[Billing Codes: 4830-01-P; 4510-029-P; 4120-01-P; 6325-64]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD-**]**

RIN 1545-XXXX

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-XXXX

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS-XXXX-X]

RIN 0938-XXXX

Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCIES: 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 protecting individuals and organizations with objections based on religious beliefs or moral convictions from requirements imposed in the regulation of healthcare. These interim final rules expand exemptions for religious beliefs and

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moral convictions for certain entities or individuals whose health plans may otherwise be subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act (ACA). These rules do not alter the discretion of the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS), to maintain the guideline requiring contraceptive coverage where no such objection exists. These rules also leave the accommodation process in place as an optional process for certain exempt entities who 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 are effective on [INSERT DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

Comments: Written comments on these interim final rules are invited and must be received by [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE **FEDERAL REGISTER**].

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.

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Comments, identified by "Preventive Services," may be submitted by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail or Hand Delivery: ***, U.S. Department of Health and Human Services, ***, Attention: Preventive Services.

Comments received will be posted without change to www.regulations.gov and available for public inspection at the Public Disclosure Room, ***, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:

[Name], Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (XXX) XXX-XXXX; Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; [NAME], Internal Revenue Service, Department of the Treasury, at (XXX) XXX-XXXX.

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

SUPPLEMENTARY INFORMATION:

I. Background

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Congress has consistently protected religious beliefs and moral convictions in the context of healthcare, including health insurance.[1] In doing so, Congress has promoted access to health services while respecting the ethical or faith-based views held by persons and entities regarding certain sensitive medical procedures. The present context arises out of discretion that Congress granted HRSA under the ACA to develop guidelines for "additional preventive care and screenings" for women, under which HRSA adopted guidelines that require coverage of contraceptives by some health plans. This rule is a product of reconsideration of how to exercise that discretion on the part of the administering agencies, in order to better balance the interests in preventive services coverage to the extent imposed through the ACA along with the interests throughout Federal law to protect individuals and organizations with religious beliefs and moral convictions.

A. The ACA

[1] See, e.g., 42 U.S.C. § 238n (protects individuals and entities that object to abortion); 42 U.S.C. § 300a-7 (protects 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. § 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" for an objection); 42 U.S.C. § 1395w-22(j)(3)(B) (same in Medicare Choice managed care plans); 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 (blocks any requirement that insurers or exchanges must cover abortion); 42 U.S.C. § 18113 (ACA clause protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); 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) (protects entities from being required to use HIV/AIDS funds contrary to their "religious or moral objection"); Sec. 726 of Title VII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act, 2016, Pub. L. No. 114-113 (protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions"); Sec. 507(d) of Title V of Div. H (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act) of the Consolidated Appropriations Act, 2016, Pub. L. No. 114-113 (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); Title III of Division I (Department of State, Foreign Operations, and Related Programs Appropriations Act) of the Consolidated Appropriations Act, 2016, Pub. L. No. 114-113 (protecting applicants for family planning funds based on their "religious or conscientious commitment to offer only natural family planning"). See also 42 U.S.C. § 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on "religious beliefs or moral convictions").

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The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010, followed by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act (ACA). In signing the ACA, the President 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)."

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

These interim final rules concern section 2713 of the PHS Act. Section 2713 generally requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage for certain preventive health care services without any cost-sharing requirements. Section 2713(a)(4) of the

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PHS Act requires coverage without cost sharing for women's preventive care and screenings "as provided for" under HRSA guidelines (hereinafter the Guidelines). Congress did not specify which services HRSA should include in the Guidelines, or whether those services should include contraception or sterilization. Instead, section 2713(a)(4) grants HRSA the authority to craft "comprehensive" Guidelines "for purposes of this paragraph." As explained below, the Departments have consistently interpreted section 2713(a)(4)'s grant of authority to include the discretion to exempt certain entities with objections to contraceptive coverage under the Guidelines. As reflected in previous regulations, the Departments relied on the statutory text and structure of section 2713 as authorizing HRSA to effectively create exemptions from the Guidelines it provides and supports under section 2713(a)(4). (See, e.g., 76 FR 46623).

Section 2713(a)(4) differs from other requirements adopted by the ACA in significant ways. First, many of the health insurance provisions and requirements adopted in Title I of the ACA are statutorily required to be applied to both grandfathered and non-grandfathered health plans under the ACA. The Departments have referred to those sections as "particularly significant protections." (75 FR 34540) They include: section 2704, prohibiting preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708 prohibiting excessive waiting periods (as of January 1, 2014); section 2711 insofar as it relates to lifetime limits; section 2712 prohibiting rescissions; section 2714 extending dependent coverage until age 26; and section 2718 bringing down the cost of health coverage (for insured coverage). (75 FR 34538, 34540, 34542)

Section 2713 is not among those protections made applicable to all health plans, including grandfathered plans. Consequently, of the 150 million nonelderly people in America

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with employer-sponsored health coverage, approximately 36.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act. Kaiser Family Foundation & Health Research & Educational Trust, Employer Health Benefits, 2016 Annual Survey 60, 230. 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).

Second, the Departments have applied section 2713 of the PHS Act in a different manner to employers with self-insured church plans within the meaning of ERISA section 3(33). Although the preventive services requirement in section 2713 does apply to group health plans through the Code, including self-insured church plans exempt from ERISA, the Departments have interpreted section 2713 to allow them to offer an accommodation to self-insured church plans. Under that accommodation, once the self-insured church plans file a self-certification or notice, they are under no further obligation to contract, arrange, pay for, or provide coverage for contraceptive services. That accommodation process would normally transfer the obligations to provide contraceptive payments to the plan's third party administrator (TPA). But "the Departments concede they lack authority to compel church plan TPAs to provide contraceptive coverage, and may not levy fines against those TPAs for failing to provide it."[2] This is because church plans are exempt from ERISA pursuant to ERISA section 4(b)(2). The PHS Act provides that states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but not to church plans that do not provide coverage through a policy issued by a health

[2] Little Sisters of the Poor v. Burwell, 794 F.3d 1151, 1166–67 (10th Cir.), vacated and remanded sub nom. Zubik v. Burwell, 136 S. Ct. 1557 (2016).

insurance issuer.[3] The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and the PHS Act's and ERISA's lack of authority to require TPAs of those plans to provide such coverage, has led to significant incongruity in contraceptive coverage among non-profit organizations with religious objections to the coverage. Under ERISA section 3(33)(C)(iv), many organizations in such church plans need not be churches, but can merely "share[] common religious bonds and convictions with [a] church or convention or association of churches." Several church plans that have brought suit against the Mandate are comprised of various non-profit organization employers that are not churches.[4] The consequence has been that many non-church, non-profit organizations' plans do not offer contraceptive coverage either through the plan or through their TPAs, while identical organizations enrolled in non-church plans have third party administrators that are required to provide or arrange payments for contraceptive services for their employees and beneficiaries pursuant to the accommodation.

B. The Regulations on Women's Preventive Services

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

1. The Institute of Medicine Report

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[3] PHS Act section 2761(a).

[4] See, e.g., Complaint ¶ 18, Little Sisters of the Poor v. Sebelius, 1:13-cv-02611-WJM-BNB (D. Colo. filed Sept. 24, 2013) ("The Christian Brothers Trust covers employees and dependents of more than 200 non-exempt Catholic employers throughout the country."); Exh. 1, Declaration of Timothy E. Head ¶ 31, Reaching Souls Int'l, Inc. v. Sebelius, 5:13-cv-01092-D, doc. # 7-1 (filed Oct. 25, 2013 W.D. Okla. 2013) ("GuideStone Plan employers currently include approximately 187 organizations, located in approximately 26 states, that are or could be reasonable construed to be 'eligible organizations' under 45 CFR 147.131(b) & (c) at 78 FR 39870, 39874.").

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In developing the Guidelines, HRSA relied on an independent Institute of Medicine (IOM, now known as the National Academy of Medicine) report 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 which charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[5]

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,[6] the IOM's recommendation included several contraceptive methods that many persons and organizations believe are abortifacient and oppose on that basis.

In a dissent to IOM 2011, IOM committee member Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, argued that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and "the committee process for evaluation of the evidence lacked transparency and

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[5] 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.

[6] 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.

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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." IOM 2011 at 231–32.

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

On August 1, 2011, HRSA adopted and released onto its website its Guidelines for women's preventive services, which adopted the recommendations of the IOM. As adopted, the Guidelines required coverage for all FDA-approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a healthcare provider (hereinafter "the Mandate"). Also on August 1, 2011, the Departments promulgated interim final rules amending their 2010 interim final rules to make clear that HRSA had 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 (76 FR 46621) (2011 interim final rules).[7] Specifically, 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 described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. The relevant sections of the Code included only churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. The practical effect of the rules' definition of "religious

[7] 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).

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employer" was to exclude from the exemption even many houses of worship or their integrated auxiliaries due to their outreach activities towards persons who do not share their religious tenets. As the basis for adopting that limited definition of religious employer, the 2011 interim final rules 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).

3. The Departments' Rulemaking on the Accommodation

Final regulations issued on February 10, 2012, adopted the definition of "religious employer" in the 2011 interim final rules without modification (2012 final regulations).[8] (77 FR 8725). The exemption did not (and does not) require religious employers to file any certification form or comply with any other information collection process. Contemporaneous with the issuance of the 2012 final regulations, HHS—with the agreement of the Departments of Labor and 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).[9] The guidance provided that the temporary enforcement safe harbor would remain in

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

[9] 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.cms.gov/CCIIO/Resources/Files/Downloads/prev-services-guidance-08152012.pdf. The guidance, as reissued on August 15, 2012, clarifies, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage are 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 meet the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

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effect until the first plan year beginning on or after August 1, 2013. The temporary safe harbor did not include non-profit organizations that have an objection to contraceptives based on moral convictions but not religious principles, nor did it apply to any for-profit businesses or organizations. The Departments also stated that they would engage in rulemaking to ensure that certain additional nonprofit organizations with religious objections to contraceptive coverage would not have to contract, arrange, pay, or refer for such coverage.

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve these goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). On February 6, 2013, following review of the comments on the ANPRM, the Departments published proposed regulations (2013 NPRM) (78 FR 8456). The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer exemption, by requiring only that a religious employer be a nonprofit organization described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code, and by eliminating the requirement 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, with respect to the contraceptive services required by the Guidelines for group health plans established, maintained, or arranged by certain "eligible" nonprofit religious organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer

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exemption). The 2013 NPRM proposed to define such eligible organizations as non-profit religious entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items, and maintain a certification to this effect in their records. The 2013 NPRM proposed to not extend the religious employer exemption to eligible organizations. The 2013 NPRM stated that eligible organizations "may be less likely than" those employed by churches or religious orders (or covered by such organizations' health plans) to share the organization's opposition to contraception, but it did not cite data for that determination. Based on that reasoning, the 2013 NPRM did not propose extending the "religious employer" exemption to eligible organizations. Instead, the 2013 NPRM 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 religious organization.[10] 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 in the eligible organization's plan.

