using the accommodation, because the accommodation does not require many accommodated entities to submit information to us. Our limited records indicate that approximately 63 entities have affirmatively submitted notices to HHS to use the

accommodation. This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. We have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or we were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage. Our records also indicate that 60 plans used the contraceptive user fees adjustments in the 2015 plan year, the last year for which we have data. This includes only self-insured plans, and it includes some plans that self-certified through submitting notices and other plans that, presumably, self-certified through the EBSA form 700.

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

In considering how many entities will use the voluntary accommodation moving forward—and how many will use the expanded exemption—we also do not have specific data. We expect the 122 nonprofit entities that specifically challenged the accommodation in court to

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

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

Lobby. This estimate is further consistent with our view, explained in more detail below, that some entities that are using the accommodation and did not bring litigation will use the exemption, but many accommodated, non-litigating entities—including the ones with the largest relative workforces among accommodated entities—will continue using the accommodation. The Departments recognize that we do not have better data to estimate the effects of these interim final rules on such entities.

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

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

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

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

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

Second, prior to the Affordable Care Act, the vast majority of entities already covered contraception, albeit not always without cost-sharing The Departments do not have data to

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

indicate why entities that did not cover contraception prior to the Affordable Care Act chose not to cover it. As noted above, however, the Departments have maintained that compliance with the contraceptive Mandate is cost-neutral to issuers, which indicates that no significant financial incentive exists to omit contraceptive coverage. As indicated by the report by HHS ASPE discussed above, we have assumed that millions of women received preventive services after the Mandate went into effect because nearly all entities complied with the Guidelines. We are not aware of expressions from most of those entities indicating that they would have sincerely held religious objections to complying with the Mandate, and therefore that they would make use of the expanded exemption provided here.

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

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

To calculate the anticipated effects of this rule on contraceptive coverage among women covered by plans provided by litigating entities, we start by examining court documents and

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

Among litigating entities that were neither exempt nor likely using self-insured church plans, our best estimate based on court documents and public sources is that such entities employed approximately 65,000 persons, male and female.[71] The average number of workers at firms offering health benefits that are actually covered by those benefits is 62 percent.[72] This amounts to approximately 34,000 employees covered under those plans. DOL estimates that for each employee policyholder, there is approximately one dependent.[73] This amounts to approximately 68,000 covered persons. Census data indicate that women of childbearing age—

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

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

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

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

that is, women aged 15–44—compose 20.2 percent of the general population.[74] In addition, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[75] Therefore, we estimate that approximately 7,221 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that have filed lawsuits challenging the Mandate, where those plans are neither exempt under the prior rule nor are self-insured church plans.

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

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

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

that 44.3 perecent of such women use contraception covered by the Guidelines,[76] we estimate that 1,462 of those women would be affected by these rules.

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

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

[76] It would appear that a smaller percentage of college-aged women use contraception—and use more expensive methods such as long acting methods or sterilization—than among other women of childbearing age. See NCHS Data Brief, "Current Contraceptive Status Among Women Aged 15-44: United States, 2011-2013" (Dec. 2014), available at https://www.cdc.gov/nchs/data/databriefs/db173.pdf.

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

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

There are two reasons to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.[78] Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these interim final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.[79] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[80] (The Departments take no view on the status of these particular plans under

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

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

[80] See supra note 66.

ERISA, but simply make this observation for the purpose of seeking to estimate the impact of these interim final rules.) Nevertheless, overall it seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these interim final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations these interim final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

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

contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

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

As discussed below, and recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the prior rule will continue to opt into it under these interim final rules. Notably, however, the data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As also cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these interim final rules would not impact the

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

contraceptive coverage their employees receive. We do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. We assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data. Based on these assumptions and without better data available, we assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, we assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.

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

It is not clear the extent to which this number overlaps with the number estimated above of 8,700 women in plans of litigating entities that may be affected by these rules. Based on our limited information from the litigation and accommodation notices, we expect that the overlap is

significant. Nevertheless, in order to estimate the possible effects of these rules, we assume there is no overlap between these two numbers, and therefore that these interim final rules would affect the contraceptive costs of approximately 31,700 women.

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

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

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

those plans. Therefore, entities using contraceptive user fees adjustments received approximately $584 per year per woman of childbearing age that use contraception covered by the Guidelines and are covered in their plans.

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

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

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

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

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

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

some of those private insurance plans were offered by government employers, encompassing approximately 10.5 million of those women aged 15 to 64.[86] The expanded exemption in these interim final rules does not apply to government plan sponsors. Thus we estimate that the number of women aged 15 to 64 covered by private sector employer sponsored insurance who receive preventive services coverage under the Affordable Care Act is approximately 36 million.

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

[86] The ASPE study relied on Census data of private health insurance plans, which included plans sponsored by either private or public sector employers. See Table 2, notes 2 & 3 (explaining the scope of private plans and government plans for purposes of Table 2), available at https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-250.pdf.

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

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

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

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

covered by the Guidelines. Therefore we estimate that 574,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.[88]

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

To begin, we estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in Hobby Lobby, where the Court observed that "HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable". 134 S. Ct. at 2774.

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

The Departments are aware of several Federal health care conscience laws[89] that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but we are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while we consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions we agree with the Supreme Court that it is improbable any will do so.

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

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

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[89] For example, 42 U.S.C. 300a-7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. No. 115-31.

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

There are 17,651 Catholic parishes in the United States[91], 197 Catholic dioceses,[92] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[93] Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so we use the number of schools to estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention. It covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[94] Christian Brothers is a plan that covers Catholic organizations. It covers Catholic churches and integrated auxiliaries, which are estimated above, but also it has said in litigation that it also covers about 500 additional entities that are not exempt as churches. In total, therefore, we estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous rules. We do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include "churches, mission-sending agencies, hospitals, educational institutions and other related ministries." Using that ratio, we estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 would be of childbearing age, and 32,100

[91] Roman Catholic Diocese of Reno, "Diocese of Reno Directory: 2016-2017," available at http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf.
[92] Wikipedia, "List of Catholic dioceses in the United States," available at https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.
[93] National Catholic Educational Association, "Catholic School Data," available at http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.
[94] Guidestone Financial Resources, "Who We Serve," available at https://www.guidestone.org/AboutUs/WhoWeServe.

would use contraceptives covered by the Guidelines. Therefore, we estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous rules nor were participants in self-insured church plans that oppose contraceptive coverage, covered 362,100 women aged 15 to 44 that use contraceptives covered by the Guidelines. As noted above, we estimate an average annual expenditure on contraceptive products and services of $584 per user. That would amount to $211.5 million in potential transfer impact among entities that did not cover contraception pre- Affordable Care Act for any reason.

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

First, as mentioned, we are not aware of information that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the

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

In addition, not all sincerely held conscientious objections to contraceptive coverage are likely to be held by persons with religious beliefs as distinct from persons with sincerely held non-religious moral convictions, whose objections would not be encompassed by these interim final rules.[96] We do not have data to indicate, among entities that did not cover contraception

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

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

pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, which ones did so based on religious beliefs and which ones did so instead based on non-religious moral convictions. Among the general public, polls vary about religious beliefs but one prominent poll shows that 89 percent of Americans say they believe in God, while 11 percent say they do not or are agnostic.[97] Therefore, we estimate that for every ten entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, one did so based on sincerely held non-religious moral convictions, and therefore are not affected by the expanded exemption provided by these interim final rules for religious beliefs.

Based on our estimate of an average annual expenditure on contraceptive products and services of $584 per user, the effect of the expanded exemptions on 120,000 women would give rise to approximately $70.1 million in potential transfer impact. This falls substantially below the $100 million threshold for economically significant and major rules. In addition, as noted above, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent x 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent, yielding a potential transfer of $63.8 million.

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

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

B. Special Analyses—Department of the Treasury

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

C. Regulatory Flexibility Act

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

the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

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

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

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

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

A description of the information collection provisions implicated in these interim final rules is given in the following section with an estimate of the annual burden. Average labor

costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.[98]

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

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

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

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

accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

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

[99] For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.
[100] Occupation code 43-6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84, https://www.bls.gov/oes/current/oes436011.htm
[101] Occupation code 11-3111 for Compensation and Benefits Managers with mean hourly wage $61.01, https://www.bls.gov/oes/current/oes113111.htm
[102] Occupation code 23-1011 for Lawyers with mean hourly wage $67.25, https://www.bls.gov/oes/current/oes231011.htm
[103] Occupation code11-1011 for Chief Executives with mean hourly wage $93.44, https://www.bls.gov/oes/current/oes111011.htm

the hour burden so each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

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

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

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

similar language. The burden for this ICR is currently approved under OMB control number 0938-1292.

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

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

[104] Occupation code 43-6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84.
[105] Occupation code 11-1021 General and Operations Managers with mean hourly wage $58.70.

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

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

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

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

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

litigating entities that were previously using the accommodation and that will revoke it fall within the estimated 109 entities that will revoke the accommodation overall.

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

As discussed above, HHS estimates that there are 257,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[111] As before, we use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 128,757 notices will be sent, of which 59,615 notices will be mailed. HHS estimates that each notice will require $0.49 in postage and

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

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

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

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

$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54. The total cost for sending approximately 59,615 notices by mail is approximately $32,192. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 64,379 notices, with an equivalent cost of approximately $16,096.

Table 1: Summary of Information Collection Burdens

Regulation Section	OMB Control Number	Number of respondents	Responses	Burden per Respondent (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Cost ($)
Self-Certification or Notices to HHS	0938-NEW	5*	5	0.83	3.75	$89.95	$337.31	$338.66
Notice of Availability of Separate Payments for Contraceptive Services	0938-NEW	55*	210,245	1.25	68.13	$68.02	$4,634.14	$57,199.59
Notice of Revocation of Accommodation	0938-NEW	55*	64,379	2.00	109	$90.82	$9,898.84	$25,994.75
Total		115*	274,629	4.08	180.88		$14,870.29	$83,533.00

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

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

We are soliciting comments on all of the information collection requirements contained in these interim final rules. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938-1292 and 0938-1248. HHS is requesting a new OMB control number that will ultimately contain the approval for the new information collection requirements contained in these interim final rules as well as the related requirements currently approved under 0938-1292 and 0938-1248. In an effort to consolidate the number of information collection requests, we will formally discontinue the control numbers

0938-1292 and 0938-1248 once the new information collection request associated with these interim final rules is approved.

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

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

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

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

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

E. Paperwork Reduction Act—Department of Labor

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

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

Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur $0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 420,489 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3

percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke its use and will therefore be required to cause the Notice of Revocation of Accommodation to be sent (the issuer or third party administrator can send the notice on behalf of the entity). These entities will spend approximately two hours in preparation time and incur $0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 128,757 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3-16 and 2590.715-2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

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

OMB Numbers: 1210-0150.

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

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

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

Frequency of Response: On occasion.

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

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

Type of Review: Revised Collection.

Agency: DOL–EBSA.

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

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, "[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." In addition, agencies are directed to "take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market." These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting costs.[113] Therefore, this interim final rule is considered an Executive Order 13771 deregulatory action.

[113] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on EO 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

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104-4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflater for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

G. Federalism

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

Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for EO 13771 designation purposes.

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

VII. Statutory Authority

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

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

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

List of Subjects

26 CFR Part 54

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

29 CFR Part 2590

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

45 CFR Part 147

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

Kirsten B. Wielobob,
Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,
Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

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

Dated: October 4, 2017.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

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Donald Wright,

Acting Secretary,

Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

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

PART 54—PENSION EXCISE TAXES

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

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

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

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

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

* * * * *

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

* * * * *

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) [Reserved]

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

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

(b) Optional accommodation - self-insured group health plans. (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party

administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

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

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

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

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

plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3-16 and this section.

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

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

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

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

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

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

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

(c) Optional accommodation - insured group health plans—(1) General rule. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of

contraceptive services for one or more plan years. To invoke the optional accommodation process--

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

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

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815-2713.

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

under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group

health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) Notice of availability of separate payments for contraceptive services - self-insured and insured group health plans. For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): "Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead,

[name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer]."

(e) Definition. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815-2713(a)(1)(iv).

(f) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

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

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

6. The authority citation for part 2590 continues to read as follows:

AUTHORITY: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Division M, Pub. L. 113-235, 128 Stat. 2130; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

7. Section 2590.715-2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715-2713 Coverage of preventive health services.

(a) Services--(1) In general. Beginning at the time described in paragraph (b) of this section and subject to § 2590.715-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by

the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

8. Section 2590.715-2713A is revised to read as follows:

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

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

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

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

(3) [Reserved]

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

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of

such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715-2715(b), if applicable, to revoke its use of the accommodation process.

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

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

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

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

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

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

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

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

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

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

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

an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) Optional accommodation - insured group health plans—(1) General rule. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

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

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715-2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name

and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711,

2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) Notice of availability of separate payments for contraceptive services - self-insured and insured group health plans. For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): "Your

employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer]."

(e) Definition. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 2590.715-2713(a)(1)(iv).

(f) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

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

9. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

10. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) In general. Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131 and 147.132, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

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

* * * * *

11. Section 147.131 is revised to read as follows:

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

(a) – (b) [Reserved]

(c) Eligible organizations for optional accommodation. An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

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

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan

participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process.

(d) Optional accommodation—insured group health plans—(1) General rule. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of §

147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Deparement of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue

collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) Notice of availability of separate payments for contraceptive services - insured group health plans and student health insurance coverage. For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) "Your

[employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments . If you have any questions about this notice, contact [contact information for health insurance issuer]."

(f) Definition. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(g) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

12. Add § 147.132 to read as follows:

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

(a) Objecting entities. (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities--

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) Objecting individuals. Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(c) Definition. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[Billing Codes: 4830-01-P; 4510-029-P; 4120-01-P; 6325-64]

[FR Doc. 2017-21851 Filed: 10/6/2017 11:15 am; Publication Date: 10/13/2017]

First Amended Complaint Exhibit B

This document is scheduled to be published in the Federal Register on 10/13/2017 and available online at **https://federalregister.gov/d/2017-21852**, and on **FDsys.gov**

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD-9828]

RIN 1545-BN91

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS-9925-IFC}

RIN 0938-AT46

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

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

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs or moral convictions. These interim final rules expand exemptions to protect moral convictions for certain entities and individuals whose health plans are subject to a mandate of contraceptive

coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the United States Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also provide certain morally objecting entities access to the voluntary "accommodation" process regarding such coverage. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

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

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

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

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

Comments, identified by "Preventive Services," may be submitted one of four ways (please choose only one of the ways listed)

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

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9925-IFC,

P.O. Box 8016,

Baltimore, MD 21244- 8016.

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

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-9925-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850

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

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

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

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

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

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

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

FOR FURTHER INFORMATION CONTACT:

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

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's 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:

I. Background

In the context of legal requirements touching on certain sensitive health care issues—including health coverage of contraceptives—Congress has a consistent history of supporting conscience protections for moral convictions alongside protections for religious beliefs, including as part of its efforts to promote access to health services.[1] Against that backdrop,

[1] See, for example, 42 U.S.C. 300a-7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their "religious beliefs or moral

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, "with respect to women, such additional preventive care and screenings … as provided for in comprehensive guidelines supported by" HRSA (the "Guidelines"). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and

convictions"); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Pub. L. No. 115-31 (protecting any "health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion for any reason); Id. at Div. C, Title VIII, Sec. 808 (regarding any requirement of "the provision of contraceptive coverage by health insurance plans" in the District of Columbia, "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions."); Id. at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions"); Id. at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their "religious or conscientious commitment to offer only natural family planning"); 42 U.S.C. 290bb-36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on "religious beliefs or moral objections"); 42 U.S.C. 1395w-22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on "conscience" as protected in State law concerning advance directives); 42 U.S.C. 1396u-2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on "religious beliefs or moral convictions"); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); see also 8 U.S.C. 1182(g) (protecting vaccination objections by "aliens" due to "religious beliefs or moral convictions"); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on "moral or religious convictions"); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their "religious or moral objection").

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

Human Services, Labor, and the Treasury (collectively, "the Departments"[3]), exercised both the discretion granted to HHS through HRSA, its component, in PHS Act section 2713(a)(4), and the authority granted to the Departments as administering agencies (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92) to issue regulations to guide HRSA in carrying out that provision. Through rulemaking, including three interim final rules, the Departments exempted and accommodated certain religious objectors, but did not offer an exemption or accommodation to any group possessing non-religious moral objections to providing coverage for some or all contraceptives. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the "contraceptive Mandate," or the "Mandate") as being inconsistent with various legal protections. These challenges included lawsuits brought by some non-religious organizations with sincerely held moral convictions inconsistent with providing coverage for some or all contraceptive services, and those cases continue to this day. Various public comments were also submitted asking the Departments to protect objections based on moral convictions.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as: the interests served by the existing Guidelines, regulations, and accommodation process[4]; the extensive litigation; Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017); Congress' history of providing protections for moral convictions alongside religious beliefs regarding certain health services (including contraception, sterilization, and

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

[4] In this IFR, we generally use "accommodation" and "accommodation process" interchangeably.

items or services believed to involve abortion); the discretion afforded under PHS Act section 2713(a)(4); the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; and the history of the regulatory process and comments submitted in various requests for public comments (including in the Departments' 2016 Request for Information). Elsewhere in this issue of the **Federal Register**, the Departments published, contemporaneously with these interim final rules, companion interim final rules expanding exemptions to protect sincerely held religious beliefs in the context of the contraceptive Mandate.

In light of these considerations, the Departments issue these interim final rules to better balance the Government's interest in promoting coverage for contraceptive and sterilization services with the Government's interests in providing conscience protections for individuals and entities with sincerely held moral convictions in certain health care contexts, and in minimizing burdens imposed by our regulation of the health insurance market.

A. The Affordable Care Act

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

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

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

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

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

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. The Congress did not intend to require entirely uniform coverage of preventive services. (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 for grandfathered plans. This exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the

Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include: section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime limits; section 2712, which prohibits rescissions of health insurance coverage; section 2714, which extends dependent coverage until age 26; and section 2718, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751, 2764 n.10 (2014).

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

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

consistent with longstanding Federal laws to protect conscience regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in consideration of the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

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

1. The Institute of Medicine Report

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

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of "contraceptives" certain drugs and devices that may not only prevent

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

conception (fertilization), but may also prevent implantation of an embryo,[7] the IOM's recommendation included several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason distinct from whether they also oppose contraception or sterilization. One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He stated that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by section 2713(a)(1) through (3) of the PHS Act leads to lower rates of disability or disease and increased rates of well-being, such that the IOM should recommend additional services to be included under Guidelines issued under section 2713(a)(4) of the PHS Act. He further stated that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and that "the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy." He also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] IOM 2011 at 231–32. In its response to Dr. LoSasso, the other 15 committee members stated in part that "At the first committee meeting, it was agreed

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

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

that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions."

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

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

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules. (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specified that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.[9] The 2011 interim final rules only offered the exemption to a narrow scope of employers, and only if they were religious. As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some "States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services." (76 FR 46623). Several comments were submitted asking that the

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

exemption include those who object to contraceptive coverage based on non-religious moral convictions, including pro-life, non-profit advocacy organizations.[10]

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

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

Contemporaneously with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).[12] The temporary safe harbor did not include nonprofit organizations that had an objection to contraceptives based on

[10] See, for example, Americans United for Life ("AUL") Comment on CMA-9992-IFC2 at 10 (Nov. 1, 2011), available at http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496.