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

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

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On April 8, 2013, the last day of the public comment period for the 2013 NPRM, then-Secretary Sebelius stated that, regarding contraception and other coverage requirements of PHS Act section 2713(a)(4), that "[t]he law was proposed to add all those benefits to the new health plans, and we provided a one year grace period for religious employers who had an objection to contraception based on religious beliefs, with the notion that at the end of the day we would provide a strategy for upholding the religious beliefs of an employer but yet offering the benefits to the employees, just the kind of balance that the question suggests. We have just completed the open comment period for the so-called accommodation, and by August 1st of this year, every employer will be covered by the law with one exception. Churches and church dioceses as employers are exempted from this benefit. But Catholic hospitals, Catholic universities, other religious entities, will be providing coverage to their employees starting August 1st. And what we have done in the accommodation is basically find a series of strategies where the employer, or the board, or the employer group doesn't have to directly offer, pay for, or refer an employee to this coverage, and yet a third party entity, whether it's a third party administrator in many of the self-insured plans, or an insurance company itself, will offer benefits to employees. So the employees will have access to no-cost range of preventive services including contraception, and the employer will not have to refer, pay for, or make available contraception. And we think that balance upholds the religious belief of some but does not impose religious views on an employee who may or may not share those religious beliefs. Having said that we are being sued, just let me make it very clear, not only by some of the religious entities who don't feel that that is appropriate—that they should have nothing to do with this whatsoever—but also by some non-religious employers, Hobby Lobby, for instance, whose CEO says he has his own religious

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exemptions to providing contraception coverage to his employees. So even though he was not ever in the accommodation or in the class group he has suggested that his religious freedom is being violated by providing a service or benefit that he doesn't believe in. So there's a debate going on in court, there's a debate going on, but we are about to promulgate the final rule, and as of August 1, 2013, every employee who doesn't work directly for a church or a diocese will be included in the benefit package."[11] Various public comments were submitted on April 8, 2013, before the comment period closed.

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 churches and religious orders without extending it to other organizations, though some commenters suggested that the exemption be extended. The Departments also finalized the 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 it, 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 participants and beneficiaries and without cost to the eligible organization. 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 that obligated the third party administrator to provide or arrange for contraceptive payments by operation of section 3(16) of

[11] Kathleen Sebelius, Remarks at The Forum at Harvard School of Public Health (Apr. 8, 2013), available at http://theforum.sph.harvard.edu/events/conversation-kathleen-sebelius (starting at 51:20).

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ERISA. The July 2013 final regulations stated that, after the eligible organization submits the self-certification form, the eligible organization thereby "complies" with the contraceptive coverage requirement, and does not have to contract, arrange, pay, or refer for contraceptive coverage. See, e.g., id. at 39874, 39896.

The July 2013 final regulations repeated the view 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, but did not cite data to support that claim. (78 FR 39874). The July 2013 final regulations stated that, where an organization's employees likely oppose contraception, exempting that organization "does not undermine the governmental interests furthered by the contraceptive coverage requirement." Id. To implement reimbursements available to third party administrators (or issuers that they hire) through the accommodation process, the July 2013 final regulations also amended 45 CFR Part 156, to permit health insurance issuers offering qualified health plans (QHPs) through a Federally-facilitated Exchange to reduce their user fee payments by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as an authorizing exception under OMB Circular No. A-25R is in effect.[12]

The Departments issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an eligible organization for purposes of the accommodation process under the July 2013 final regulations. This self-certification form was provided for use in

[12] 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.

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the accommodation process after the expiration of the temporary enforcement safe harbor (that is, for plan years beginning on or after January 1, 2014). The EBSA Form 700 stated that "[t]his form or a notice to the Secretary is an instrument under which the plan is operated," and that, in the case of a self-insured plan with a third party administrator, "[t]he obligations of the third party administrator are set forth in 26 CFR 54.9815-2713A, 29 CFR 2510.3-16, and 29 CFR 2590.715-2713A" to ensure the provision of contraceptive coverage to which the eligible organization objects.

In addition, 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. This 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 enforcement safe harbor if no prior form had been submitted.

4. Litigation Over the Mandate and the Departments' Accommodation Process

During the time the Departments were publishing and modifying their regulations on the Mandate, religiously- and morally-motivated organizations filed dozens of lawsuits against the Mandate. Religious plaintiffs principally argued that the Mandate violated their right to exercise religion under the Religious Freedom Restoration Act of 1993 (RFRA) by forcing them to provide coverage or payments for contraceptive, sterilization, and early abortifacient items against their religious beliefs. Plaintiffs included religious non-profit organizations, businesses run by religious families, and non-religious pro-life organizations opposed to certain items required under the Mandate. In July 2012, a Federal district court issued a preliminary injunction banning the Departments from enforcing the Mandate against a family-owned

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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).

Among the plaintiffs challenging the Mandate were several for-profit businesses, to whom 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 U.S. Court of Appeals for the Tenth Circuit sitting en banc, while similar rulings against the Departments were issued by the Seventh and 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. Sec'y of U.S. Dep't of Health & Human Servs., 724 F.3d 377 (3d Cir. 2013), to resolve the circuit split. On June 30, 2014, the Supreme Court issued its decision in the case of Burwell v. Hobby Lobby Stores, Inc. 134 S. Ct. 2751 (2014). The Court held that, under RFRA, the requirement to provide contraceptive coverage could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[13] The Court

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

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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, it was inadequate for the Departments to rely on interests "couched in very broad terms, such as promoting 'public health' and 'gender equality,'" but rather, the Departments had to demonstrate that a compelling interest was served by refusing an exemption to the "particular claimant[s]" seeking an exemption. Id. at 2779. Assuming without deciding that a compelling interest existed, the Court held that the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner. In particular, 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 have "not provided any estimate of the average cost per employee of providing access to these contraceptives," and have not "provided 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. 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 and approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs." Id. at 2781-2782. The Court explained that the "already

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established" accommodation process available to nonprofit organizations was a less-restrictive alternative that "serve[d] HHS's stated interests equally well." Id. at 2781-2782. The Court emphasized, however, that its decision did not decide whether the accommodation process "complie[d] with RFRA for purposes of all religious claims." Id. at 2782.

A number of lawsuits also challenged the accommodation as inconsistent with plaintiffs' religious beliefs. In one such case, Wheaton College, a Christian liberal arts college in Illinois, objected, under RFRA, that the accommodation was a compliance process that rendered it complicit in delivering payments for abortifacient contraceptive services to its employees. Accordingly, the college refused to execute the EBSA Form 700 required under the July 2013 final regulations. Wheaton College was denied a preliminary injunction in the Federal district and appellate courts, and on June 30, 2014, the college sought an emergency injunction pending appeal from the U.S. Supreme Court. On July 3, 2014, the Supreme Court issued an interim order in Wheaton College v. Burwell. 134 S. Ct. 2806 (2014). The Court's order stated 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." Id. at 2807. The order stated that Wheaton College need not 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 this injunctive relief. Id.

On August 27, 2014, the Departments issued another set of interim final rules (August 2014 interim final rules). (79 FR 51092). These regulations changed the accommodation process

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so that it could be initiated either by self-certification through use of the EBSA Form 700 or through notice to the Secretary of HHS that an eligible organization had religious objections to coverage of all or a subset of contraceptive services. Simultaneously, the Departments issued a notice of proposed rulemaking (August 2014 proposed rules). (79 FR 51118). In response to the decision in Hobby Lobby, the August 2014 proposed rules proposed extending the accommodation process to include closely-held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations. 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, which HHS conveyed to DOL, so as to trigger the accommodation process. Wheaton College had not executed the EBSA Form 700 or submitted a notice to HHS that it was an eligible organization objecting to coverage of some (or all) contraceptive services.

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 encompass issues related to other preventive services coverage.) The preamble to the July 2015 final regulations states that, through the accommodation, payments for contraceptives and sterilization are provided in a way that is "seamless" with the coverage that eligible employers provide to their plan participants and beneficiaries. Id. at 41328. With regard to the alternative notices finalized in the accommodation, the July 2015 final regulations specified that notices submitted as an alternative to the EBSA

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Form 700 must include not only the eligible organization's name and an expression of its religious objection, but also 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 them to administer the accommodation process.

The July 2015 final regulations provide that, when an eligible organization maintains an insured group health plan or student health plan and provides the alternative notice, 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 July 2015 final regulations provide that the Department of Labor (DOL) would work with HHS to send a separate notification to the self-insured plan's third party administrator(s). The regulations provide that such notification is an instrument under which the plan is operated for the purposes of section 3(16) of ERISA and designates the third party administrator as the entity obligated to provide 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 ERISA section 4(b)(2), but acknowledge that in the operation of the accommodation process ERISA section 3(16) does not provide a mechanism to impose an obligation to provide contraceptive coverage as a plan administrator on those eligible organizations' third party administrators.

A number of religious non-profit organizations challenged the Mandate's accommodation because they believed it impermissibly burdened their religious beliefs because it utilized the

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plans they sponsored to provide the services to which they objected on religious grounds. They also objected to the self-certification requirement on the same basis. The non-profit religious organization lawsuits engendered a conflict among Federal appellate courts. In most cases, non-profit religious organizations lost their challenges on the theory that the accommodation process was not a substantial burden to their religious beliefs, even though the religious plaintiffs asserted they were being required to undertake actions that violated their consciences. See, e.g., 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 non-profit employers. Dordt College v. Burwell, 801 F.3d 946, 949–50 (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 it asked the parties to submit supplemental briefs. 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 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

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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 the eligible organization plaintiffs in those cases. 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 insurers and third party administrators to provide contraceptive coverage for participants in the plaintiffs' group health plans under the accommodation.

On July 26, 2016, the Departments issued a Request for Information ("RFI"), 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 HRSA-supported Women's Preventive Services Guidelines via its website, https://www.hrsa.gov/womensguidelines2016/index.html. HRSA announced that, for plans subject to the Guidelines, the updated Guidelines apply to the first plan year beginning after December 20, 2017. 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. Among other changes, the updated Guidelines specify that the coverage includes follow-up care (e.g., management and evaluation, as well as changes to, and removal or discontinuation of, the contraceptive method). HRSA expanded the coverage requirements under the Guidelines by specifying that coverage should

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include instruction in fertility awareness-based methods for women desiring an alternative method. The updated Guidelines did not alter the religious employer exemption or accommodation process.

On January 9, 2017, the Departments issued "FAQs About Affordable Care Act Implementation Part 36" ("FAQ").[14] The FAQ stated that, after reviewing comments submitted in RFI and considering various options, the Departments 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.

Not all of the non-profit organizations challenging the Mandate have been religious. Certain non-religious, pro-life organizations share the belief that some contraceptives have an abortifacient effect, and under the Mandate those organizations neither receive an exemption nor qualify for the accommodation process. In the first of such cases, the organization that since 1974 has sponsored the annual March for Life in Washington, D.C., filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and that it was arbitrary and capricious under the Administrative Procedure Act. Citing, for example, 77 FR 8727, March for Life pointed out that the Departments' stated purposes for the Mandate were only advanced among women who "want" the coverage so as to prevent "unintended" pregnancy. Accordingly, March for Life observed that the Departments exempted certain religious employers by relying on the assertion that their employees "likely" oppose contraceptives (without citing a source for that likelihood), and that the Departments

[14] 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.

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therefore declared such an exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement." (See, e.g., 78 FR 39874). 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 on them, and the Departments had no rational basis to deny them the exemption being offered religious employers. March for Life's employees, who are personally religious, also sued as co-plaintiffs, contending 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 wants to offer them or in the individual market, because the Departments offer no exemptions in either circumstance.

The district court agreed with the March for Life plaintiffs on the equal protection and RFRA claims (not specifically ruling on the APA claim), granted summary judgment to the plaintiffs, and issued a permanent injunction against the Departments. March for Life v. Burwell, 128 F. Supp. 3d 116 (D.D.C. 2015). A Federal district court in Pennsylvania disagreed, however, and ruled against similar claims brought by a non-religious, non-profit pro-life organization and its religious employees. Real Alternatives, Inc. v. Burwell, 150 F. Supp. 3d 419 (M.D. Pa. 2015).

On May 4, 2017, the President issued an "Executive Order Promoting Free Speech and Religious Liberty." The order provides, regarding "Conscience Protections with Respect to Preventive-Care Mandate," that "[t]he 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."

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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). Congress did not exempt section 2713 from RFRA when it enacted the ACA. As discussed above, in Hobby Lobby the Supreme Court stated, "we must next ask whether the HHS contraceptive mandate 'substantially burden[s]' the exercise of religion. 42 U.S.C. § 2000bb-1(a). We have little trouble concluding that it does." 134 S. Ct. at 2775.

The Departments previously concluded that the Mandate served compelling governmental interests, including "public health and gender equality interests." (78 FR 39872) Based in part on that determination, the Departments provided a narrow exemption covering only churches and their integrated auxiliaries. Other organizations with religious objections were either required to comply with the Mandate or offered only the accommodation process. Despite multiple rounds of rulemaking, however, that accommodation process has not satisfied the religious objections of numerous organizations with sincere religious objections to contraceptive coverage or resolved the pending litigation. To the contrary, the Departments have been litigating RFRA challenges to the Mandate and related regulations for more than five years, and dozens of those challenges remain pending today. That litigation, and the related modifications to the accommodation, have consumed substantial governmental resources while also creating uncertainty for objecting organizations, issuers, third party administrators, and employees and

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beneficiaries. One significant reason for granting the exemptions set forth in these interim final rules is the Government's desire to resolve the pending litigation.

Under the circumstances, the Departments have determined that it is appropriate to revisit the importance of the Government interests served by the Mandate, reweigh the balance of any Government interests in light of conscientious objections to the Mandate, and reconsider whether the existing exemption and accommodation are the most appropriate administrative response to the conscientious objections of many organizations and the substantial burden on religious exercise that the Supreme Court identified in Hobby Lobby. That reexamination is particularly appropriate because the Mandate was not imposed by Congress, but rather was the result of HRSA's discretionary decision to include contraceptives among the preventive services required to be covered under section 2713(a)(4) of the PHS Act, and to limit the exemption from the Mandate to churches and their integrated auxiliaries.

These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines (and also leave unchanged many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women). But the Departments are expanding the existing exemption from the Mandate to a broader range of entities and individuals that object to contraceptive coverage on religious grounds, while also leaving the existing accommodation in place as an optional alternative. As explained below, the Departments continue to interpret PHS Act section 2713(a)(4) to authorize HRSA to grant exemptions from the Mandate even apart from RFRA, and the Departments are exercising that authority to provide exemptions for entities and individuals with both moral and religious objections to contraceptives. But the expanded exemptions for religious

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objectors also rests on an additional, independent ground: the Departments have determined that, in light of RFRA, an expanded exemption, rather than the existing accommodation, is the most appropriate administrative response to the substantial burden identified by the Supreme Court in Hobby Lobby.

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

At the same time, the Departments' decision to exercise discretion to exempt objecting entities does not rest solely on the Departments' conclusion that applying the contraceptive coverage requirement to those entities would violate RFRA. The Departments have the discretion to exempt objecting entities in providing and supporting Guidelines under PHS Act section 2713.

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Nevertheless, given the Departments' previous assertion that they had a compelling interest to overcome the objections when they were defending challenges to the Guidelines, see, e.g., 78 FR 39886–88, the Departments consider it important to rebalance the Government's general interest in contraceptive coverage and with the respect the Government owes to the interests of conscientious objectors, and under RFRA, religious objectors specifically.

RFRA requires the Government to respect religious beliefs under "the most demanding test known to constitutional law," the compelling interest test. 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, 406-409 (1963); Wisconsin v. Yoder, 406 U.S. 205, 221-229 (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). Instead, 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. The question here is not whether the Government's broad interests in health and equality are compelling. Instead, it is whether, under the ACA, the Government has a compelling interest in denying exemptions to those who object to the contraceptive coverage requirements, after the Departments have rebalanced the broad interests of coverage with the Government's interests in providing for conscientious objection. Upon further examination of the relevant provisions of the ACA and the administrative record on

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which the Mandate was based, the Departments have concluded that the application of the Mandate to such entities does not serve a compelling governmental interest.

We begin by noting that Congress did not mandate that contraception be covered at all under the ACA—merely that, among other preventive services to be covered are "such additional preventive care and screenings" for women "provided for in comprehensive guidelines supported by [HRSA]." Congress, thus, left the identification of the required preventive services to administrative discretion. And the fact that Congress granted HHS (through HRSA) discretion to decide whether to require contraceptive coverage at all indicates that the Departments' judgment about the relative importance of the Government's interest in applying the Mandate to the narrow category of entities at issue here should carry particular weight.

Further, while Congress specified that many health insurance requirements added by the ACA—including provisions adjacent to section 2713—were so important that Congres required they be applied to all health plans immediately, the preventive services requirement in section 2713 was not made applicable to "grandfathered plans." That feature of the ACA is significant: six years after the ACA's enactment, approximately 36.5 million people were estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act. Kaiser Family Foundation & Health Research & Educational Trust, Employer Health Benefits, 2016 Annual Survey 60, 230. The Departments have previously described those ACA provisions applicable to grandfathered plans as "particularly significant protections." (75 FR 34540) 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. "Even a compelling interest may be outweighed in some circumstances by another even weightier consideration." Hobby

Lobby, 134 S. Ct. at 2780. But Congress's decision not to apply section 2713 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's decision to leave section 2713 out of that "significant" category is, thus, relevant to the Departments' assessment of whether Congress intended in PHS Act section 2713 to serve an interest of the "highest" order.

The case for a compelling interest is also undermined by the way the Departments applied the accommodation based on their statutory authority. The Departments correctly interpreted PHS Act section 2713 to confer discretion to exempt eligible organizations from the contraceptive coverage requirement, and to create an accommodation under which those organizations bore no obligation to provide for such coverage after submitting a self-certification or notice. But because Congress did not provide a mechanism to enforce the accommodation process against the third party administrators of self-insured church plans after such organizations were relieved of their coverage obligation, the employees of hundreds of religious organizations that are not exempt as houses of worship[15]—and that instead fall under the accommodation—are not required to receive the offer of contraceptive payments (and, to the Departments' knowledge, they are not receiving those offers because their plans and plan sponsors have stated in litigation that they object to extending such offers). By contrast, organizations that are very similar—such as religious educational institutions—are required to

[15] See supra note 3.

either comply with the Mandate fully or deemed compliant under the accommodation by which their employees receive offers of contraceptive payments from their issuer or third party administrator. The effect is that many similarly situated employees of religious organizations are being treated very differently with respect to receiving offers of contraceptive payments, even though the Departments claimed a compelling interest to deny exemptions to 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).

In evaluating the weight of the Government's interests, the Departments have also considered the particular characteristics of the employers at issue. By definition, the relevant employers have sincere religious objections to providing contraceptive coverage. 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. Some of these entities claim that their employees are required to adhere to a statement of faith which includes the entities' moral views on certain contraceptive items.[16] The Departments recognize, of course, that not all employees who work for these entities necessarily share their employers' religious objections to contraceptives. At the same time, it has become apparent from filings in dozens of cases—encompassing hundreds of organizations—that many religious non-profit

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[16] See, e.g., 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."); cf. March for Life v. Burwell, 128 F. Supp. 3d 116, 123 (D.D.C. 2015) (requiring employees to oppose certain contraceptives on either religious or moral grounds, where the employees at the time the complaint was filed asserted they did so based on religious grounds).

organizations express their beliefs publicly. Employees of such organizations, even if not required to sign a statement of faith, will often have public access to, and knowledge of, the views of their non-profit employers and will, in many cases, have nonetheless chosen to work for such organizations and to help advance those organizations' goals. Such public information would include non-profit organizations' publicly filed lawsuits objecting to providing such coverage, the attendant media coverage of such lawsuits, and employee benefits disclosures about whether their health plans will cover contraception.

The Departments have concluded that the governmental interest in ensuring that the employees of such organizations receive contraceptive coverage as part of their employer-sponsored health plan is less significant than previously stated. That determination is consistent with the Departments' prior conclusion that the governmental interests supporting the Mandate are not undermined by the existing exemption for thousands of houses of worship. In previously denying an exemption to eligible organizations, the Departments did not identify data to support a distinction between the beliefs of employees of churches and their integrated auxiliaries on the one hand, and employees of non-profit organizations on the other. Yet the Departments reasoned that the exemption for churches "does not undermine the governmental interests furthered by the contraceptive coverage requirement" because "[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection." (78 Fed. Reg. 39874) As explained above, that reasoning extends further than the Departments had previously acknowledged, so as to include other non-profit organizations whose principles oppose contraceptive coverage.

The Departments also previously asserted that the exemption for churches was offered to respect a certain sphere of church autonomy. (80 FR 41324) That explanation does not adequately account for denying the exemption to other religious non-profit organizations. RFRA does not make a distinction between the respect to be afforded to churches and that which the Government owes to other religious organizations or claimants. Indeed, the Departments' exemption for integrated auxiliaries of churches, which are defined by 26 CFR 1.6033-2(h), includes many organizations such as schools that operate in a very similar fashion to other religious organizations not so exempt. Moreover, because there is no statutory authority to compel the third party administrators of self-insured church plans to provide contraceptive payments, the Departments' accommodation for those plans has effectively functioned an exemption for many religious organizations (such as colleges) that operate in a very similar fashion to other non-exempt non-profit religious groups. As discussed elsewhere herein, when the Departments drafted the exemption narrowly to include only houses of worship, they relied in part on a small minority of state laws which contained similar narrow exemptions. (See 76 FR 46623). The Departments now find it significant that most other states either offer broader exemptions or impose no contraceptive requirement in the first place.[17] The broadening of exemptions contained in these interim final rules does not remove any of the exemptions the Departments previously offered to churches, so that the exemption the Departments provided to group health plans established or maintained by religious employers (78 FR 39874) is continued by these interim final rules. But these rules also offer an exemption for the interests of other

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

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organizations and individuals that object based on religious beliefs or moral convictions. For all these reasons, the Departments' rationale of affording special respect for church autonomy is not a sufficient reason not to expand exemptions to other organizations.