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

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

moral convictions but not religious beliefs, nor did it include for-profit entities of any kind. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve "two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services." (77 FR 8727).

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

The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer-- (1) have the inculcation of religious values as its purpose; (2) primarily employ persons who share its religious tenets; and (3) primarily serve persons who share its religious tenets. The proposed expanded definition still encompassed only religious entities.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain

contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations "may be less likely than" employees of exempt houses of worship and integrated auxiliaries to share their employer's faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization's plan—and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries. The proposed accommodation process was not to be offered to non-religious nonprofit organizations, nor to any for-profit entities. Public comments again included the request that exemptions encompass objections to contraceptive coverage based on moral convictions and not just based on religious beliefs.[14] On August 15, 2012, the Departments extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for

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

[14] See,for example, AUL Comment on CMS-9968-P at 5 (Apr. 8, 2013), available at http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115.

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

The July 2013 regulation also finalized an accommodation for eligible organizations, which were then defined to include solely organizations that are religious. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization's plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the HHS Secretary requests and an authorizing exception under OMB Circular

No. A-25R is in effect.[15] With respect to fully insured group health plans, the issuer was expected to bear the cost of such payments,[16] and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations. The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. Religious for-profit entities won various court decisions leading to the Supreme Court's ruling in Burwell v. Hobby Lobby Stores, Inc. 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[17]

On August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking

[15] See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally-facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.
[16] "[P]roviding payments for contraceptive services is cost neutral for issuers." (78 FR 39877).
[17] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

(August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of HHS that an eligible organization had religious objections to coverage of all or a subset of contraceptive services. (79 FR 51092). In response to Hobby Lobby, the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations. (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption; neither added a certification requirement for exempt entities; and neither encompassed objections based on non-religious moral convictions.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

Meanwhile, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On November 6, 2015, the

U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, Zubik v. Burwell. On May 16, 2016, the Supreme Court issued a per curiam opinion in Zubik, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases "in light of the substantial clarification and refinement in the positions of the parties" that had been filed in supplemental briefs. 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would "allow the parties sufficient time to resolve any outstanding issues between them." Id. The Court also specified that "the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice" while the cases remained pending. Id. at 1561.

After remand, as indicated by the Departments in court filings, meetings were held between attorneys for the Government and for the plaintiffs in those cases. The Departments also issued a Request for Information ("RFI") on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in Zubik and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016. Those comments included the request that the exemption be expanded to include those who oppose the Mandate for either religious "or moral" reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.[18]

[18] See, for example, https://www.regulations.gov/document?D=CMS-2016-0123-54142; see also https://www.regulations.gov/document?D=CMS-2016-0123-54218 and https://www.regulations.gov/document?D=CMS-2016-0123-46220.

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations asserted that they believe some methods classified by FDA as contraceptives may have an abortifacient effect and therefore, in their view, are morally equivalent to abortion. These organizations have neither received an exemption from the Mandate nor do they qualify for the accommodation. For example, the organization that since 1974 has sponsored the annual March for Life in Washington, D.C. (March for Life), filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, (77 FR 8727), March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who "want" the coverage so as to prevent "unintended" pregnancy. March for Life contended that because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and therefore doing so was arbitrary and capricious in violation of the APA. March for Life further contended that because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on our assumption that such entities are relatively more likely than other religious nonprofits to have employees that share their views against contraception), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and therefore violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. Real Alternatives, Inc. v. Burwell, 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the Federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims (not specifically ruling on the APA claim), and issued a permanent injunction against the Departments that is still in place. March for Life v. Burwell, 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in March for Life is pending and has been stayed since early 2016. In another case, Federal district and appellate courts in Pennsylvania disagreed with the reasoning from March for Life and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. Real Alternatives, 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in Real Alternatives dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. Id. at *18.

On December 20, 2016, HRSA updated the Guidelines via its website, https://www.hrsa.gov/womensguidelines2016/index.html. HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning

after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the contraceptive method). They also specified, for the first time, that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process, nor did they extend the exemption or accommodation process to organizations or individuals that oppose certain forms of contraception (and coverage thereof) on moral grounds.

On January 9, 2017, the Departments issued a document entitled, "FAQs About Affordable Care Act Implementation Part 36."[19] The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. The Departments did not adopt the approach requested by certain commenters, cited above, to expand the exemption to include those who oppose the Mandate for moral reasons.

On May 4, 2017, the President issued Executive Order 13798, "Promoting Free Speech and Religious Liberty." Section 3 of that order declares, "Conscience Protections with Respect to Preventive-Care Mandate. The Secretary of the Treasury, the Secretary of Labor, and the

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

Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code."

II. Expanded Exemptions and Accommodations for Moral Convictions

These interim final rules incorporate conscience protections into the contraceptive Mandate. They do so in part to bring the Mandate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues, cognizant that Congress neither required the Departments to impose the Mandate nor prohibited them from providing conscience protections if they did so. Specifically, these interim final rules expand exemptions to the contraceptive Mandate to protect certain entities and individuals that object to coverage of some or all contraceptives based on sincerely held moral convictions but not religious beliefs, and these rules make those exempt entities eligible for accommodations concerning the same Mandate.

A. Discretion to Provide Exemptions under Section 2713(a)(4) of the PHS Act and the Affordable Care Act

The Departments have consistently interpreted HRSA's authority under section 2713(a)(4) of the PHS Act to allow for exemptions and accommodations to the contraceptive Mandate for certain objecting organizations. Section 2713(a)(4) of the PHS Act gives HRSA discretion to decide whether and in what circumstances it will support Guidelines providing for additional women's preventive services coverage. That authority includes HRSA's discretion to include contraceptive coverage in those Guidelines, but the Congress did not specify whether or to what extent HRSA should do so. Therefore, section 2713(a)(4) of the PHS Act allows HRSA to not apply the Guidelines to certain plans of entities or individuals with religious or moral

objections to contraceptive coverage, and by not applying the Guidelines to them, to exempt those entities from the Mandate. These rules are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg-92).

Our protection of conscience in these interim final rules is consistent with the structure and intent of the Affordable Care Act. The Affordable Care Act refrains from applying section 2713(a)(4) of the PHS Act to millions of women in grandfathered plans. In contrast, we anticipate that conscientious exemptions to the Mandate will impact a much smaller number of women. President Obama emphasized in signing the Affordable Care Act that "longstanding Federal law to protect conscience"—laws with conscience protections encompassing moral (as well as religious) objections—specifically including (but not limited to) the Church Amendments (42 U.S.C. 300a-7), "remain intact." Executive Order 13535. Nothing in the Affordable Care Act suggests Congress' intent to deviate from its long history, discussed below, of protecting moral convictions in particular health care contexts. The Departments' implementation of section 2713(a)(4) of the PHS Act with respect to contraceptive coverage is a context similar to those encompassed by many other health care conscience protections provided or supported by Congress. This Mandate concerns contraception and sterilization services, including items believed by some citizens to have an abortifacient effect—that is, to cause the destruction of a human life at an early stage of embryonic development. These are highly sensitive issues in the history of health care regulation and have long been shielded by conscience protections in the laws of the United States.

B. Congress' History of Providing Exemptions for Moral Convictions

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on nearly 50 years of statutory law and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health insurance coverage. Congress very recently expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808, Pub. L. No. 115-31 (May 5, 2017). In support of these interim final rules, we consider it significant that Congress' most recent statement on the prospect of Government mandated contraceptive coverage specifically intends that a conscience clause be included to protect moral convictions.

The many statutes listed in Section I-Background under footnote 1, which show Congress' consistent protection of moral convictions alongside religious beliefs in the Federal regulation of health care, includes laws such as the 1973 Church Amendments, which we discuss at length below, all the way to the 2017 Consolidated Appropriations Act discussed above. Notably among those laws, the Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w-22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396u-2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"). The Congress has also

protected individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Pub. L. No. 115-31.

C. The Church Amendments' Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations. These sections of the United States Code are known as the Church Amendments, named after their primary sponsor Senator Frank Church (D-Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions. Among other things, the amendments protect the recipients of certain Federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object "on the basis of religious beliefs or moral convictions," and they prohibit recipients of certain Federal health funds from discriminating against any personnel "because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions" (42 U.S.C. 300a-7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to "any lawful health service," or to "any part of a health service program." (42 U.S.C. 300a-7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute "any lawful health

service" or a "part of a health service program." As such, the protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court's decision in Roe v. Wade, 410 U.S. 113 (1973). Even though the Court in Roe required abortion to be legal in certain circumstances, Roe did not include, within that right, the requirement that other citizens must facilitate its exercise. Thus, Roe favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared "Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles." 410 U.S. at 144 & n.38 (1973). Likewise in Roe's companion case, Doe v. Bolton, the Court observed that, under State law, "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions "obviously . . . afford appropriate protection." Id. at 198. As an Arizona court later put it, "a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either." Planned Parenthood Ariz., Inc. v. Am. Ass'n of Pro-Life Obstetricians & Gynecologists, 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains relevant discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only Roe v. Wade but also an instance where a Federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D-IL) rose to ask that the amendment be changed to specify that it also protects objections to

abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record is particularly relevant to this discussion:

> Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.
>
> One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.
>
> As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?
>
> Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words "or moral"?
>
> Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words "or moral conviction" were added after "religious belief." I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the

> general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.
>
> Mr. STEVENSON. The Senator's suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18.

As the debate proceeded, Senator Church went on to quote Doe v. Bolton's reliance on a Georgia statute that stated "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 119 Congr. Rec. at S5722 (quoting 410 U.S. at 197–98). Senator Church added, "I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations." Id. Considering the scope of the protections, Senator Gaylord Nelson (D-WI) asked whether, "if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, 'We are not going to bother with this kind of procedure in this hospital,' would the pending amendment permit that?" 119 Congr. Rec. at S5723. Senator Church responded that the amendment would not encompass such an objection. Id.

Senator James L. Buckley (C-NY), speaking in support of the amendment, added the following perspective:

> Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the recent Supreme Court decisions will likely unleash a series of

court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic][20] to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words "moral conviction," because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. at S5723.

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R-MA)[21] likewise observed that "the right of conscience has long been recognized in the parallel situation in which the individual's right to conscientious

[20] The Senator might have meant "[forced] . . . against his will."
[21] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

objector status in our selective service system has been protected" and "expanded by the Supreme Court to include moral conviction as well as formal religious belief." 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, "We are concerned here only with the right of moral conscience, which has always been a part of our national tradition." Id. at 4149.

These first of the Church Amendments, codified at 42 U.S.C. 300a-7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion: see 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. No. 115-31;
- Protections for entities and individuals that object to providing or covering contraceptives: see id. at Div. C, Title VIII, Sec. 808; id. at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act); and id.at Div. I, Title III; and
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives: see 42 U.S.C. 290bb-36; 42 U.S.C. 14406; 42 U.S.C. 18113; and 42 U.S.C. 1396a(w)(3).

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

D. Court Precedents Relevant to These Expanded Exemptions

The legislative history of the protection of moral convictions in the first Church Amendments shows that Members of Congress saw the protection as being consistent with Supreme Court decisions. Not only did Senator Church cite the abortion case Doe v. Bolton as a parallel instance of conscience protection, but he also spoke of the Supreme Court generally giving "comparable treatment to deeply held moral convictions." Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court's protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as Welsh v. United States, 398 U.S. 333 (1970), which the Supreme Court decided just 3 years earlier.

Welsh involved what is perhaps the Government's paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on "religious training and belief," that protection would also extend to avowedly non-religious objections to war held with the same moral strength. Id. at 343. The Court declared, "[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to that filled by … God' in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as

much entitled to a 'religious' conscientious objector exemption … as is someone who derives his conscientious opposition to war from traditional religious convictions."

The Departments look to the description of moral convictions in Welsh to help explain the scope of the protection provided in these interim final rules. Neither these interim final rules, nor the Church Amendments or other Federal health care conscience statutes, define "moral convictions" (nor do they define "religious beliefs"). But in issuing these interim final rules, we seek to use the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as Welsh to support the addition of language protecting moral convictions. In protecting moral convictions parallel to religious beliefs, Welsh describes moral convictions warranting such protection as ones: (1) that the "individual deeply and sincerely holds"; (2) "that are purely ethical or moral in source and content; (3) "but that nevertheless impose upon him a duty"; (4) and that "certainly occupy in the life of that individual a place parallel to that filled by … God' in traditionally religious persons," such that one could say "his beliefs function as a religion in his life." (398 U.S. at 339–40). As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises "capriciously." Instead, along with the requirement that protected moral convictions must be "sincerely held," this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

In the context of this particular Mandate, it is also worth noting that, in Hobby Lobby, Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan's opinion in Welsh, 398 U.S. at 357–58, in support of her statement that "[s]eparating moral convictions from religious beliefs would be of questionable legitimacy." 134

S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious beliefs constitute an illegitimate "separat[ion]" of moral convictions, nor do we assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress' intent in the Church Amendments and in later Federal conscience statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

E. Conscience Protections in Regulations and Among the States

The tradition of protecting moral convictions in certain health contexts is not limited to Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[22] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs when they have determined that it is appropriate to do so in particular circumstances. The Equal Employment Opportunity Commission has consistently protected "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views" alongside religious views under the "standard []

[22] See, for example, 42 CFR 422.206 (declaring that the general Medicare Advantage rule "does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds."); 42 CFR 438.102 (declaring that information requirements do not apply "if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds"); 48 CFR 1609.7001 ("health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs."); 48 CFR 352.270-9 ("Non-Discrimination for Conscience" clause for organizations receiving HIV or Malaria relief funds).

developed in United States v. Seeger, 380 U.S. 163 (1965) and [Welsh]." (29 CFR 1605.1). The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so "is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics." (28 CFR 26.5).[23]

Forty-five States have health care conscience protections covering objections to abortion, and several of those also cover sterilization or contraception.[24] Most of those State laws protect objections based on "moral," "ethical," or "conscientious" grounds in addition to "religious" grounds. Particularly in the case of abortion, some Federal and State conscience laws do not require any specified motive for the objection. (42 U.S.C. 238n). These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts.

The contraceptive Mandate implicates that governmental interest. Many persons and entities object to this Mandate in part because they consider some forms of FDA-approved contraceptives to be abortifacients and morally equivalent to abortion due to the possibility that some of the items may have the effect of preventing the implantation of a human embryo after fertilization. Based on our knowledge from the litigation, all of the current litigants asserting purely non-religious objections share this view, and most of the religious litigants do as well.

[23] See also 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA's request will depend in part on "[c]ultural, religious, or moral objections to the request").

[24] According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). "Refusing to Provide Health Services" (June 1, 2017), available at https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.

The Supreme Court, in describing family business owners with religious objections, explained that "[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions." Hobby Lobby, 134 S. Ct. at 2751. Outside of the context of abortion, as cited above, Congress has also provided health care conscience protections pertaining to sterilization, contraception, and other health care services and practices.

F. Founding Principles

The Departments also look to guidance from the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. As quoted above, in supporting protecting conscience based on non-religious moral convictions, Senator Buckley declared "[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred." Rep. Heckler similarly stated that "the right of moral conscience . . . has always been a part of our national tradition." This tradition is reflected, for example, in a letter President George Washington wrote saying that "[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: a policy worthy of imitation. All possess alike liberty of conscience and immunities of citizenship."[25] Thomas Jefferson similarly declared that "[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience

[25] From George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790), available at https://founders.archives.gov/documents/Washington/05-06-02-0135.

against the enterprises of the civil authority."[26] Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience "the most sacred of all property," and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that "the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed."[27]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context. We do not suggest that the specific protections offered in this rule would also be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These interim final rules do not address in any way how the Government would balance its interests with respect to other health services not encompassed by the contraceptive Mandate.[28] Instead we highlight this tradition of respect for conscience from our Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4) of the PHS Act, while protecting conscience in the exercise of moral convictions. We believe that these interim final rules are consistent both with the American tradition of respect for conscience and with Congress' history of providing conscience protections in the kinds of health care matters involved in this Mandate.

[26] Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809), available at https://founders.archives.gov/documents/Jefferson/99-01-02-9714.
[27] James Madison, "Essay on Property" (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).
[28] As the Supreme Court stated in Hobby Lobby, the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

G. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in the expanded exemptions and accommodations of these rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for "religious" beliefs, but for "conscience." We interpret that term to include moral convictions and not just religious beliefs. Likewise, President Trump's first Executive Order, EO 13765, declared that "the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." This Mandate imposes both a cost, fee, tax, or penalty, and a regulatory burden, on individuals and purchasers of health insurance that have moral convictions opposed to providing contraceptive coverage. These interim final rules exercise the Departments' discretion to grant exemptions from the Mandate to reduce and relieve regulatory burdens and promote freedom in the health care market.

H. Litigation Concerning the Mandate

The sensitivity of certain health care matters makes it particularly important for the Government to tread carefully when engaging in regulation concerning those areas, and to respect individuals and organizations whose moral convictions are burdened by Government regulations. Providing conscience protections advances the Affordable Care Act's goal of

expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in Hobby Lobby declared that, if HHS requires owners of businesses to cover procedures that the owners "could not in good conscience" cover, such as abortion, "HHS would effectively exclude these people from full participation in the economic life of the Nation." 134 S. Ct. at 2783. That would be a serious outcome. As demonstrated by litigation and public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that some of those items may cause early abortions. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) of the PHS Act in a way that respects the moral convictions of our citizens so that they are more free to engage in "full participation in the economic life of the Nation." These expanded exemptions do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. See March for Life v. Burwell, 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court recently affirmed a district court ruling that allows the previous regulations to be imposed in a way that violates the moral convictions of a small nonprofit pro-life organization and its employees. See Real Alternatives, 2017 WL 3324690. Our litigation of these cases has led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The

organizations that have sued seeking a moral exemption have all adopted moral tenets opposed to contraception and hire only employees who share this view. It is reasonable to conclude that employees of these organizations would therefore not benefit from the Mandate. As a result, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, and our requirement to comply with permanent injunctive relief currently imposed in March for Life, provide substantial reasons for the Departments to protect moral convictions through these interim final rules. Even though, as discussed below, we assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, we know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, we consider it appropriate to issue the protections set forth in these interim final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so we, too, believe that "our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government" in this situation.