The Departments' conclusion after rebalancing the interests in this matter—that applying the Mandate to entities and individuals with religious objections does not serve a compelling interest—is also based on their reexamination of the administrative record on which the Mandate rests. In reconsidering previous positions and reexamining the evidence, the Departments now conclude that, in this context, the evidence on which the Mandate rests must be reweighted in light of the high threshold for a compelling interest.

First, in support of the IOM's recommendations, which HRSA adopted, the IOM identified several studies showing a preventive services gap because women need to use more preventive care than men. IOM 2011 at 19–21. Those studies did not identify contraceptives or sterilization as comprising a specific portion of that gap, and the Committee 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. The coverage of the other women's preventive services required under both the HRSA Guidelines and throughout section 2713(a)—including annual well-woman visits and a variety of tests, screenings, and counseling services—serves to diminish the cost gap identified by IOM even for women whose employers decline to cover some or all contraceptive on religious grounds. All objectors to the Mandate identified in litigation have been willing to cover all of the other preventive services without cost sharing required by section 2713.

Second, there are multiple Federal, state, and local programs that provide free or subsidized contraceptives for low-income women, including Medicaid (with a 90% Federal match for family planning services), Title X, 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.[18] Various state programs supplement Federal programs, and 28 states have their own mandates of contraceptive coverage as a matter of state law. For example, the Title X program, administered by the HHS Office of Population Affairs (OPA), provides voluntary family planning information and services for clients based on their ability to pay, through a network that includes 4,200 family planning centers. http://www.hhs.gov/opa/title-x-family-planning/ The program is dedicated solely to supporting the delivery of family planning and related preventive health care. It is designed to provide contraceptive supplies and information to all who need them, with priority given to low-income individuals. Title X-funded service sites offer a broad range of contraceptive methods on a voluntary and confidential basis through grants to public health departments and community health, family planning, and other private nonprofit agencies which support service delivery at nearly 4,000 sites. 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 (government or private) is authorized or obligated to pay for these services. Individuals with incomes between 101% and 250% 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 on their own income

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

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level rather than their family's income. The availability of such programs to serve the most at-risk women identified by IOM diminishes the Government's interest in applying the Mandate to objecting employers. Most forms of contraception are available for around $50 per month, including long-acting methods such as the birth control shot and the IUD.[19] Other more permanent forms of contraception like implantables bear a higher one-time cost, but when calculated over the duration of use, the cost is similar to other forms of contraception.[20]

Third, the evidence does not show a direct causal nexus between denying exemptions to the Mandate and harm being caused to a compelling government interest. The 2011 IOM report identified the most at-risk women with respect to unintended pregnancy as being "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." With respect to objecting plan sponsors and individuals, the Mandate applies in employer-based group health plans and student insurance at private colleges and universities. In this way the Mandate's application to objecting employer entities is not tailored to the at-risk population specifically identified by the IOM. The Guttmacher Institute, on which the IOM relies, reported that 89% of women who are at risk of unintended pregnancy and are living at 0–149% of the poverty line are already using contraceptives, as are 92% of those with incomes of 300% or more of the Federal poverty level.[21] At significant times, contraception use has increased even the proportion of unintended

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[19] See, e.g., https://www.plannedparenthood.org/learn/birth-control; http://www.webmd.com/sex/birth-control/ss/slideshow-birth-control-options; https://www.bedsider.org/questions/151-how-much-does-the-internal-condom-cost; https://www.bedsider.org/methods/iud#costs_tab; https://www.babycenter.com/0_female-sterilization_1282183.bc; https://www.babycenter.com/0_vasectomy_1289785.bc; https://www.bedsider.org/methods/emergency_contraception#costs_tab.

[20] See id.

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

pregnancies has not decreased. While "[t]he proportion of unmarried women at risk of unintended pregnancy who were using contraceptives increased from 80% in 1982 to 86% in 2002,"[22] nevertheless, "[c]hanges in contraceptive method choice and use have not decreased the overall proportion of pregnancies that are unintended between 1995 and 2008."[23]

The rates of—and reasons for—unintended pregnancy are notoriously difficult to measure.[24] In particular, association and causality can be hard to disentangle, and the studies on which the 2011 IOM Report relies speak more to association than causality. For example, IOM 2011 declares that, "as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined (Boonstra et al., 2006)," and 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 (Santelli and Melnikas, 2010)." IOM 2011 at 105. The cited portions of these studies are insufficient to demonstrate a causal link between the harm identified and the Mandate, for two reasons. First, both of these assertions rely on association rather than

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

[23] Jo Jones et al., "Current Contraceptive Use in the United States, 2006-2010, and Changes in Patterns of Use Since 1995," Nat'l Health Stat. Rep. at 1, 11 (Oct. 2012).

[24] 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," i.e., 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).

causation. Second, they associate reduction in unintended pregnancy with increased use of contraception, not merely with increased access.

There is significant reason to believe that causality is more complicated than the IOM Report suggests. With respect to teens, which comprise a significant portion of women IOM identifies as at-risk, the Santelli and Melnikas study observes the long term trend that, between 1960 and 1990, as contraception became available and its use increased, teen sexual activity outside of marriage likewise increased.[25] Another study focused on teens has 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."[26] Regarding emergency contraception in particular, "[i]ncreased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates."[27] Other studies have suggested similar results.[28]

The present Mandate applies to the plans of objecting employers and individuals, which is a broader population than the specific at-risk group of women identified by IOM. Imposing a

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[25] John S. Santelli & Andrea J. Melnikas, "Teen Fertility in Transition: Recent and Historic Trends in the United States," 31 Ann. Rev. Pub. Health 371, 375–76 (2010).

[26] 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.

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

[28] See, e.g., 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% to 80%, 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).

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coverage Mandate on objecting entities—whose plans cover many enrollee families who may share objections to contraception—could, among some populations, exacerbate the long run negative effect of changing sexual behavior by, for example, providing contraceptive access to teenagers and young adults who are not necessarily in the sexually active at-risk population of women.[29]

The conclusion that the Government does not have a compelling interest in applying the Mandate to entities with religious and moral objections is further bolstered by evidence from studies the post-date the enactment of the Mandate. In 2016 HRSA awarded a five-year cooperative agreement to the American College of Obstetricians and Gynecologists to develop recommendations for updated Women's Preventive Services Guidelines. Under the agreement an expert panel called the Women's Preventive Services Initiative (WPSI) was formed, and issued a report in 2016 (WPSI report).[30] After observing that "[p]rivate companies are increasingly challenging the contraception provisions in the ACA," the WPSI report cited studies through 2013 stating that application of HRSA Guidelines to non-objecting entities had applied contraceptive coverage to 55 million women and led to a 70% decrease in out-of-pocket expenses for contraceptive services among commercially insured women. Id. at 57–58. Notably, as discussed above, through that same time period (2011–2013) church groups were exempt from the Mandate, other non-profit religious organizations that objected to it were not required to comply because of the temporary non-enforcement safe harbor, and hundreds of accommodated

[29] For further discussion, see Helen M. Alvare, "No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom," 58 Vill. L. Rev. 379 (2013), available at http://digitalcommons.law.villanova.edu/vlr/vol58/iss3/2.

[30] "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.

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self-insured church plan entities were not—and still are not—subject to enforcement of the Mandate through their third party administrators. In addition, dozens of for-profit entities that had filed lawsuits against the Mandate were protected by court orders pending the Supreme Court's resolution of similar RFRA claims in Hobby Lobby in June 2014. Therefore, it would appear that the benefits recorded by the report occurred even though most objecting entities were not in compliance.[31]

Despite the Departments' previous view that increased contraceptive access through a coverage mandate would reduce unintended pregnancy, other data indicates that, in 28 states where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[32]

All of these methodological uncertainties and lack of tailoring support the Departments' present conclusion that the interest in applying the Mandate to objecting entities is not compelling. The Departments do not take a position on these empirical questions in this rule.

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[31] 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 report does not specify the extent to which applying the Mandate among commercially insured women in general, or among commercially insured women at objecting entities specifically, serves to deliver contraceptive coverage to low income women 18 to 24 years of age and most at risk of unintended pregnancy. The WPSI report observes that between 2008 and 2011—before the contraceptive coverage requirement was implemented—unintended pregnancy decreased to the lowest rate in 30 years. Id. at 58. The WPSI report does not address how to balance contraceptive coverage interests with religious or moral objections.

[32] 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.

Rather, the uncertainty informs the conclusion that the Departments should rebalance their interests with interests of objecting organizations, and that the Government does not have a compelling interest in applying the Mandate to objecting organizations. The exemptions offered in these interim final rules do not remove HRSA's discretion to continue to require contraceptive coverage for most entities to which section 2713 applies, since most entities do not raise conscientious objections.

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 through coverage offered by religious objectors, for example, through "a family member's employer," "an Exchange," or "another government program."[33]

For all of these reasons, and as further explained below, the Departments now believe that it is appropriate to modify the July 2015 final regulations to expand the exemption and change the accommodation to an optional rather than mandatory process. Under this approach, HRSA maintains the discretion to require contraceptive coverage for nearly all entities to which the Mandate previously applied (since most plan sponsors do not possess religious or moral objections), and this approach also does not alter other Government subsidies of contraception.

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

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The Departments believe this approach is sufficiently respectful of conscientious objections while still allowing the Government to advance other interests.

Most of the RFRA challenges to the Mandate have been brought by entities that object on religious grounds to providing contraceptive coverage. In addition, however, some individuals have brought RFRA challenges to the Mandate because they object on religious grounds to being covered under an insurance policy that includes coverage for contraceptives. See, e.g., Wieland v. HHS, 196 F. Supp. 3d 1010 (E.D. Mo. 2016); March for Life v. Burwell, 128 F. Supp. 3d 116 (D.D.C. 2015). 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, they have also concluded that they do not have a compelling interest in applying the Mandate to employers and insurers to the extent that those entities provide coverage to individuals who object to being covered by policies that include contraceptive 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 equality as being advanced among women who "want" the coverage so as to prevent "unintended" pregnancy." (See, e.g., 77 FR 8727). The Government's interests are not advanced by provision of contraceptive coverage for individuals who do not want such coverage or items because no unintended pregnancies will be avoided or costs reduced by imposing the coverage.

While 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

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require—insurers and employers to omit contraceptives from the coverage provided to objecting individuals does not undermine any compelling interest. See Wieland, 196 F. Supp. 3d at 1019-1020; March for Life, 128 F. Supp. 3d at 132. The extent to which plans cover contraception is far from uniform, especially given the various ways in which Congress did not require compliance with section 2713 by all entities. The existence of the exemption for houses of worship shows that the integrity of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many cases. 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 exemptions undermine the operation of the many other programs subsidizing contraception. Accordingly, as further explained below, the Departments have provided an exemption for objecting individuals.