I. The Departments' Rebalancing of Government Interests

For additional discussion of the Government's balance of interests concerning religious beliefs issued contemporaneously with these interim final rules, see the related document published by the Department elsewhere in this issue of the **Federal Register**. There, we acknowledge that the Departments have changed the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlying it, and we

assert that we now believe the Government's legitimate interests in providing for contraceptive coverage do not require us to violate sincerely held religious beliefs while implementing the Guidelines. For parallel reasons, the Departments believe Congress did not set forth—and we do not possess—interests that require us to violate sincerely held moral convictions in the course of generally requiring contraceptive coverage. These changes in policy are within the Departments' authority. As the Supreme Court has acknowledged, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2125 (2016). This "reasoned analysis" requirement does not demand that an agency "demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." United Student Aid Funds, Inc. v. King, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing FCC v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009)); see also New Edge Network, Inc. v. FCC, 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").[29]

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. In addition to the apparent fact that many entities with non-religious moral

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

objections to the Mandate appear to only hire persons that share those objections, Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 requirements on grandfathered plans benefitting millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including through various other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, and which these interim final rules leave unchanged.[30] As the Government is under no constitutional obligation to fund contraception, cf. Harris v. McRae, 448 U.S. 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their moral convictions. Cf. Rust v. Sullivan, 500 U.S. 173, 192–93 (1991) ("A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.").

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. Our expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after reconsidering the interests served by the Mandate in this particular

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

context, the objections raised, and the relevant Federal law, the Departments have determined that expanding the exemptions to include protections for moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to take advantage of these exemptions and accommodations may be small, we believe that it is important formally to codify such protections for objections based on moral conviction, given the long-standing recognition of such protections in health care and health insurance context in law and regulation and the particularly sensitive nature of these issues in the health care context. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including 3 previous interim final rules), public comments, and the long-running litigation from non-religious moral objectors to the Mandate, as well as the information contained in the companion interim final rules issued elsewhere in this issue of the **Federal Register**. These interim final rules seek to resolve these matters by directing HRSA, to the extent it requires coverage for certain contraceptive services in its Guidelines, to afford an exemption to certain entities and individuals with sincerely held moral convictions by which they

object to contraceptive or sterilization coverage, and by making the accommodation process available for certain organizations with such convictions.

For all of the reasons discussed and referenced above, the Departments have determined that the Government's interest in applying contraceptive coverage requirements to the plans of certain entities and individuals does not outweigh the sincerely held moral objections of those entities and individuals. Thus, these interim final rules amend the regulations amended in both the Departments' July 2015 final regulations and in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

These interim final rules expand those exemptions to include additional entities and persons that object based on sincerely held moral convictions. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no objection specified in the regulations exists, and if section 2713 of the PHS Act otherwise applies. These interim final rules also maintain the existence of an accommodation process as a voluntary option for organizations with moral objections to contraceptive coverage, but consistent with our expansion of the exemption, we expand eligibility for the accommodation to include organizations with sincerely held moral convictions concerning contraceptive coverage. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[31]

1. Exemption for Objecting Entities Based on Moral Convictions

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

In the new 45 CFR 147.133 as created by these interim final rules, we expand the exemption that was previously located in § 147.131(a), and that was expanded in § 147.132 by the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

With respect to employers that sponsor group health plans, §147.133(a)(1) and (a)(1)(i) provide exemptions for certain employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held moral convictions.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption in § 147.133(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.133(a)(1) and (a)(1)(i), by specifying that "[a] group health plan and health insurance coverage provided in connection with a group health plan" is exempt "to the extent the plan sponsor objects as specified in paragraph (a)(2)," exempt the group health plans the sponsors of which object, and exempt their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815-2713T(a)(1)(iv) and 29 CFR 2590.715-2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or

certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[32] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures should reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.133(a) apply "to the extent" of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan

[32] See, for example, 29 USC 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).

sponsor or institution of higher education in § 147.133(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsors have no qualifying objection. The objection of a health insurance issuer in § 147.133(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

2. Exemption of Certain Plan Sponsors

The rules cover certain kinds of non-governmental employer plan sponsors with the requisite objections, and the rules specify which kinds of entities qualify for the exemption.

Under these interim final rules, the Departments do not limit the exemption with reference to nonprofit status as previous rules have done. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities without regard to whether they operate as nonprofits or for-profit entities. In addition, a significant majority of states either impose no contraceptive coverage requirement, or offer broader exemptions than the exemption contained in the July 2015 final regulations.[33] States also generally protect moral convictions in health care conscience laws, and they often offer those protections whether or not an entity operates as a nonprofit.[34] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the Affordbable Care Act, nor is it a statement about what the Federal Government may do consistent with other protections or limitations in federal law, such state practice can be informative as to the viability of offering

[33] See Guttmacher Institute, "Insurance Coverage of Contraceptives" (Aug. 1, 2017), available at https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.
[34] See, for example, Guttmacher Institute, "Refusing to Provide Health Services" (Aug. 1, 2017), available at https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.

protections for conscientious objections in particularly sensitive health care contexts. In this case, the existence of many instances where conscience protections are offered, or no underlying mandate of this kind exists that could violate moral convictions, supports the Departments' decision to expand the Federal exemption concerning this Mandate as set forth in these interim final rules.

Section 147.133(a)(1)(i)(A) of the rules specifies that the exemption includes the plans of a plan sponsor that is a nonprofit organization with sincerely held moral convictions.

Section 147.133(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of a plan sponsor that is a for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

Extending the exemption to certain for-profit entities is consistent with the Supreme Court's ruling in Hobby Lobby, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in Hobby Lobby, religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the Departments' argument to the contrary. 134 S. Ct. 2768–75. Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after Hobby Lobby.[35] The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held moral convictions, is a matter of

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

well-established State law with respect to corporate decision-making,[36] and the Departments expect that application of such laws would cabin the scope of this exemption.

The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. Any such positive definition runs up against the myriad state differences in defining such entities, and potentially intrudes into a traditional area of state regulation of business organizations. The Departments implicitly recognized the difficulty of defining closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely "substantially similar" to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. Instead of attempting to positively define closely held businesses for the purpose of this rule, the Departments consider it much more clear, effective, and preferable to define the category negatively by reference to one element of our previous definition, namely, that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

In this way, these interim final rules differ from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in § 147.132(a)(1)—those extend to for-profit entities whether or not they are closely held or publicly traded. The Departments seek public comment on whether the exemption in § 147.133(a)(1)(i) for plan

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

sponsors with moral objections to the Mandate should be finalized to encompass all of the types of plan sponsors covered by § 147.132(a)(1)(i), including publicly traded corporations with objections based on sincerely held moral convictions, and also non-federal governmental plan sponsors that may have objections based on sincerely held moral convictions.

In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without precluding publicly traded and governmental entities from using those protections. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 300a-7(b)). Thus, under section 300a-7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a-7(b), the protections of that section would apply. The Coats-Snowe Amendment likewise provides certain protections for health care entities and postgraduate physician training programs that choose not to perform, refer for, or provide training for abortions, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 238n).

The Weldon Amendment[37] provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans

[37] Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. No. 115-31.

that do not provide, pay for, provide coverage of, or refer for abortions, and the statute does not limit those protections based on whether the entity is publicly traded or governmental. The Affordable Care Act provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing, and the statute similarly does not limit those protections based on whether the entity is publicly traded or governmental. (42 U.S.C. 18113).[38]

Sections 1395w-22(j)(3)(B) and 1396u-2(b)(3) of 42 U.S.C. protect organizations that offer Medicaid and Medicare Advantage managed care plans from being required to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds, and those paragraphs do not further specify that publicly traded entities do not qualify for the protections. Congress' most recent statement on Government requirements of contraceptive coverage specified that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808. Congress expressed no intent that such a conscience should be limited based on whether the entity is publicly traded.

At the same time, the Departments lack significant information about the need to extend the expanded exemption further. We have been subjected to litigation by nonprofit entities

[38] The lack of the limitation in this provision may be particularly relevant since it is contained in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—are promulgated.

expressing objections to the Mandate based on non-religious moral convictions, and we have been sued by closely held for-profit entities expressing religious objections. This combination of different types of plaintiffs leads us to believe that there may be a small number of closely held for-profit entities that would seek to use an exemption to the contraceptive Mandate based on moral convictions. The fact that many closely held for-profit entities brought challenges to the Mandate has led us to offer protections that would include publicly traded entities with religious objections to the Mandate if such entities exist. But the combined lack of any lawsuits challenging the Mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity, leads us to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so in a way parallel to the protections set forth in § 147.132(a)(1)(i). We agree with the Supreme Court that it is improbable that many publicly traded companies with numerous "unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs" (or moral convictions) and thereby qualify for the exemption. Hobby Lobby, 134 S. Ct. at 2774. We are also not aware of other types of plan sponsors (such as non-Federal governmental entities) that might possess moral objections to compliance with the Mandate, including whether some might consider certain contraceptive methods as having a possible abortifacient effect. Nevertheless, we would welcome any comments on whether such corporations or other plan sponsors exist and would benefit from such an exemption.

Despite our a lack of complete information, the Departments know that nonprofit entities have challenged the Mandate, and we assume that a closely held business might wish to assert non-religious moral convictions in objecting to the Mandate (although we anticipate very few if

any will do so). Thus we have chosen in these interim final rules to include them in the expanded exemption and thereby remove an obstacle preventing such entities from claiming an exemption based on non-religious moral convictions. But we are less certain that we need to use these interim final rules to extend the expanded exemption for moral convictions to encompass other kinds of plan sponsors not included in the protections of these interim final rules. Therefore, with respect to plan sponsors not included in the expanded exemptions of § 147.133(a)(1)(i), and non-federal governmental plan sponsors that might have moral objections to the Mandate, we invite public comment on whether to include such entities when we finalize these rules at a later date.

The Departments further conclude that it would be inadequate to merely provide entities access to the accommodation process instead of to the exemption where those entities object to the Mandate based on sincerely held moral convictions. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way "seamless" to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. This has led many religious groups to challenge the accommodation in court, and we expect similar challenges would come from organizations objecting to the accommodation based on moral convictions if we offered them the accommodation but not an exemption. When we took that narrow approach with religious nonprofit entities it led to multiple cases in many courts that we needed to litigate to the Supreme Court various times. Although objections to the accommodation were not specifically litigated in the two cases brought by nonprofit non-religious organizations (because we have not even made them eligible for the accommodation),

those organizations made it clear that they and their employees strongly oppose coverage of certain contraceptives in their plans and in connection with their plans.

3. Exemption for Institutions of Higher Education

The plans of institutions of higher education that arrange student health insurance coverage will be treated similarly to the way that plans of employers are treated for the purposes of such plans being exempt or accommodated based on moral convictions. These interim final rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

The Departments are not aware of institutions of higher education that arrange student coverage and object to the Mandate based on non-religious moral convictions. We have been sued by several institutions of higher education that arrange student coverage and object to the Mandate based on religious beliefs. We believe the existence of such entities with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible so that we should provide protections for them in these interim final rules. But based on a lack of information about such entities, we assume that none will use the exemption concerning student coverage at this time.

4. Exemption for Issuers

These interim final rules extend the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection (whether the objection is based on moral convictions, as set forth in these rules, or on religious beliefs, as set forth in exemptions created by the companion interim final rules published elsewhere in this issue of the **Federal Register**). Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt.

Under the rules as amended, issuers with objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions, and issuers with sincerely held religious beliefs could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Issuers that hold moral objections should identify to plan sponsors the lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Protecting issuers that object to offering contraceptive coverage based on sincerely held moral convictions will help preserve space in the health insurance market for certain issuers so that exempt plan sponsors and individuals will be able to obtain coverage.

The Departments are not currently aware of health insurance issuers that possess their own religious or moral objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w-22(j)(3)(B) and 1396u-2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations from being required to provide coverage or pay for abortions. See, for example, Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. No. 115-31. The most recently enacted Consolidated Appropriations Act declares that Congress supports a "conscience clause" to protect moral convictions concerning "the provision of contraceptive coverage by health insurance plans." See id. at Div. C, Title VIII, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. The Departments solicit public comment; however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have moral convictions implicated by the Mandate.[39]

5. Scope of Objections Needed for the Objecting Entity Exemption

[39] The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for business entities. Because the issuer exemption operates more narrowly than the exemption for business plan sponsors operates, in the ways described here, and exists in part to help preserve market options for objecting plan sponsors, the Departments consider it appropriate to not draw such a distinction among issuers.

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.133(a)(2). That section specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.133(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) for coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held moral convictions.

6. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the "individual exemption"). Section 147.133(b) provides that nothing in §147.130(a)(1)(iv), 26 CFR 54.9815-2713T(a)(1)(iv) and 29 CFR 2590.715-2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan and/or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held moral convictions. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals

in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' moral convictions, or against the individual employees who accept such offers. See Wieland, 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the sincerely held moral objections of individual employees by offering them plans that omit contraception, even if those governmental entities do not object to offering contraceptive coverage in general.

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

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would

violate their sincerely held moral convictions.[40] At the same time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement,"[41] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered. In addition, because the individual exemption only operates when the employer and/or issuer, as applicable, are willing, the exemption will not undermine any governmental interest in the workability of the insurance market, because we expect that any workability concerns will be taken into account in the decision of whether to be willing to offer the individual morally acceptable coverage.

For similar reasons, we have changed our position and now believe the individual exemption will not undermine any Government interest in uniformity in the health insurance market. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. The Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our accommodation of self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[42]

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[40] This prospect has been raised in cases of religious individuals—see, for example, Wieland, 196 F. Supp. 3d at 1017, and March for Life, 128 F. Supp. 3d at 130—where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to "forgo health insurance altogether."

[41] 78 FR 39874.

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

With respect to operationalizing this provision of these rules, as well as the similar provision protecting individuals with religious objections to purchasing insurance that covers some or all contraceptives, in the interim final rules published elsewhere in this issue of the **Federal Register**, the Departments note that a plan sponsor or health insurance issuer is not required to offer separate and different benefit package options, or separate and different forms of policy, certificate, or contract of insurance with respect to those individuals who object on moral bases from those who object on religious bases. That is, a willing employer or issuer may offer the same benefit package option or policy, certificate, or contract of insurance—which excludes the same scope of some or all contraceptive coverage—to individuals who are exempt from the Mandate because of their moral convictions (under these rules) or their religious beliefs (under the regulations as amended by the interim final rules pertaining to religious beliefs).

7. Optional Accommodation

In addition to expanding the exemption to those with sincerely held moral convictions, these rules also expand eligibility for the optional accommodation process to include employers with objections based on sincerely held moral convictions. This is accomplished by inserting references to the newly added exemption for moral convictions, 45 CFR 147.133, into the regulatory sections where the accommodation process is codified, 45 CFR 147.131, 26 CFR 54.9815-2713AT, and 29 CFR 2590.715-2713A. In all other respects the accommodation process works the same as it does for entities with objections based on sincerely held religious beliefs, as described in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

The Departments are not aware of entities with objections to the Mandate based on sincerely held moral convictions that wish to make use of the optional accommodation, and our present assumption is that no such entities will seek to use the accommodation rather than the exemption. But if such entities do wish to use the accommodation, making it available to them will both provide contraceptive coverage to their plan participants and respect those entities' objections. Because entities with objections to the Mandate based on sincerely held non-religious moral convictions have not previously had access to the accommodation, they would not be in a position to revoke their use of the accommodation at the time these interim final rules are issued, but could do so in the future under the same parameters set forth in the accommodation regulations.

8. Regulatory Restatements of section 2713(a) and (a)(4) of the PHS Act

These interim final rules insert references to 45 CFR 147.133 into the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815-2713T(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715-2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv).

9. Conclusion

The Departments believe that the Guidelines, and the expanded exemptions and accommodations set forth in these interim final rules, will advance the legitimate but limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for moral exemptions with respect to various health care matters. These interim final rules maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines if no regulatorily recognized exemption exists (and in plans where Congress applied section 2713 of the PHS Act). As cited above, these interim final rules also leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. The Departments believe this array of programs and requirements better serves the interests of providing contraceptive coverage while protecting the moral convictions of entities and individuals concerning coverage of some or all contraceptive or sterilization services.

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

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

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

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

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

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

Two lawsuits have been pending for several years by entities raising non-religious moral objections to the Mandate.[43] In one of those cases, the Departments are subject to a permanent injunction and the appeal of that case has been stayed since February 2016. In the other case, Federal district and appeals courts ruled in favor of the Departments, denying injunctive relief to the plaintiffs, and that case is also still pending. Based on the public comments the Departments have received, we have reason to believe that some similar nonprofit entities might exist, even if it is likely a small number.[44]

For entities and individuals facing a burden on their sincerely held moral convictions, providing them relief from Government regulations that impose such a burden is an important and urgent matter, and delay in doing so injures those entities in ways that cannot be repaired retroactively. The burdens of the existing rules undermine these entities' and individuals' participation in the health care market because they provide them with a serious disincentive—indeed a crisis of conscience—between participating in or providing quality and affordable health insurance coverage and being forced to violate their sincerely held moral convictions. The existence of inconsistent court rulings in multiple proceedings has also caused confusion and uncertainty that has extended for several years, with different federal courts taking different positions on whether entities with moral objections are entitled to relief from the Mandate.

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[43] March for Life, 128 F. Supp. 3d 116; Real Alternatives, 867 F.3d 338.

[44] See, for example, Americans United for Life ("AUL") Comment on CMA-9992-IFC2 at 10 (Nov. 1, 2011), available at http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496, and AUL Comment on CMS-9968-P at 5 (Apr. 8, 2013), available at http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115.

Delaying the availability of the expanded exemption would require entities to bear these burdens for many more months. Continuing to apply the Mandate's regulatory burden on individuals and organizations with moral convictions objecting to compliance with the Mandate also serves as a deterrent for citizens who might consider forming new entities consistent with their moral convictions and offering health insurance through those entities.

Moreover, we separately expanded exemptions to protect religious beliefs in the companion interim final rules issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. Because Congress has provided many statutes that protect religious beliefs and moral convictions similarly in certain health care contexts, it is important not to delay the expansion of exemptions for moral convictions set forth in these rules, since the companion rules provide protections for religious beliefs on an interim final basis. Otherwise, our regulations would simultaneously provide and deny relief to entities and individuals that are, in the Departments' view, similarly deserving of exemptions and accommodations consistent, with similar protections in other federal laws. This could cause similarly situated entities and individuals to be burdened unequally.

In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and to what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. As noted above, the public comments in response to both the RFI and various prior rulemaking proceedings included specific requests that the exemptions be expanded to include those who oppose the

Mandate for either religious or "moral" reasons.[45] In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

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

[45] See, for example, http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496, http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115, https://www.regulations.gov/document?D=CMS-2016-0123-54142, https://www.regulations.gov/document?D=CMS-2016-0123-54218, and https://www.regulations.gov/document?D=CMS-2016-0123-46220.

proceeding with exemptions and accommodations for moral objectors here would delay the implementation of those alternative opt-outs for moral objectors.

Delaying the availability of the expanded exemption could also increase the costs of health insurance for some entities. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover contraception. As such, they may wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. To the extent that entities with objections to the Mandate based on moral convictions but not religious beliefs fall into this category, they may be refraining from making those changes—and therefore may be continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. We are not aware of the extent to which such entities exist, but 17 percent of all covered workers are in grandfathered health plans, encompassing tens of millions of people.[46] Issuing these rules on an interim final basis reduces the costs of health insurance and regulatory burdens for such entities and their plan participants.

These interim final rules also expand access to the optional accommodation process for certain entities with objections to the Mandate based on moral convictions. If entities exist that wish to use that process, the Departments believe they should be able to do so without the delay that would be involved by not offering them the optional accommodation process by use of interim final rules. Proceeding otherwise could delay the provision of contraceptive coverage to those entities' employees.