Finally, the Departments note that the exemptions created here do not burden third parties to such an extent that counsels against providing the exemptions. Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose section 2713 to benefit millions of persons in grandfathered plans. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created here or because of other exemptions to the Mandate have other avenues for obtaining it, including the various government programs discussed above. 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 in

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violation of their religious beliefs or 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.").[34]

III. Exemptions to the Mandate Based on Moral Convictions

RFRA does not provide protection for nonreligious, moral conscientious objections. The Departments nevertheless believe they have legal authority and significant interests in respecting not only religious beliefs, but also moral convictions, in crafting the exemptions set forth in these interim final rules. The Departments rely on HRSA's authority under section 2713 to exempt entities by choosing not to provide or support the Guidelines' application to such entities. In addition, as cited above, Congress has protected religious beliefs alongside moral convictions in the Federal regulation of healthcare for well over 40 years.[35] Those statutes include, to highlight only a few:

- the 1973 protection that certain Federal health fund recipients cannot discriminate against personnel "because he refused to perform or assist in the performance of [a sterilization] 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(c)(1);

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[34] 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.").

[35] See supra note 1.

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- protections for health plans or care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counselling or referral services. 42 U.S.C. § 1396u-2(b)(3); 42 U.S.C. § 1395w-22(j)(3)(B);
- protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions." Sec. 726 of Title VII of Division C (Financial Services and General Government Appropriations Act) of the Consolidated Appropriations Act, 2016, Pub. L. No. 114-113.

Most recently, in the Consolidated Appropriations Act of 2017, Congress 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." Sec. 808 of Title VIII of Division C (Financial Services and General Government Appropriations Act), Enrolled Bill, 2017 Cong. HR 244 (signed into law May 5, 2017); see also Consolidated Appropriations Act of 2016, Public Law No. 114-113 (same). Multiple regulations likewise protect objections based on both religious beliefs and moral convictions.[36]

[36] See, e.g., 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); 28 CFR 26.5 ("No officer or employee of the Department of Justice shall be required to be in attendance at or to participate in any execution if such attendance or participation 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."); cf. 29 CFR 1605 (defining "religious practices to include moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views"); 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").

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Together, such statutes and regulations comprise a consistent history of protecting moral convictions alongside religious beliefs. In healthcare, the rules specifically protect conscientious objection for for-profit entities, entities objecting to contraception or sterilization, and entities with objections that are moral but not religious (and, in some cases, with objections that need no particular motivation).

The Supreme Court has long affirmed that it is appropriate to protect moral beliefs alongside religious beliefs in healthcare conscience clauses. In Doe v. Bolton, although the Court affirmed a right to abortion, the Court simultaneously 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. Likewise, in Roe v. Wade, the Court 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. 113, 144 & n.38 (1973).

Shortly after Roe, Congress enacted the first of the aforementioned healthcare conscience protections in 42 U.S.C. § 300a-7, protecting objections based on both religious beliefs and moral convictions. That statute and many later conscience protections are not limited to abortion, variously including sterilization, contraception, and, in some cases, any lawful health service. Notably, many persons and entities objecting to this Mandate, including all current litigants asserting purely nonreligious objections, consider some forms of FDA-approved contraceptives

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to be morally akin to abortion because they have the effect of preventing implantation of an embryo after fertilization.

The Supreme Court has also recognized the propriety of respecting moral convictions alongside religious beliefs in the setting of conscientious exemptions outside healthcare. In a case involving the Government's paradigmatic compelling interest—the need to defend the nation militarily—the court insisted that, where the Government protected objections based on "religious training and belief," it should protect avowedly nonreligious objections to war held with the same strength. Welsh v. United States, 398 U.S. 333, 343 (1970). 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."

Citing Justice Harlan's opinion in Welsh, 398 U.S. at 357–58, the dissenters in Hobby Lobby declared that "[s]eparating moral convictions from religious beliefs would be of questionable legitimacy." 134 S. Ct. at 2789 n.6.[37] The Equal Employment Opportunity Commission, in issuing guidelines on what constitutes "discrimination because of religion," has issued regulations declaring that it will follow Welsh and similar armed services cases so as to

[37] While the Departments disagree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause, the Departments believe, in the healthcare context, that the principle in favor of respecting religious beliefs provides reinforcement as a matter of policy to the rationale for protecting parallel moral convictions.

"define religious practices to include moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." 29 CFR 1605. 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.

Protecting conscience from Government mandates runs to the heart of America's founding. George Washington wrote that, "[w]hile we are contending for our own liberty, we should be very cautious not to violate the rights of conscience in others, ever considering that God alone is the judge of the hearts of men, and to him only in this case they are answerable."[38] Thomas Jefferson similarly declared that "[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority."[39] James Madison called conscience "the most sacred of all property," and proposed as a restriction on the Federal Government the principle: "nor shall the full and equal rights of conscience be in any manner, or on any pretext infringed."[40] 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, "HHS would effectively exclude these people from full participation in the economic life of the Nation." 134 S. Ct. at 2783.

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[38] Letter to Benedict Arnold, (September 14, 1775).

[39] Letter to the Society of the Methodist Episcopal church at New London, Connecticut (February 4, 1809).

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

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The Departments' goal is to provide rules so that the healthcare system can be inclusive of people who possess different conscientious views on certain sensitive matters. The issue of contraceptive services has long been an issue for which conscientious objection is particularly appropriate. In one of the earliest federal conscience statutes, 42 U.S.C. 300a-7, sections (b), (c)(1), and (e) protect objections to sterilization alongside abortion, and sections (c)(2) and (d) apply to objections to any health service. Also, as discussed above, multiple appropriations riders express Congress' intent to protect conscientious objections relating to contraceptive insurance coverage. In addition to the religious or moral objections to contraception expressed by litigants against the Mandate, several insurance or benefits organizations have stated in comments submitted to the Departments that "it is questionable" whether a policy covering only contraception "could properly qualify as covering a specified 'disease' or 'illness,' given that fertility is neither a disease nor an illness."[41] In light of the inherent sensitivity of whether contraceptive coverage involves a disease to be prevented or a healthy condition, the Departments consider it appropriate in implementing the ACA to respect conscientious objection if HRSA includes contraception and sterilization services in preventive services Guidelines.

The ACA was enacted with the intention to follow Congress' history of protecting conscience in healthcare based on religious beliefs and moral convictions. Contemporaneous with signing the ACA, the President emphasized in Executive Order 13535 that conscience protections encompassing both religious and moral objections, including but not limited to 42 U.S.C. 300a-7, "remain intact," and further emphasized HHS's role in enforcing such

[41] See, e.g., Comments of BlueCross BlueShield Association, re: CMS–9931–NC (filed Sept. 19, 2016) (quoting comments of Groom Law Group, submitted April 8, 2013).

protections. The ACA gives HRSA discretion not to require contraception to be covered as a preventive service. As the Departments have interpreted the ACA since its enactment, this section gives HRSA discretion to decide to what extent it does or does not support coverage requirements under section 2713(a)(4)—including by not supporting the requirement for objecting organizations. The Departments consider it appropriate for HRSA to refrain from supporting its Guidelines where it would violate moral convictions to do so.

One court has issued a permanent injunction requiring the Departments 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), and two cases raising such objections are currently pending. In issuing its permanent injunction, a Federal court declared "it makes no rational sense—indeed, no sense whatsoever to deny March for Life that same respect" that the Departments offered religiously exempt organizations in the particular context of this Mandate, where March for Life and its employees categorically oppose the contraceptives the Mandate forces them to cover. Id. at 128. The interests that the Departments have stated for the Mandate are not advanced by imposing it on non-religious organizations and their employees that both oppose and will not use contraceptive items. The reasons discussed above explaining the Departments' lack of a compelling interest to impose the Mandate on objecting entities in violation of their religious beliefs apply to the same extent when the objection is moral rather than religious.

Among the lawsuits filed against the Mandate, only a small minority have stated moral objections that exist separate from religious objections. Thus the Departments anticipate that very few moral nonreligious objectors will adopt a view opposing coverage of these particular items, and therefore that offering exemptions protecting moral convictions will have little

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relative impact on the number of entities making use of exemptions. Yet as evidenced by the two lawsuits and permanent injunction discussed above, the number of nonreligious morally objecting entities is greater than zero, so some protection of moral convictions consistent with similar protections in other healthcare regulations is needed. Moreover, there is generally an increasing recognition in society, on issues not necessarily pertaining to contraception, that companies can and sometimes should adopt strong moral positions even if those positions are not necessarily religious.[42] The Departments consider it appropriate to protect objecting nonreligious, moral entities and persons that wish to participate in health care coverage without violating their deeply held convictions with respect to coverage of contraceptive services.

For all these reasons, the Departments believe it is appropriate to provide exemptions for moral convictions alongside religious beliefs, as pertains to this particular coverage requirement.

IV. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history 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 by extending the exemption under the HRSA Guidelines to encompass entities, and plans of individuals, with religious beliefs or moral convictions objecting to contraceptive or sterilization coverage, and by making the accommodation process optional for eligible organizations instead of mandatory.

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[42] See, e.g., Geoff Colvin & Ryan Derousseau, "CEOs Embrace Activism," Fortune.com (Feb. 7, 2017), available at http://fortune.com/2017/02/07/ceos-embrace-activism/ . See also Tim Cook, CEO of Apple, Inc.: "We believe that a company that has values and acts on them can really change the world. There is opportunity to do work that is infused with moral purpose," quoted in Andrew Ross Sorkin, "For Apple, a Search for a Moral High Ground in a Heated Debate," N.Y. Times Dealbook (Feb. 22, 2016), available at https://www.nytimes.com/2016/02/23/business/dealbook/for-apple-the-moral-high-ground-lacks-clearly-defined-boundaries.html?_r=0 .

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We acknowledge that the foregoing analysis represents a change from the policies and interpretations the Departments 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)); 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").

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 objecting entities does not outweigh the objections of entities and individuals that object to contraceptive coverage on religious grounds or, based on the distinct analysis set forth above, on moral grounds.

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 religious beliefs or

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moral convictions. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no objection exists, and to the extent that PHS Act section 2713 otherwise applies. These interim final rules maintain the existence of an accommodation process, but consistent with our expansion of the exemption they make the process optional for eligible organizations rather than requiring such organizations to choose between the accommodation or unconditional compliance with the Mandate. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[43]

With respect to employers, the expanded exemption in these rules covers employers that have religious beliefs or moral convictions objecting to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling. The rules cover any kind of employer but, for the sake of clarity, these regulations also include an illustrative list of employers whose objection qualifies the plans they sponsor for an exemption.

Consistent with the current 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, existing ERISA rules governing group health plans require that a plan documents include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. If there is a reduction in a covered service or benefit, the plan has to disclose that change to participant in the plan.[44] Thus where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage, the plan document and otherwise applicable ERISA disclosures. should reflect the

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

[44] See, e.g., 29 CFR 2520.102-2, 102-3 and 104b-3(d);; and 29 CFR 2590.715-2715.

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omission of coverage. This is not an added obligation, but it will serve to help provide notice of what plans do and do not cover.

As in the previous rule, institutions of higher education that arrange student health insurance coverage will continue to be treated similar to the way employers are treated for the purposes of such plans being exempt. These interim final rules also exempt group health plans sponsored by an entity other than an employer that object based on religious beliefs or moral convictions to coverage of contraceptives or sterilization. The rules also exempt health coverage offered or provided to certain individuals with their own religious or moral objections, as described below.

The Departments consider it appropriate to issue these rules under the broad discretion Congress afforded to the Departments. Congress did not mandate universal and enforceable coverage of PHS Act section 2713, specify that contraception and sterilization be covered, or prohibit exemptions for religious beliefs and moral convictions.[45] Instead Congress provided HRSA discretion in shaping Guidelines in section 2713(a)(4), and has consistently enacted statutes such as RFRA and many protections of religious beliefs and moral convictions in healthcare.

Although these interim final rules adopt a different scope of exemptions than the Departments have adopted previously, the Departments have consistently taken the position that section 2713(a)(4) of the PHS Act grants HRSA flexibility to issue Guidelines that provide for and support exemptions from a contraceptive coverage requirement. Unlike other provisions in

[45] As some commenters have noted, between 1997 and 2010 over 20 bills were introduced in Congress to require private health insurance plans to cover contraceptives, but none of those bills were reported out of a committee or subcommittee.

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section 2713, section 2713(a)(4) does not require that the guidelines be "evidence-based" or "evidence-informed." Section 2713(a)(4) only requires women's preventive services coverage "as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." Therefore, to the extent the HRSA Guidelines do not provide for or support the application of such coverage to exempt entities, the ACA does not require the coverage. For this reason, 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. In addition, these interim final rules modify the restatements of the requirements of PHS Act section 2713 contained in 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130, so that they conform to the statutory text of section 2713, without adding additional words and phrases, such as "evidence-informed" or "binding," where Congress did not apply those words.

Since the beginning of rulemaking on this Mandate, HRSA and the Departments have repeatedly exercised their discretion to create and modify various exemptions within the Guidelines. Over the past almost six years, the Departments: created an exemption only for houses of worship that primarily serve persons who share their religious tenets, and later expanded that exemption to all houses of worship; created a non-enforcement safe harbor for other religious nonprofit organizations, then an accommodation process for those organizations, and later an expanded accommodation to include some for-profit entities; adjusted the forms to be submitted under the accommodation process, expanded it to included additional notices, and later treated other documents as constituting constructive notice. As in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., "the fact that the agency has adopted different

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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." 467 U.S. 837, 863–64 (1984).

The Departments believe the approach of these interim final rules better aligns our implementation of PHS Act section 2713(a)(4) with Congress's intent in the ACA and throughout other Federal healthcare laws. As discussed above, many Federal healthcare laws and regulations provide exemptions for objections based on religious beliefs and moral convictions, and RFRA applies to the ACA. Expanding the exemption removes religious and moral obstacles that entities and certain individuals may face who otherwise wish to participate in the healthcare market. This advances the ACA's goal of expanding health insurance 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 limited access to contraceptives.[46] 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 religious beliefs or moral convictions. The Departments conclude that it would be inadequate to refuse to expand exemptions to entities and simply attempt to amend the accommodation process. The Departments have acknowledged in their court briefing that the existing accommodation with respect to self-insured plans requires contraceptive payments as "part of the same plan as the coverage provided by the employer" and

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[46] See, e.g., 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.

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 also 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 stated in January 2017 that they were unable to develop such an approach at that time.

These interim final rules expand the exemption that was created in 45 CFR 147.131(a). The new language of paragraph 147.131(a)(1) and (a)(1)(i) provides exemptions based on objections of non-governmental plan sponsors. To avoid any possible confusion, the Departments wish to explain here the scope and applicability of the exemption when a plan sponsor objects. This explanation is consistent with how prior rules have worked by means of similar language. Paragraphs 147.131(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 both the group health plans regarding which the plan sponsor objects, and their health insurance issuers in providing the coverage in that plan (whether or not the issuer has its own objection). Consequently, the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty derived from the Guidelines for omitting the contraceptive coverage from the benefits of the plan participants and beneficiaries. The rules specify a non-exhaustive list of non-governmental plan sponsors that are covered by this exemption, including but not limited to a variety of plan sponsor employers. The rules also specify, in paragraph (a)(1)(ii), that the exemption is extended in the case of institutions of higher education as defined in 20 U.S.C. § 1002 in their arrangement of student health insurance coverage, in a manner comparable 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.

These interim final rules further extend the exemption, in paragraph (a)(1)(iii), to health insurance issuers offering group health insurance coverage that hold religious or moral objections in certain circumstances. The Departments are not currently aware of health insurance issuers that possess their own religious or moral objections to offering contraceptive coverage. But protecting issuers that object to offering contraception based on religious beliefs or moral convictions will leave room in the health insurance market for issuers that are inclined to offer products that do not include coverage for contraceptive items and services to plan sponsors who also hold such an objection. Where an issuer that holds an objection provides coverage in connection with a group health plan sponsored by an organization that does not also object, the group health plan must ensure that benefits for contraceptive items and services are provided without cost-sharing by other means. Issuers 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.

Many of the Federal healthcare conscience laws and regulations protect issuers or plans specifically. For example, 42 U.S.C. 1396u-2(b)(3) and 1395w-22(j)(3)(B) protect plans or care organizations in Medicaid or Medicare Advantage. HMOs, health insurance plans, and any other health care organizations are protected from being required to provide coverage or pay for abortions. Consolidated Appropriations Act of 2016, Pub. L. No. 114-113, Div. H, Title V, Sec. 507(d). The most recent versions of Consolidated Appropriations Acts declare Congress' intent to include a "conscience clause" which provides exceptions for religious beliefs and moral

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convictions by the District of Columbia if it requires "the provision of contraceptive coverage by health insurance plans." See id. at Div. C, Title VIII, Sec. 808; Div. C, Title VIII, Sec. 808, Enrolled Bill, 2017 Cong. HR 244 (signed into law May 5, 2017).

Under these interim final rules, the HRSA Guidelines do not define the exemption with reference to section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code, as previous rules have done. While prior regulations relied in part on a small minority of state exemptions for their use of section 6033 to define the exemption (76 FR 46623), the Departments now consider a broader exemption to be more consistent with the much larger number of other state laws concerning contraceptive coverage. 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.[47]

The exemption in these interim final rules for group health plans applies "to the extent" of the plan sponsor's religious or moral objection. Thus employer plan sponsors that object to covering some but not all contraceptive items would be exempt for the items to which they object, but not for the items to which they do not object. Likewise, an employer plan sponsor's objection exempts its plan, health insurance coverage offered by a health insurance issuer with respect to its plan, and an issuer in its offering of such coverage, but such exemption does not extend to coverage provided by that issuer to other group health plans where no objection exists by the plan sponsor.

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

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These interim final rules extend the exemption to plans sponsored by objecting employers, whether or not they operate as a non-profit organization. This is consistent with the Supreme Court's ruling in Hobby Lobby, which declared that an entity is capable of possessing and pursuing religious or moral principles regardless of whether the entity operates as a non-profit organization, and rejecting the Departments' argument to the contrary. 134 S. Ct. 2768–75. The July 2015 final regulations attempt to define extensively what constitutes a closely-held for-profit entity. However, the legal concept of what makes a company closely held is not well-defined or universally-accepted and the Departments have now concluded that it is too imprecise to be imposed in this regulatory scheme. This difficulty is reflected in the July 2015 final regulations, where an entity satisfies the definition if its structure is merely "substantially similar" to otherwise specified parameters. The definition allows companies to write to HHS to determine whether they are or are not closely held, but permitted HHS to decline to answer the inquiry. In other areas of public policy, it is becoming widely recognized that businesses large and small take positions on matters of social justice, community benefit, and ethical concerns beyond profit. In Hobby Lobby, the Supreme Court determined that RFRA protects corporations because they are "persons," as that term is defined in 1 U.S.C. 1, which includes business organizations of all forms, regardless of whether they are closely held. Therefore, the Departments consider it appropriate to exempt any entity possessing religious beliefs or moral convictions against the coverage required by the Mandate, regardless of its corporate structure or ownership interests. The mechanisms for determining whether a company has adopted and holds

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such principles or views is a matter of well-established state law with respect to corporate decision-making.[48]

The exemption does not specifically include third party administrators, though the optional accommodation process under these interim final rules specifies that third party administrators cannot be required to continue to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by church plans exempt from ERISA that provide health coverage. Such plans are now exempt under these interim final rules and their third party administrators are under no obligation under PHS Act section 2713(a)(4) to provide benefits for contraceptive services. Third party administrators, as claims processors, are not directly required to comply with section 2713(a)(4), which applies to plans and issuers. 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 ERISA section 3(16) plan administrators. 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 payments 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 or continue contracts as third party administrators of such plans. For these reasons, these interim final rules

[48] 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.

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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 or moral convictions implicated by the Mandate.

These interim final rules contain an exemption pertaining to individuals, which provides that nothing in section 147.130(a)(4) may be construed prevent a willing plan sponsor of a group health plan or a willing health insurance issuer offering group 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 or moral convictions. Accordingly, the exemption extends to the coverage unit in which the plan participant or subscriber is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but it does not relieve the plan or issuer's obligation to comply with the Mandate with respect to the group health plan at large or with respect to any other individual coverage.

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. This individual exemption also should not be construed to require the guarantee availability of coverage omitting contraception to any plan sponsor or individual who does not have a sincerely held religious or moral objection. This individual exemption is limited to the requirement to provide contraception under PHS Act section 2713, and does not affect any other Federal or state

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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.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously- or morally-acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not. This individual exemption can apply with respect to individuals in plans sponsored by either 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 will not discriminate against individual employees or their insurance issuers for offering health plans that omit contraception based on the employees' religious beliefs or moral convictions. See Wieland, 196 F. Supp. 3d at 1015–16 (citing Mo. Rev. Stat. 191.724). Under this individual exemption, employers sponsoring governmental plans would be free to honor the objections of individual employees, even if those entities also otherwise offer contraceptive coverage.

The Departments believe the individual exemption will increase the ACA's goal of increasing health coverage because it will reduce the incidence of certain individuals having health coverage to which they have a religious or moral objection, which could otherwise act as an obstacle to coverage.[49] At the same time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement,"[50] because the

[49] See, e.g., Wieland, 196 F. Supp. 3d at 1017, and March for Life, 128 F. Supp. 3d at 130, where individual employees express the Mandate's effect of pressuring them to "forgo health insurance altogether."

[50] 78 FR 39874.

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individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

Despite expanding the scope of the exemption, these rules also keep the accommodation process, but revise it so as to make it optional rather than mandatory. In this way, religious nonprofits that object are no longer required to choose between direct compliance with the Mandate or compliance through the accommodation. These rules likewise expand the optional accommodation to employers with moral convictions, for the reasons described above. Consequently, under these interim final rules objecting employers may make use of the exemption, or may choose to pursue the optional accommodation process. If an eligible organization pursues the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it will be voluntarily shifting an obligation to provide separate but seamless contraceptive payments to its issuer or third party administrator.

The reimbursement process for qualifying health insurers or third party administrators pursuant to 45 CFR Part 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.