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

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

V. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011),, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354, 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 one year), and an "economically significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations and the Departments have provided the following assessment of their impact. .

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations and do so in conjunction with the amendments made in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. These interim final rules expand the exemption from the

requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process to make entities with such convictions eligible to use it. The expanded exemption would apply to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to providing coverage for some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action is taken, among other reasons, to provide for conscientious participation in the health insurance market free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to resolve lawsuits that have been filed against the Departments by some such entities, and to avoid similar legal challenges.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these interim final rules, they believe it to be small.

With respect to the expanded exemption for nonprofit organizations, as noted above the Departments are aware of two small nonprofit organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree

with their opposition to the coverage.[47] Based on comments submitted in response to prior rulemakings on this subject, we believe that at least one other similar entity exists. However, we do not know how many similar entities exist. Lacking other information we assume that the number is small. Without data to estimate the number of such entities, we believe it to be less than 10, and assume the exemption will be used by nine nonprofit entities.

We also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with our conclusion in previous rules that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (See 76 FR 46625 and 78 FR 39889). We reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception, and without even requiring that such entities actually oppose contraception in order to be exempt (in contrast, the expanded exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to the coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, we relied on our assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is supported with respect to the expanded exemption for nonprofit organizations. To our knowledge, the vast majority of organizations objecting to the Mandate

[47] Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

assert religious beliefs. The only nonprofit organizations of which we are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these interim final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under our previous rules that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[48] Although we are unable to find sufficient data on this issue, we believe that there are far fewer non-religious moral nonprofit organizations opposed to contraceptive coverage than there are churches with religious objections to such coverage. Based on our limited data, we believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose the coverage. Therefore, we expect that the expanded exemption for nonprofit entities will have no effect of reducing contraceptive coverage to employees who want that coverage.

These interim final rules expand the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and they make exempt entities with moral objections eligible to use the accommodation. The Departments are not aware of either kind of entity. We believe the number of entities that object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education,

[48] Cf., for example, Gallup, "Americans, Including Catholics, Say Birth Control Is Morally OK," (May 22, 2012) ("Eighty-two percent of U.S. Catholics say birth control is morally acceptable"), available at http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx.

and appear to hold objections that we assume would likely lead them to reject the accommodation process. Therefore, for the purposes of estimating the anticipated effect of these interim final rules on contraceptive coverage of women who wish to receive such coverage, we assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on similar reasons to those given above for why the exemptions and accommodations are extended to other entities. We invite public comment on whether and how many such entities will make use of these interim final rules.

The expanded exemption for issuers will not result in a distinct effect on contraceptive coverage for women who wish to receive it because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein. The expanded exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The expanded moral exemption would also cover for-profit entities that do not have publicly traded ownership interests, and that have non-religious moral objections to the Mandate. The Departments are not aware of any for-profit entities that possess non-religious moral objections to the Mandate. However, scores of for-profit entities have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—both were nonprofit. Among the general public polls vary about religious beliefs, but one prominent poll shows that 89 percent of

Americans say they believe in God.[49] Among non-religious persons, only a very small percentage appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.[50] Combined, this suggests that 0.2 percent of Americans at most[51] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. We have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral convictions set forth in these interim final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, we assume that some similar for-profit entities with non-religious moral objections exist. But we expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities that do not have publicly traded ownership interests and that have objections to the Mandate based on sincerely held moral convictions, we expect that fewer than 10 entities, if any, will do so—we assume nine for-profit entities will use the exemption in these interim final rules.

The expanded exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS-IC) to obtain an estimate of the number of

[49] Gallup, "Most Americans Still Believe in God" (June 14–23, 2016), available at http://www.gallup.com/poll/193271/americans-believe-god.aspx.
[50] Pew Research Center, "Where the Public Stands on Religious Liberty vs. Nondiscrimination" at page 26 (Sept. 28, 2016), available at http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.
[51] The study defined religiously "unaffiliated" as agnostic, atheist or "nothing in particular" (id. at 8), as distinct from several versions of Protestants, or Catholics. "Nothing in particular" might have included some theists.

policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.[52] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known what size the for-profit employers will be that might claim this exemption, but as discussed above these interim final rules do not include publicly traded companies (and we invite public comments on whether to do so in the final rules), and both of the two nonprofit entities that challenged the Mandate included fewer than five policyholders in each entity. Therefore we assume the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For nine entities, the total number of policyholders would be 81. DOL estimates that for each policyholder, there is approximately one dependent.[53] This amounts to 162 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—comprise 20.2 percent of the general population.[54] This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.[55] Thus we estimate that 15 women may incur contraceptive costs due to for-

[52] "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf
Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey - Insurance

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

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

[55] See https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.

profit entities using the expanded exemption provided in these interim final rules.[56] In the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, within health plans that cover contraception, is $584. Consequently, we estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded exemption in these interim final rules is approximately $8,760.

The Departments estimate that these interim final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will use the accommodation, although we wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, we do not anticipate that these interim final rules will result in any burden from such entities revoking their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the rules expanded exemptions. The Departments acknowledge uncertainty

[56] We note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion—and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

in the estimate and therefore conducted a second analysis using an alternative framework, which is set forth in the companion interim final rule concerning religious beliefs issued contemporaneously with this interim final rule and published elsewhere in this issue of the **Federal Register**. Under either estimate, this interim final rule is not economically significant.

We reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

We request comment on all aspects of the preceding regulatory impact analysis.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments estimate that the likely effect of these interim final rules will be that entities will use the exemption and not the accommodation. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The interim final rules are exempt from the APA, both because the PHS

Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

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

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

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

clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We estimate that these interim final rules will not result in additional burdens not accounted for as set forth in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. As discussed there, regulations covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burdens related to those ICRs are currently approved under OMB Control Numbers 0938-1248 and 0938-1292. These interim final rules amend the accommodation regulations to make entities with moral objections to the Mandate eligible to use the same accommodation processes. The Departments will update the forms and model notices regarding these processes to reflect that entities with sincerely held moral convictions are eligible organizations.

As discussed above, however, we assume that no entities with non-religious moral objections to the Mandate will use the accommodation, and we know that no such entities were eligible for it until now, so that they do not possess accommodated status to revoke. Therefore we believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938-1248 and 0938-1292, as described in the interim final rules concerning religious beliefs issued contemporaneously with these interim final rules.

We are soliciting comments on all of the possible information collection requirements contained in these interim final rules, including those discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and

published elsewhere in this issue of the **Federal Register**, for which these interim final rules provide eligibility to entities with objections based on moral convictions. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938-1292 and 0938-1248.

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

1. Access CMS' website address at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

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

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210-0150 and 1210-0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at http://www.RegInfo.gov. PRA ADDRESSEE: G. Christopher

Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N-5718, Washington, DC 20210. Telephone: 202-693-8410; Fax: 202-219-4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these interim final rules make entities with certain moral convictions eligible for the accommodation, we assume that no entities will use it rather than the exemption, and such entities were not previously eligible for the accommodation so as to revoke it. Therefore we believe these interim final rules do not involve additional burden not accounted for under OMB control number 1210-0150.

Regarding the ICRs discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, the forms for which would be used if any entities with moral objections used the accommodation process in the future, DOL submitted those ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. OMB approved the ICRs under the emergency clearance process. In an effort to consolidate the number of information collection requests, DOL indicated it will combine the ICR related to the OMB control number 1210-0152 with the ICR related to the OMB control number 1210-0150. Once the ICR is approved, DOL indicated it will discontinue 1210-0152. OMB approved the ICR under control number 1210-0150 through [DATE]. A copy of the information collection request may be obtained free of charge on the RegInfo.gov website at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001. This approval allows respondents temporarily to utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and

burden. Contemporaneously with the publication of these interim final rules, DOL will publish a notice in the **Federal Register** informing the public of its intention to extend the OMB approval.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, "[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." In addition, agencies are directed to "take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market." These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

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

detail in the preceding analysis, this interim final rule lessens incremental reporting costs.[57] Therefore, this interim final rule is considered an EO 13771 deregulatory action.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104-4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on States, the relationship

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

between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

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

VI. Statutory Authority

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

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

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and

1412, Pub. L. 111-148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

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

29 CFR Part 2590

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

45 CFR Part 147

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

Kirsten B. Wielobob,
Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017

David J. Kautter,
Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

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

Dated: October 4, 2017

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Seema Verma

Administrator,

Centers for Medicare & Medicaid Services.

Approved: October 4, 2017

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Donald Wright,

Acting Secretary,

Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

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

PART 54—PENSION EXCISE TAXES

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

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

§54.9815-2713T [Amended]

2. Section 54.9815-2713T, as added elsewhere in this issue of the **Federal Register**, is amended in paragraph (a)(1)(iv) by removing the reference "147.131 and 147.132" and adding in its place the reference "147.131, 147.132, and 147.133".

§54.9815-2713AT [Amended]

3. Section 54.9815-2713AT, as added elsewhere in this issue of the **Federal Register**], is amended—

a. In paragraph (a)(1) by removing " or (ii)" and adding in its place "or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)";

b. In paragraph (a)(2) by removing the reference "147.132(a)" and adding in its place the reference "147.132(a) or 147.133(a)";

c. In paragraph (b)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

d. In paragraph (b)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

e. In paragraph (c)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

f. In paragraph (c)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”; and

g. In paragraph (c)(2) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

3. The authority citation for part 2590 continues to read as follows:

AUTHORITY: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Division M, Pub. L. 113-235, 128 Stat. 2130; Secretary of Labor's Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

§2590.715-2713 [Amended]

4. Section 2590.715-2713, as amended elsewhere in this issue of the **Federal Register**], is further amended in paragraph (a)(1)(iv) by removing the reference "147.131 and 147.132" and adding in its place the reference "147.131, 147.132, and 147.133".