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 eligible organization must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by Secretary. This revocation applies both prospectively to eligible organizations who decide at a later date to avail themselves of the optional accommodation and subsequently decide to revoke the accommodation, as well as to organizations that were included in the accommodation prior to the effective date of this interim

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final rule 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 the Departments that the accommodation applies. Consistent with other applicable laws, they must promptly notify their plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage. If contraception 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 thirty 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, sixty-days notice may be given pursuant to PHS Act section 2715(d)(4) if applicable.

The Departments have eliminated the provision in the previous accommodation reflecting that where an issuer relies reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation the issuer is considered to comply with the Mandate even if the representation is later determined to be incorrect. Under the prior rules, eligible organizations were not exempt from contraceptive coverage requirements and could potentially misrepresent their eligibility, exposing the issuer to liability for failing to comply with the contraceptive coverage requirements of PHS Act section 2713. Because any organization with a sincerely held religious or moral objection to contraceptive coverage now eligible for the optional accommodation under these interim final rules is also exempt, and its issuer with respect to that coverage is likewise exempt, the reliance provision is no longer necessary.

These rules fully leave in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. These

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interim final rules also maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines and to the extent Congress applied section 2713, if no objection exists.

The Departments believe this array of programs and requirements better serve the interest of providing contraceptive coverage than continuing to deny an exemption to entities that have a religious or moral objection to some or all contraceptive or sterilization services. These programs, the Guidelines, and the exemptions expanded herein will advance the limited purposes for which Congress imposed section 2713 while acting consistent with Congress's well-established record of allowing for religious and moral exemptions with respect to healthcare and health insurance requirements.

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

V. Interim Final Rules and Request for Comments

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 PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815. 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).

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In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.), 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 provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

However, even if these provisions of the APA were applicable, the Departments have determined that good cause exists to publish these interim final rules because 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, and announced that it plans to continually update the Guidelines in a similar fashion. Dozens of lawsuits over the Mandate are pending, some for nearly five years. The Supreme Court remanded several of those cases a year ago for the purpose of resolving disputes brought by religious non-profit entities subject to the accommodation process. Many organizations are currently being shielded by temporary court orders 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 PHS Act section 2713 and its enforcement due to Congress' limited application of that requirement. Millions of public comments have already been submitted on the scope of

the Guidelines, including the issue of whether to expand the exemptions. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received public comments. In connection with past regulations, the Departments have offered or expanded a temporary non-enforcement safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines.

As the court stated with respect to an earlier IFR issued with respect to this rule 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), "several reasons support HHS's decision not to engage in notice and comment here. First, the agency made a good cause finding in the rule it issued. Second, the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues; moreover, HHS will expose its interim rule to notice and comment before its permanent implementation. Third, the modifications made in the interim final regulations are minor, meant only to augment current regulations in light of the Supreme Court's interim order[.]" (Citations and internal quotations omitted.) Furthermore, "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 to avail themselves of the relief afforded by these interim final rules and would further extend the uncertainty caused by years of litigation and regulatory changes under section 2713(a)(4). Issuing interim final rules with comment period provides the public with an

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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.

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 publication in the **Federal Register**.

VI. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 13771, the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354, 5 U.S.C. 601-612), 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), and the Congressional Review Act (5 U.S.C. 804(2)).

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

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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). 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. These final regulations have been designated a "significant regulatory action," although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, these final regulations have been reviewed by the Office of Management and Budget.

<u>1. Need for Regulatory Action</u>

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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 instead of mandatory. The expanded exemption would apply to individuals and entities which have religious or moral objection 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, in order to comply with RFRA and to resolve many of the lawsuits that have been filed against the Departments for failure to comply with RFRA.

2. Anticipated Effects

The Departments expect that these interim final rules will not result in any additional burden on, or costs to, entities that are extended an exemption. Absent expansion of the exemption, the Guidelines would require many of these entities and individuals to pay for coverage of services that they find religiously or morally objectionable, or require that they 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 entangle them in the provision of such objectionable coverage. These interim final rules remove, rather than add to, the burdens imposed on these entities and individuals by recognizing their religious or moral 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 instead of mandatory under those Guidelines.

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To the extent that entities choose to revoke their accommodation 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 change to coverage during a plan year. If the entities wait until the start of their next plan year instead of changing to exempt status 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, even assuming that all of the existing entities using the 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 only be $46,900.

These interim final rules will result in some enrollees in plans of exempt entities not receiving coverage or payments for contraceptive services. When the Departments granted exemptions to churches and integrated auxiliaries and expanded those definitions, they concluded no additional significant burden or costs would result. (76 FR 46625; 78 FR 39889) As discussed above, the Departments believe there is insufficient evidence to distinguish the employees of other religiously- or morally-objecting non-profit entities from the employees of churches and integrated auxiliaries in this regard. As a result, the Departments believe that these interim final rules will not result in any additional significant burden on or costs to such employees.

These interim final rules extend exemptions to for-profit entities. The Departments are not aware of data reflecting how many such entities may make use of the exemption. In estimating the costs to enrollees of such entities, it is relevant that under the previous accommodation process the total contraceptive Federally-facilitated Exchange (FFE) user fee adjustment for self-insured plans for the 2015 benefit year, where an authorizing exception under OMB Circular No. A-25R was in effect, was $33 million. The Departments previously estimated that of the 209 entities making use of that adjustment, 87 were for-profit entities. (79 FR 51096; 80 FR 41336) Using those numbers, the fraction of the FFE user fee adjustment attributable to self-insured for-profit entities was approximately $13.9 million. Under 45 CFR 156.50(d)(3)(ii), 9 percent of the adjustment was attributable to administrative costs and margin, so that the amount attributable to employee cost in self-insured plans of for-profit employers was $12.6 million. The Departments estimate that most of the 87 for-profit entities using the accommodation will claim the exemption. The Departments estimate that a similar number of insured for-profit employers will use the exemption, and the Departments estimate that contraceptive costs are similar in insured and self-insured plans. In addition, there are entities that now qualify for an exemption but did not previously qualify for an accommodation, namely, for-profit entities that are not closely held, and morally- but not religiously- objecting organizations. The Departments are not aware of any morally-objecting for-profit entities. Likewise, no for-profit entities that are not closely-held have filed lawsuits challenging the Mandate. Thus the Departments estimate that no more than the same number of for-profit entities that previously used the accommodation will now use their exempt status. Therefore the

Departments estimate that the enrollee cost of for-profit employers using the exemption will be approximately $25 million.

The Departments estimate that these interim final rules will not result in any additional burdens or costs on issuers or third party administrators. Based on the number of objecting entities that have filed lawsuits opposing the accommodation, the Departments believe that the vast majority of entities making use of the accommodation process will instead make use of their newly exempt status. This will reduce burdens on issuers and third party administrators that were previously required to fulfill obligations and send notices under the accommodation process, but will no longer be required to do so. The Departments are not aware of data reflecting how many entities will use the optional accommodation process, but as explained below, they believe it will be many fewer entities than used it before, and estimate that it will be less than half. This will lead to a net decrease in burdens and costs on issuers and third party administrators to whom obligations are shifted under the accommodation process.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain IRS regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments anticipate that more entities that are reluctantly using the existing mandatory accommodation will choose to operate under the newly expanded exemption and not opt into the accommodation, than there will be entities not currently using the accommodation that will opt into it. This will lead to fewer overall adjustments made to the Federally-facilitated Exchange user fees for entities using the accommodation process, as long as an authorizing

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exception under OMB Circular No. A-25R is in effect. 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 regulations are exempt from the APA, because the Departments 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. Moreover, by exempting from the Mandate small businesses and nonprofit organizations with religious or moral 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,

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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 5 CFR 1320.13(a)(2)(i) 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)). 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, and the use of normal clearance procedures is reasonably likely to cause a statutory or court ordered

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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 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.

The Department of Health and Human Services submitted an ICR 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.

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.[51]

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

Each organization seeking to be treated as an eligible organization to use the optional accommodation process offered under these interim final regulations must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious or moral objection to coverage of all or a subset of contraceptive services. Specifically, these interim final regulations continue to allow eligible organizations to notify an issuer or third party

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

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administrator using EBSA Form 700, or to notify HHS of their religious or moral 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. HHS is not able to estimate how many organizations would utilize this optional accommodation process. HHS observed in its August 2014 interim final rules that there were 122 eligible entities that had filed litigation against the accommodation process, and in the July 2015 final regulations HHS estimated that there were 87 closely held for-profit entities that would seek the accommodation. (79 FR 51096; 80 FR 41336) Under the exemptions and optional accommodation process in these interim final rules, HHS anticipates that all of the entities that have brought litigation against the accommodation process will not opt into it, but will make use of their exempt status, and that most for-profit entities (which had brought a similar round of lawsuits against the Departments before the accommodation process was expanded to include them) will also not make use of the optional accommodation process. But, because the exemption is expanded, HHS anticipates that some newly exempt entities might make use of the accommodation process. HHS estimates that in total far fewer entities will opt into the accommodation process than have brought litigation against it or have used it while litigation over the accommodation was pending. For the purposes of this calculation, therefore, HHS estimates that no more than 100 entities will opt into the accommodation process.

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

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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.[52] HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour, 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour, 5 minutes for legal counsel at a cost of $134.50 per hour, and 5 minutes by a senior executive at a cost of $186.88 per hour)[53] 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 83.3 hours with an equivalent cost of approximately $7,496 for 100 entities. As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the hour burden so each will account for approximately 42 burden hours with an equivalent cost of approximately $3,748.

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

[52] 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.

[53] Occupation codes 43-6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84, 11-3111 for Compensation and Benefits Managers with mean hourly wage $61.01, 23-1011 for Lawyers with mean hourly wage $67.25, and 11-1011 for Chief Executives with mean hourly wage $93.44.

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the self-certifications or notices to HHS by mail is approximately $27. As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the cost burden so each will account for $13.50 of the cost burden.

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

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 100 entities will seek the optional accommodation. 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 100. It is estimated that each issuer or third party administrator will need

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approximately 1 hour of clerical labor (at $55.68 per hour)[54] and 15 minutes of management review (at $117.40 per hour)[55] 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 125 hours, with an equivalent cost of $8,503. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 62.50 burden hours with an equivalent cost of $4,251, with approximately 50 respondents.

The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS-IC) to obtain an estimate of the number of policyholders that will need to receive a notice.[56] The average number of policyholders (9) in plans with under 100 participants and the average number of policyholders (315) in plans with 100 or more participants were obtained. It is not known how many plans will be large or small. It was assumed that half the affected plans will be small and half the plans will be large. This leads to a weighted average estimate of 162 policyholders per plan that will need to receive a notice. For 100 entities, the total number of notices will be 16,200. For purposes of this

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

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

[56] "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

analysis, the Departments also assume that 53.7 percent of notices will be sent electronically.[57] Therefore, approximately 7,500 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 7,500 notices by mail is approximately $4,050. As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the cost burden so each will account for $2,025 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 and its issuer or third party administrator must provide written notice of such revocation to be provided to participants and beneficiaries as soon as practicable. HHS anticipates that most or all of the 209 entities that have brought litigation against the accommodation process will revoke its use 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). HHS assumes that for each entity, a compensation and benefits 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 compensation and benefits manager at a cost of $122.02 per hour, 30 minutes for legal counsel at a cost of $134.50 per hour, 1 hour for clerical labor at a cost

[57] 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.

of $55.68 per hour).[58] The burden per respondent will be 2 hours with an equivalent cost of $183.94 and for 209 entities, the total burden will be 418 hours with an equivalent cost of approximately $38, 443. As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the hour burden so each will account for 209 burden hours with an equivalent cost of approximately $19,222.

As before, HHS estimates that revocation notices will need to be sent to an average of 162 policyholders per plan and that 53.7 percent of notices will be sent electronically. For 209 entities, the total number of notices will be 33,858. Therefore, approximately 15,676 notices will be mailed. HHS estimates that each notice to 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 15,676 notices by mail is approximately $8,465. As the Department of Labor and the Department of Health and Human Services share jurisdiction they are splitting the cost burden so each will account for $4,233 of the cost burden.

Table XX: Summary of Information Collection Burdens

Regulation Section	OMB Control Number	Number of respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital Cost of Reporting ($)	Total Cost ($)
Self-Certification or Notices to HHS (§147.131(c)(3))	0938-New	50	50	0.83	41.67	$89.95	$3,747.92	$13.50	$3,761.42

58 Occupation codes 11-3111 for Compensation and Benefits Managers with mean hourly wage $61.01, 23-1011 for Lawyers with mean hourly wage $67.25, and 43-6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84.

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Regulation Section	OMB Control Number	Number of respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Capital Cost of Reporting ($)	Total Cost ($)
Notice of Availability of Separate Payments for Contraceptive Services (§147.131(f))	0938-New	50	50	1.25	62.50	$68.02	$4,251.50	$2,025.16	$6,276.66
Notice of Revocation of Accommodation (§147.131(c)(4))	0938-New	105	105	2	209	$91.97	$19,221.73	$4,232.59	$23,454.32
Total		155	205	4.08	313.17	$249.94	$27,221.15	$6,271.25	$33,492.40

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We are soliciting comments on all of the information collection requirements contained in this interim final rule. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938-1292 and 0938-1248. The Departments is requesting a new OMB control number that will ultimately contain the approval for the new requirements contained in this interim final rule 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 they are approved in the new information collection request associated with this interim final rule.

Written comments and recommendations from the public will be considered for this emergency information collection request if received by **[Insert date XX days after date of publication in the Federal Register]**. We are requesting OMB review and approval of this

information collection request by **[Insert date XX days after date of publication in the Federal Register]**, with a 180-day approval period. During the 180-day approval period, the Department will initiate the resubmission process to obtain a full 3-year approval.

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 http://www.cms.hhs.gov/PaperworkReductionActof1995.
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 collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of this interim final rule with comment period.

E. Paperwork Reduction Act—Department of Labor and Department of the Treasury

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 ICRs 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

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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 regulations amend the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer who revokes their accommodation. The Department of Labor 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 response, OMB approved the ICRs under control numbers 1210-0150 and 1210-1210-0152 through [DATE]. A copy of the information collection request may be obtained free of charge on the RegInfo.gov Web site at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201408-1210-001. This approval allows respondents temporarily to utilize the additional flexibility these final regulations provide, while the Department seeks public comment on the collection methods—including their utility and burden. Contemporaneously with the publication of these interim final regulations, the Department of Labor published a notice elsewhere in today's issue of the Federal Register informing the public of their intention to extend the OMB approval.

Consistent with the analysis in the HHS PRA section above the Departments expect that each of the estimated 100 eligible organizations will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to satisfy the requirements, and each of their 100 issuers or third party administrators will spend approximately 1.25 hours to satisfy the requirements. The DOL information collections in this rule are found in 29 CFR 2510.3-16 and 2590.715-2713A and are summarized as follows:

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Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services Under the Affordable Care Act.

OMB Numbers: 1210-0150.

Affected Public: Private Sector—Not for profit and religious organizations.

Total Respondents: 121 (combined with 1210-0152 and HHS total is 409).

Total Responses: 14,722 (combined with 1210-0152- and HHS total is 50,158).

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 185 (combined with 1210-0152 and HHS total is 626 hours. Estimated Total Annual Burden Cost: $3,694 (combined with 1210-0152 and HHS total is $12,543).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services Under the Affordable Care Act For-Profit Entities.

OMB Number: 1210-0152.

Affected Public: Private Sector—businesses or other for profits.

Total Respondents: 83 (combined with HHS 1210-0150 and total is 409).

Total Responses: 14,772 (combined with 1210-0150 and HHS total is 50,158).

Frequency of Response: On occasion.

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Estimated Total Annual Burden Hours: 128 (combined with 1210-0150 and HHS total is 626 hours.

Estimated Total Annual Burden Cost: $2,557 (combined with 1210-0150 and HHS total is $12,543).

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that the "the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [Affordable Care] Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, [or] purchasers of health insurance…." 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 RFRA] to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities.

Executive Order 13771 (January 30, 2017) declares that "it is important that for every one new regulation issued, at least two prior regulations be identified for elimination," and that "whenever an executive department or agency (agency) publicly proposes for notice and

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comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed." These interim final rules create no new regulations in the Code of Federal Regulations (CFR). Rather, these interim final rules eliminate three regulations, 26 CFR Part 54.9815-2713A, 29 CFR Part 2510.3-16, and 29 CFR Part 2590.715-2713A, and they simplify and eliminate multiple paragraphs in other parts of the CFR.

In addition, Executive Order 13771 requires, for fiscal year 2017, "the total incremental cost of all new regulations, including repealed regulations, to be finalized this year shall be no greater than zero," that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." These interim final rules impose no incremental costs. The exemption expanded in these interim final rules imposes no incremental cost or burden. Rather, the Departments believe that, by permitting organizations and individuals with religious or moral objections to some or all contraceptives or sterilization to be exempt from the requirement to pay for or provide such coverage, these interim final rules lessen incremental costs and regulatory burden. The Departments intend that the regulatory repeals and cost savings realized by these interim final rules will be available and attributable to offset the enactment of another regulation to be identified in the future.

Executive Order 13777 (February 24, 2017) declares, "It is the policy of the United States to alleviate unnecessary regulatory burdens placed on the American people." These interim final rules reduce the costs and burdens associated with the Affordable Care Act by expanding an exemption that lifts the burden that the accommodation process imposes on unwilling entities and rendering the accommodation process optional for eligible organizations rather than

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mandatory. In addition, these interim final rules remove the regulatory burden of having to comply with the Mandate from several categories of organizations that were previously not eligible for either the exemption or the accommodation process, including nonprofit and other organizations with a nonreligious, moral objection to the provision of contraceptives or sterilization, and objecting businesses that would not qualify for the accommodation because they did not meet the definition of a closely held corporation.

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—Department of Health and Human Services and Department of Labor

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

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among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

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

VII. Statutory Authority

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

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

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and

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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.

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Signed this *** day of ***, 2017.

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*****NAME*****

Acting Deputy Commissioner for Services and Enforcement,

Internal Revenue Service.

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*****NAME*****

Acting Assistant Secretary of the Treasury (Tax Policy).

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Signed this *** day of ***, 2017.

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

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Dated: ***, 2017

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Seema Verma
Administrator,
Centers for Medicare & Medicaid Services.

Approved: ***, 2017.

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Thomas E. Price, M.D.
Secretary,
Department of Health and Human Services.

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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

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

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

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

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

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

* * * * *

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

3. Section 54.9815-2713A is revised as follows:

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

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

(1) The organization is an objecting entity described in 45 CFR 147.131(a)(1)(i) or (ii);

(2) Notwithstanding its exempt status under 45 CFR 147.131, 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 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) Revocation of accommodation. 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. If contraception 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

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plan year that begins thirty 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, sixty-days notice may be given pursuant to PHS Act section 2715(d)(4) if applicable.

(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 Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.131(a)(2) 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 147.131(a)(2) 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

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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 ERISA section 3(33)); 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 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 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 contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a 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), or imposing a 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.

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(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of ERISA section 3(33) 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) <u>Optional accommodation - insured group health plans</u> — (1) <u>General rule.</u> 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 Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.131(a)(2) 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.

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(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 147.131(a)(2) 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 ERISA section 3(33)); 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 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 § 54.9815-2713(a)(1)(iv).

(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 147.131(a)(2) 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

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

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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

4. The authority citation for part 2590 continues to read, in part, as follows:

Authority: 29 U.S.C. 1027, * * *

5. 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) * * *

(1) In general. Beginning at the time described in paragraph (b) of this section and subject to § 2590.717-2713A, 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.

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6. Section 2590.715-2713A is amended 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 147.131(a)(1)(i) or (ii);

(2) Notwithstanding its exempt status under 45 CFR 147.131, 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 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) Revocation of accommodation. 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. .

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If contraception 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 thirty 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, sixty-days notice may be given pursuant to PHS Act section 2715(d)(4) if applicable.

(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 Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.131(a)(2) 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 147.131(a)(2) 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 ERISA section 3(33)); 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 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 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 contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a

deductible), or imposing a 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), or imposing a 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

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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 Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.131(a)(2) 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 Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.131(a)(2) 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 invoke 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

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147.145(a) or a church plan within the meaning of ERISA section 3(33)); 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 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 § 2590.715-2713(a)(1)(iv).

(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 147.131(a)(2) 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

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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, "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, services, or related patient education or counseling, to the extent specified for purposes of § 2590.715-2713(a)(1)(iv).

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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

7. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

8. 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, 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.

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* * * * *

9. Section 147.131 is amended to read as follows:

§ 147.131 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 the 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, the integrated auxiliary of a church, a convention or association of churches, or a religious order;

(B) A nonprofit religious organization;

(C) A nonprofit organization, to the extent not covered by § 147.131(a)(1)(i)(A) or (B);

(D) A closely held for-profit entity;

(E) A for-profit entity that is not closely-held; or

(F) 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

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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 a references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group 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 the requirement to provide contraceptive services unless it is also exempt under paragraph (a)(1)(i) or (ii), or paragraph (b), of this section.

(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) for coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held:

(A) Religious beliefs, or

(B) 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)(4) 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

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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:

(1) Religious beliefs, or

(2) Moral convictions.

(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 paragraph (a)(1)(i) or (ii) of this section.

(2) Notwithstanding its exempt status under paragraph (a) of this section, 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.

(5) Revocation of accommodation. 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. If

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contraception 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 thirty 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, sixty-days notice may be given pursuant to PHS Act section 2715(d)(4) if applicable.

(d) Optional accommodation—insured group health plans—(1) General rule. A group health plan established or maintained, or arranged (as applicable) by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation process 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 Health and Human Services that it is an eligible organization and of its objection as described in paragraph (a)(2) of this section 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 Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in

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paragraph (a)(2) of this section 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 ERISA section 3(33)); 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 Health and Human Services. 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 (d)(1)(ii) of this section and describing the obligations of the issuer under § 147.130(a)(1)(iv).

(2) If an issuer receives a copy of the self-certification 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 paragraph (a)(2) 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), 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. 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 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

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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 or third party administrator, 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 (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 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/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, "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, 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

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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 other persons not similarly situated or to other dissimilar circumstances.

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