§2590.715-2713A [Amended]

5. Section 2590.715-2713A, as revised elsewhere in this issue of the **Federal Register**], is further amended—

a. In paragraph (a)(1) by removing "(ii)" and adding in its place "(ii), or 45 CFR 147.133(a)(1)(i) or (ii)";

b. In paragraph (a)(2) by removing the reference "147.132(a)" and adding in its place the reference "147.132(a) or 147.133(a)";

c. In paragraph (b)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

d. In paragraph (b)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

e. In paragraph (c)(1)(ii) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”;

f. In paragraph (c)(1)(ii)(B) by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”; and

g. In paragraph (c)(2) introductory text by removing the reference “147.132” and adding in its place the reference “147.132 or 147.133”.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

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

6. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

§147.130 [Amended]

7. Section 147.130, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraphs (a)(1) introductory text and (a)(1)(iv) by removing the reference "§§ 147.131 and 147.132" and adding in its place the reference "§§ 147.131, 147.132, and 147.133".

§147.131 [Amended]

8. Section 147.131, as revised elsewhere in this issue of the **Federal Register**, is further amended--

a. In paragraph (c)(1) by removing the reference "(ii)" and adding in its place the reference "(ii), or 45 CFR 147.133(a)(1)(i) or (ii)".

b. In paragraph (c)(2) by removing the reference "§147.132(a)" and adding in its place the reference "§147.132(a) or 147.133"; and

c. In paragraphs (d)(1)(ii) introductory text, (d)(1)(ii)(B) and (d)(2) by removing the reference "§147.132" and to adding in its place the reference "§ 147.132 or 147.133".

9. Add §147.133 to read as follows:

§147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) Objecting entities. (1) Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under §147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) Objecting individuals. Guidelines issued under §147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in §147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(c) Definition. For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) Severability. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[Billing Codes: **4830-01-P; 4510-029-P; 4120-01-P; 6325-64**]

[FR Doc. 2017-21852 Filed: 10/6/2017 11:15 am; Publication Date: 10/13/2017]

First Amended Complaint Exhibit C

Women's Preventive Services Guidelines

On December 20, 2016, HRSA updated the HRSA-supported Women's Preventive Services Guidelines. Read the most current version.

Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 20, 2017. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the 2011 guidelines.

Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being

The Affordable Care Act – the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010 – helps make prevention affordable and accessible for all Americans by requiring health plans to cover preventive services and by eliminating cost sharing for those services. Preventive services that have strong scientific evidence of their health benefits must be covered and plans can no longer charge a patient a copayment, coinsurance or deductible for these services when they are delivered by a network provider.

Women's Preventive Services Guidelines Supported by the Health Resources and Services Administration

Under the Affordable Care Act, women's preventive health care – such as mammograms, screenings for cervical cancer, prenatal care, and other services – generally must be covered with no cost sharing. However, the law recognizes and HHS understands the need to take into account the unique health needs of women throughout their lifespan.

The HRSA-supported health plan coverage guidelines, developed by the Institute of Medicine (IOM), will help ensure that women receive a comprehensive set of preventive services without having to pay a co-payment, co-insurance or a deductible. HHS commissioned an IOM study to review what preventive services are necessary for women's health and well-being and therefore should be considered in the development of comprehensive guidelines for preventive services for women. HRSA is supporting the IOM's recommendations on preventive services that address health needs specific to women and fill gaps in existing guidelines.

Health Resources and Services Administration Women's Preventive Services Guidelines

Non-grandfathered plans (plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) generally are required to provide coverage without cost sharing consistent with these guidelines in the first plan year (in the individual market, policy year) that begins on or after August 1, 2012.

Type of Preventive Service	HHS Guideline for Health Insurance Coverage	Frequency

Learn More

- Women's Preventive Services Initiative report
- 2011 IOM Report *Clinical Preventive Services for Women: Closing the Gaps*
- US Preventive Services Task Force
- Bright Futures
- Advisory Committee on Immunization Practices
- Previous Preventive Services Guidelines (August 2011)

For Further Information

Contact
wellwomancare@hrsa.gov.

Exhibit C

Well-woman visits.	Well-woman preventive care visit annually for adult women to obtain the recommended preventive services that are age and developmentally appropriate, including preconception care and many services necessary for prenatal care. This well-woman visit should, where appropriate, include other preventive services listed in this set of guidelines, as well as others referenced in section 2713.	Annual, although HHS recognizes that several visits may be needed to obtain all necessary recommended preventive services, depending on a woman's health status, health needs, and other risk factors.* (see note)
Screening for gestational diabetes.	Screening for gestational diabetes.	In pregnant women between 24 and 28 weeks of gestation and at the first prenatal visit for pregnant women identified to be at high risk for diabetes.
Human papillomavirus testing.	High-risk human papillomavirus DNA testing in women with normal cytology results.	Screening should begin at 30 years of age and should occur no more frequently than every 3 years.
Counseling for sexually transmitted infections.	Counseling on sexually transmitted infections for all sexually active women.	Annual.
Counseling and screening for human immune-deficiency virus.	Counseling and screening for human immune-deficiency virus infection for all sexually active women.	Annual
Contraceptive methods and counseling. ** (see note)	All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.	As prescribed
Breastfeeding support, supplies, and counseling.	Comprehensive lactation support and counseling, by a trained provider during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment.	In conjunction with each birth
Screening and counseling for interpersonal and domestic violence.	Screening and counseling for interpersonal and domestic violence.	

** Refer to guidance issued by the Center for Consumer Information and Insurance Oversight entitled Affordable Care Act Implementation FAQs, Set 12, Q10.*

***(I)(a) Objecting entities—religious beliefs.*

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting

organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (I)(a)(2) of this note. Such non-governmental plan sponsors include, but are not limited to, the following entities:
(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order;
(B) A nonprofit organization;
(C) A closely held for-profit entity;
(D) A for-profit entity that is not closely held; or
(E) Any other non-governmental employer;
(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (I)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and
(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (I)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (I)(a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (I)(a) will apply to the extent that an entity described in paragraph (I)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.
(b) Objecting individuals—religious beliefs. These Guidelines do 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 (I)(b), and nothing in 45 CFR 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(II)(a) Objecting entities—moral convictions.

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (II)(a)(2) of this note:
(A) A nonprofit organization; or
(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);
(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (II)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and
(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (II)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (II)(a)(1)(iii), 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 these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (II)(a) will apply to the extent that an entity described in paragraph (II)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) Objecting individuals—moral convictions. These Guidelines do 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 (II)(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.

(III) Definition. For the purposes of this note, 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 these Guidelines.

See Federal Register Notice: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act.

HRSA, in concert with an external review committee, will review, and continually update, the *Women's Preventive Services' Guidelines*.

Date Last Reviewed: October 2017

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First Amended Complaint Exhibit D

Presidential Documents

Executive Order 13798 of May 4, 2017

Promoting Free Speech and Religious Liberty

By the authority vested in me as President by the Constitution and the laws of the United States of America, in order to guide the executive branch in formulating and implementing policies with implications for the religious liberty of persons and organizations in America, and to further compliance with the Constitution and with applicable statutes and Presidential Directives, it is hereby ordered as follows:

Section 1. *Policy.* It shall be the policy of the executive branch to vigorously enforce Federal law's robust protections for religious freedom. The Founders envisioned a Nation in which religious voices and views were integral to a vibrant public square, and in which religious people and institutions were free to practice their faith without fear of discrimination or retaliation by the Federal Government. For that reason, the United States Constitution enshrines and protects the fundamental right to religious liberty as Americans' first freedom. Federal law protects the freedom of Americans and their organizations to exercise religion and participate fully in civic life without undue interference by the Federal Government. The executive branch will honor and enforce those protections.

Sec. 2. *Respecting Religious and Political Speech.* All executive departments and agencies (agencies) shall, to the greatest extent practicable and to the extent permitted by law, respect and protect the freedom of persons and organizations to engage in religious and political speech. In particular, the Secretary of the Treasury shall ensure, to the extent permitted by law, that the Department of the Treasury does not take any adverse action against any individual, house of worship, or other religious organization on the basis that such individual or organization speaks or has spoken about moral or political issues from a religious perspective, where speech of similar character has, consistent with law, not ordinarily been treated as participation or intervention in a political campaign on behalf of (or in opposition to) a candidate for public office by the Department of the Treasury. As used in this section, the term ''adverse action'' means the imposition of any tax or tax penalty; the delay or denial of tax-exempt status; the disallowance of tax deductions for contributions made to entities exempted from taxation under section 501(c)(3) of title 26, United States Code; or any other action that makes unavailable or denies any tax deduction, exemption, credit, or benefit.

Sec. 3. *Conscience Protections with Respect to Preventive-Care Mandate.* The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code.

Sec. 4. *Religious Liberty Guidance.* In order to guide all agencies in complying with relevant Federal law, the Attorney General shall, as appropriate, issue guidance interpreting religious liberty protections in Federal law.

Sec. 5. *Severability.* If any provision of this order, or the application of any provision to any individual or circumstance, is held to be invalid, the remainder of this order and the application of its other provisions to any other individuals or circumstances shall not be affected thereby.

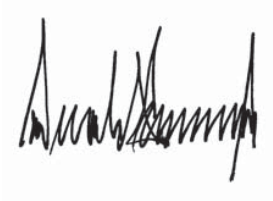
Sec. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
May 4, 2017.

[FR Doc. 2017–09574
Filed 5–8–17; 11:15 am]
Billing code 3295–F7–P

Exhibit D